Risk Analysis for Movements of Live Aquatic Animals

An Introductory Training Course

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Foreword

Risk analysis is now widely applied in many fields that touch our daily lives. These include decisions about risks due to chemical and physical stressors (natural disasters, climate change, contaminants in food and water, pollution, etc.), biological stressors (human, plant and animal pathogens; plant and animal pests; invasive species, invasive genetic material), social and economic stressors (unemployment, financial losses, public security, including risk of terrorism), construction and engineering (building safety, fire safety, military applications) and business (project operations, insurance, litigation, credit, etc.). Risk analysis is thus a pervasive but often unnoticed component of modern society that is used by governments, private sector and individuals in the political, scientific, business, financial, social sciences and other communities.

The application of risk analysis in aquaculture has recently gained attention. Because it is not always possible to know and predict every potential source of harm and its pathways, applying risk analysis can be an effective management and decision-making tool to assess the threats and uncertainties from new species or innovations in aquaculture development. It offers a common approach when making informed decisions on managing biosecurity threats, in a systematic manner to protect the health and well-being of animals, plants and people, and to maintain the functions and services of the ecosystems.

This manual will assist in facilitating the understanding and application of the risk analysis process in order to support FAO's goal of contributing to food and nutritional security through responsible and sustainable aquaculture development.

Jia Jiansan
Chief, Aquaculture Service

Preparation of this document

For more than 15 years, the Food and Agriculture Organization of the United Nations (FAO), through its Fisheries and Aquaculture Department, has been assisting FAO Member countries in developing risk analysis capacity for the safe movement of live aquatic animals. During this period, numerous workshops and trainings have been conducted at the regional and national levels in various parts of the world. One of the most significant of these was the FAO/NACA Expert Workshop on Understanding and Applying Risk Analysis in Aquaculture, held in Rayong, Thailand, from 7 to 11 June 2007 (Bondad-Reantaso, Arthur and Subasinghe, 2008). A major accomplishment of the workshop was the commissioning of practical guidance on "Understanding and applying risk analysis in aquaculture: a manual for decision-makers" (Arthur *et al.,* 2009) which provided a unified overview of the application of risk analysis in seven aquaculture risk sectors.

This manual, "*Risk Analysis for Movements of Live Aquatic Animals. An Introductory Training Course"* was conceived by Dr Melba B. Reantaso, Aquaculture Officer, Aquaculture Service (FIRA) as a means of presenting risk analysis training materials (Working Group exercises and supporting lecture materials, i.e. powerpoint presentations) developed through FAO activities in a format that could be easily adapted for use in short courses (four days duration) by regional and national experts charged with preparing risk analysis training course offerings for local participants.

This manual draws particularly on (i) a series of Working Group Exercises and supporting materials (including case studies) that were developed as part of the FAO/FSM Department of Resources Development "National Workshop on Risk Assessment in Aquaculture Development", which was held in Pohnpei, Federated States of Micronesia (FSM) from 24 to 27 May 2010. These exercises were supported by (ii) a series of powerpoint lecture presentations on risk analysis and aquatic animal health management prepared by Dr Richard Arthur (FAO consultant) and Dr Melba B. Reantaso for various national and regional workshops organized by FAO. Preparation and publication of this document was made possible by FAO funds provided through the FAO project TCP/MIC/3201: Risk Assessment in Aquaculture Development in FSM, developed and implementation facilitated by Mr Masanami Izumi, Fisheries and Aquaculture Officer of the FAO Subregional Office for the Pacific Islands (SAP).

Abstract

Risk analysis is complex subject that is best learned by actual experience. This manual will assist national competent authorities and others involved in the assessment and management of risks associated with the international or domestic moment of live aquatic animals in training professional staff and raising awareness and understanding among other stakeholders of the principles and methodology of risk analysis. Using the training course manual and the recommended supplementary materials, responsible managers will be able to train staff in the planning and supervision of risk analyses. The training course will also assist specialists in the fields of disease, genetics or ecology of aquatic animals to successfully conduct risk analyses in a manner that incorporates best scientific knowledge, is transparent and includes adequate stakeholder consultation.

Using a structured step-wise process, the training course guides trainees through the risk analysis process as applied in the analysis of ecological, genetic and pathogen risks. Through the use of a series of lectures (provided on an accompanying CD in the form of 11 PowerPoint presentations), and using case studies and a series of five linked working group exercises that should be adapted by trainers to reflect local situations and priorities, the course provides an in-depth look at risk analysis as currently applied for evaluation of risks due to pathogens (import risk analysis). Trainees are guided from the initial process of establishing a commodity description and scoping a risk analysis through to conducting the four risk analysis components of hazard identification, risk assessment, risk management and risk communication. They are also encouraged to evaluate their national experiences with introductions and transfers of live aquatic animals, and to assess their current capacity, and any policy, legislative or technical improvements needed to effectively implement risk analysis for the safe movements of live aquatic animals.

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Contents

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Abbreviations and acronyms

ALOP	Appropriate level of protection
ALOR	Acceptable level of risk
CBD	Convention of Biological Diversity
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
EUS	Epizootic ulcerative syndrome
FAO	Food and Agriculture Organization of the United Nations
FIPS	Statistics and Information Service
FIRA	Aquaculture Service
FSM	Federated States of Micronesia
KHV	Koi herpesvirus
MCRV	Mud crab reovirus
OIE	World Organisation for Animal Health
Ppt	Powerpoint presentation
SAP	Sub-Regional Office for the Pacific Islands of FAO
SPS Agreement	Sanitary and Phytosanitary Agreement of WTO
TAADs	Transboundary Aquatic Animal Diseases
UN	United Nations
UNCLOS	United Nations Convention on the Law of the Sea
WG	Working Group
WSSV	Whitespot syndrome virus
WTO	World Trade Organization

1.1 Purpose

1.1 Purpose

The purpose of this manual is to present a structured step-wise process, including supporting materials, that can be used by national and regional trainers as a basis for formulating short-courses (four days duration) on the application of risk analysis to aquaculture development.

Such training courses are designed to assist in raising awareness and understanding on the application of risk analysis to aquaculture production among government policy-makers, managers and technical officers (fisheries officers, aquaculture specialists, researchers, etc.) and members of the private sector (aquatic animal health professionals, aquatic veterinarians, non-government agencies, private aquaculturists) by providing basic knowledge on the risk analysis process and how it can be applied to assist decision-making and the development of a responsible and sustainable aquaculture sector.

Its primary goal is to provide information and experience needed to design risk analyses and oversee their conduct so that they can ensure that risk analyses are conducted in a manner that incorporates best scientific knowledge, is transparent and includes adequate stakeholder consultation.

Risk analysis is a complex subject, with each aquaculture risk sector having its own methodologies and requiring its own specialized expertise (see Arthur *et al.,* 2009). Thus by itself, this manual will not prepare most participants to undertake a formal risk analysis. However, following this introduction and drawing on the supplementary resources (see Chapters 4 and 5), specialists with wide experience in the fields of disease, genetics or ecology of aquatic animals should be able to successfully initiate risk analyses. In this regard, it should be noted that risk analysis is a discipline that is best learned by actual experience.

1.2 Overview of course structure and content

1.2.1 Course structure

The core of this training manual is a series of seven **Working Group (WG) Exercises** that are based on hypothetical **aquatic species translocation scenarios (see Figures 1 and 2)** and which lead the participants through the complete risk analysis process as it is conducted for pathogen risk analysis.

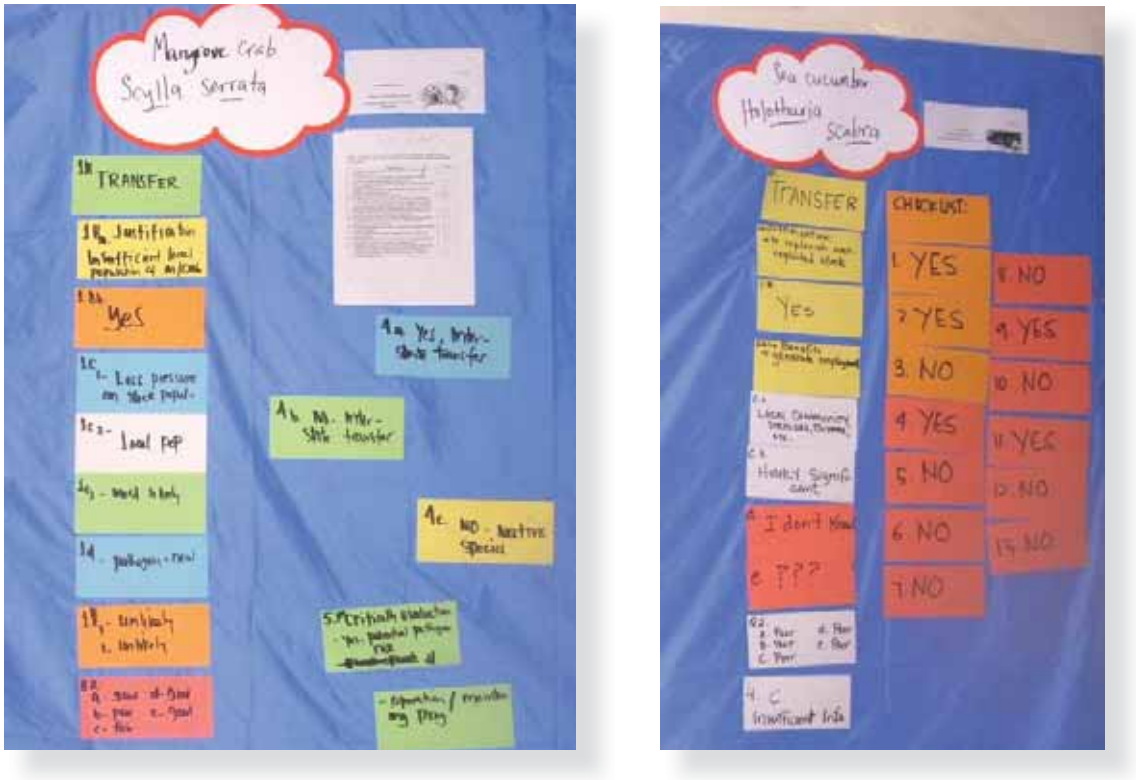


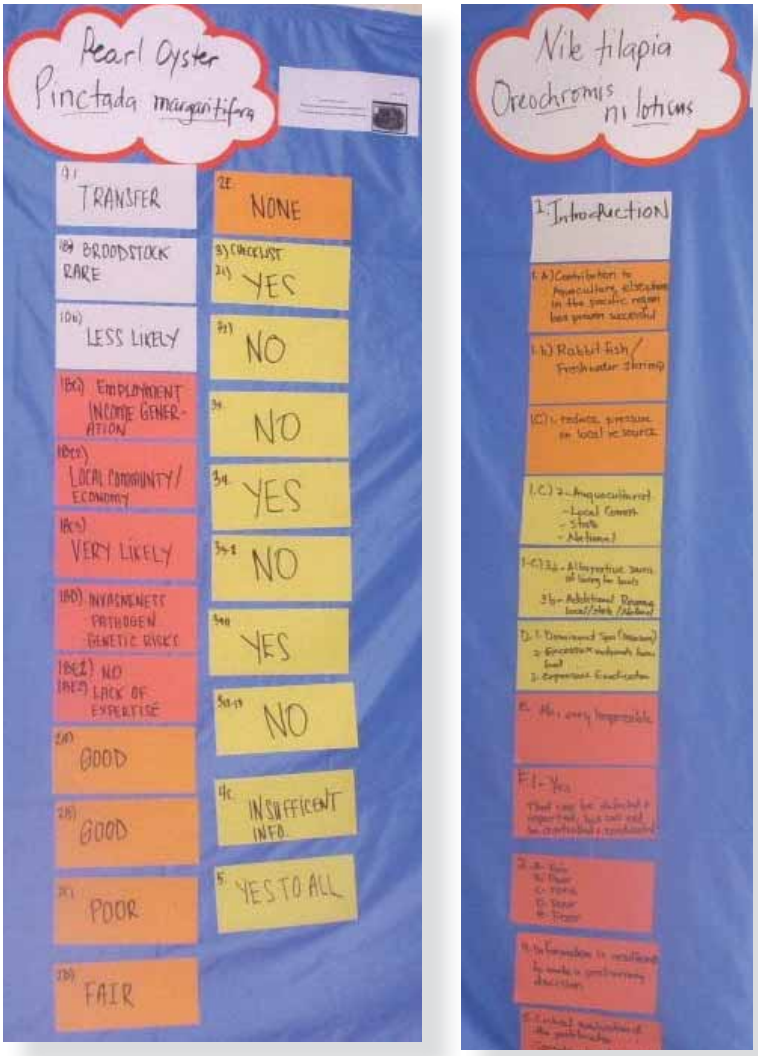
Figure 1. Examples of translocation scenarios

Each **WG** is assigned a **commodity** (an aquatic species, chosen for its relevance to the national or regional context of the particular training course being offered) that is being proposed for introduction or transfer for aquaculture development.

Each WG then follows its assigned commodity through the risk analysis process (using a qualitative risk analysis approach and drawing from pathogen risk analysis methodology), including: proposal assessment, establishing a risk analysis team, scoping a risk analysis, hazard identification, risk assessment (release assessment, exposure assessment, consequence assessment and risk estimation) and risk management (risk evaluation, option evaluation, implementation, and monitoring and review).

1.2.1 Course structure

Figure 2. Examples of translocation scenarios



Each WG Exercise concludes with presentation of WG findings, plenary discussion and preparation and presentation of a synthesis of results and conclusions by the course facilitators.

The WG Exercises are to be supported by a **series of lectures** and **case studies**. Background information on the risk analysis process relevant to each exercise is presented in the lecture(s) preceding the exercise.

To assist trainers in preparing appropriate lecture material, a **CD-ROM containing a series of 11 lectures** (of approximately 20 to 60 minutes length each) that have been developed and tested through previous FAO training workshops is provided with the manual. Readers should note that as each course must be tailored to local circumstances.

These powerpoint (ppt) presentations are provided as a resource to be used in the preparation of lectures appropriate to the course that is to be offered. The material is so structured that trainers can easily adapt it to fit their specific needs and objectives.

1.2.1 Course structure

As shown in the **example Training Course Programme** given in **Table 1** (see below), various introductory and concluding lectures should be prepared as appropriate to the precise focus of the course, the time allotted, the geographical region or country in which the training is being held and the knowledge and experience of the participants.

TABLE 1
Example programme for a four-day training workshop on introduction to risk analysis for aquaculture development.[1]

Date	Activities
Day 1	**24 May, Monday**
08:30-09:00	Registration
09:00-09:15	Chairman of the workshop: Deputy Assistant Secretary, FSM- Department of Resources and Development **Workshop opening** • Welcome statement (FAO Subregional Representative for the Pacific) • Opening statement (Acting Secretary, FSM Department of Resources and Development) Introduction of participants
09:15-09:25	**Presentation 1:** Background and objectives of the workshop
09:25-09:45	**Presentation 2:** Regional trends in aquaculture and key issues for sustainable development
09:45-10:15	**Presentations 3:** Current status and future trends in aquaculture development in FSM (i) Chuuk State (ii) Kosrae State (iii) Pohnpei State (iv) Yap State
10:15-10:40	Group photo Tea/Coffee
10:40-11:00	**Presentation 4:** Movements of live aquatic animals: Historical experience in FSM and potential future proposals

[1] Participants at this example workshop were primarily staff from relevant national and State agencies, but also included representatives from local NGOs and the private sector. In addition to risk analysis training, the workshop also included presentations providing orientation to the regional, national and state situations regarding aquaculture development, past experience and likely future proposals for introductions and transfers, and current procedures used when considering requests for movements.

1.2.1 Course structure

(TABLE 1 *cont.*)

11:00-11:20	**Presentation 5:** Current procedures for assessing proposals for translocations of aquatic species in FSM
11:20-12:20	Working Group Exercise 1: Identifying issues and potential risks in proposals for species translocations for aquaculture development in FSM
12:20-13:15	Lunch
13:15-14:45	**Presentation 6:** Introduction to risk analysis – Overview and general principles
14:45-15:00	Tea/Coffee
15:00-16:00	**Presentation 7:** Pathogens and pests: Issues and impacts based on global experience • Pathogen risks • Ecological/pest and invasive species/environmental risks • Genetic risks
16:00-17:00	Working Group Exercise 2: Identifying current risk analysis frameworks and procedures for FSM
Day 2	**25 May, Tuesday**
08:30-09:30	**Presentation 8**: Introduction to global risk analysis frameworks and guidance
09:30-10:00	**Presentation 9:** Conducting a risk analysis: Example using pathogens as risks - Part 1 • Preliminary activities • Risk communication • Hazard identification
10:00-10:20	Tea/Coffee
10:20-11:00	**Presentation 9** (continued)
11:00-12:00	Working Group Exercise 3: Case Studies – Pathogen risk analysis for FSM - Scoping to hazard identification
12:00-13:00	Lunch
13:00-14:40	Working Group Exercise 3 (continued)
14:40-15:00	Tea/Coffee
15:00-15:40	**Presentation 10:** Appropriate Level of Protection (ALOP), the Precautionary Principle

1.2.1 Course structure

(TABLE 1 *cont.*)

15:40-17:00	Working Group Exercise 4: Determining an ALOP for FSM
Day 3	**26 May, Wednesday**
08:30-09:30	**Presentation 11:** Conducting a risk analysis: Example using pathogens as risks: Part 2-Risk assessment and risk management (risk evaluation) • Risk assessment: Release, exposure, and consequence assessment • Risk assessment: Risk estimation • Risk management: Risk evaluation
09:30-09:50	Tea/Coffee
09:50-12:00	Working Group Exercise 5: Case Studies: Risk assessment (release, exposure, and consequence assessment); risk estimation; risk management (risk evaluation)
12:00-13:00	Lunch
13:00-14:40	**Presentation 12:** Conducting a risk analysis: example using pathogens as risks: Part 3- Risk management • Option evaluation • Implementation • Monitoring and review
14:40-15:00	Tea/Coffee
15:00-17:00	Working Group Exercise 6: Case Studies: Risk management (continued) (option evaluation, implementation, monitoring and review)
Day 4	**27 May, Thursday**
08:30-09:15	**Presentation 12:** Summary of results of risk analysis
09:15-10:15	**Presentation 13:** Summary of four risk analysis Case Studies • Pearl oyster • Tilapia • Sea cucumber • Mangrove crab
10:15-10:35	Tea/Coffee
10:35-12:00	Discussion
12:00-13:00	Lunch
13:30-15:30	Working Group Exercise 7: Implementing risk analysis in FSM: Identification of needs and recommendations
15:00-15:30	Tea/Coffee
15:30-16:10	Presentation 13: Conclusions and way forward
16:10-16:25	Workshop closing

1.2.2 Course content

The seven **WG Exercises** are presented in **Sections 2.1 to 2.7** of this manual. **WG Exercises** flow logically from one to the next, presenting the risk analysis process (as used in pathogen risk analysis) in a simplified form.

The exercises are supported by a series of **Resource documents** (presented following each **WG Exercise**). It is envisioned that each course offering will be supported by a series of introductory and concluding presentations that are course-specific (see **Table 1**, see pages 7-9 for example).

The more general presentations on the risk analysis process should be tailored to cover the information essential to allow the participants to complete each subsequent **WG Exercise**. These can be drawn from the series of 11 ppt presentations (contained on the accompanying **CD-ROM**) and whose contents are summarized below.

Using materials drawn from the literature on pathogen risk analysis and from a series of case studies prepared by FAO (see example given as **Annex 1**, see page 125), the participants are then asked to conduct a simple qualitative risk analysis, through which they gain experience in hazard identification, risk assessment (release assessment, exposure assessment, consequence assessment and risk estimation, including the use of pathways analysis and scenario trees), risk management (risk evaluation, options evaluation, monitoring and review) and risk communication.

Each exercise begins with **brief summary** of what should be covered in the **supporting lecture(s)** (drawing on the ppt presentations given in the accompanying **CD-ROM**), and a **summary description** of the WG or Plenary Group activity, including its **learning objectives, intended learning outcomes** and its **approximate duration**.

The **WG Exercises** and their supporting **resource documents** were prepared specifically for the FAO/FSM Department of Resources Development "National Workshop on Risk Assessment in Aquaculture Development" held in Pohnpei, Federated States of Micronesia, from 24

to 27 May 2010 (see **Figure 3**). However, they can be easily modified by trainers for use in similar risk analysis training courses to be given in other countries and regions.

Figure 3. Participants and resource persons during the FAO/FSM Department of Resources Development "National Workshop on Risk Assessment in Aquaculture Development", Pohnpei, FSM, 24 - 27 May 2010.

1.2.2 Course content

The contents of each **WG Exercise** are presented below:

- **WG Exercise 1 (Resource Document 1.1) – Identifying issues and potential risks in proposals for species translocations for aquaculture development:** Presents each WG with a series of questions designed to stimulate thought and discussion on the possible benefits and risks of a hypothetical species movement and develop skills for the critical evaluation of proposals for species movements.

- **WG Exercise 2 (Resource Document 2.1) – Identifying current risk analysis frameworks and procedures:** As a group in plenary session, participants outline the major steps in the current national process used to reach a decision on a proposal to introduce or transfer an aquatic species, assess the current process with regard to various broad criteria relevant to risk analysis, and identify the international and regional treaties, agreements and memberships that obligate their country when considering introductions and transfers. They briefly evaluate their nation's past experiences, identify current problems related to invasive species, and weigh the value that their country places on its natural biodiversity.

- **WG Exercise 3 (Resource Document 3.1) – Pathogen risk analysis – Scoping to hazard identification:** During the exercise, the WGs will evaluate a commodity description for completeness and will make an initial decision (e.g. approve, reject, request more information). They will then define the scope of a hypothetical risk analysis. Using the pathogen list and the pathogen summaries provided, they will then conduct a short hazard identification. Finally, the WGs will conduct a brief risk communication exercise, in which they identify potential stakeholders and outline a risk communication strategy.

- **WG Exercise 4 (Resource Document 4.1) – Determining an appropriate level of protection (ALOP):** Through examination of relevant national policy statements, past history of introductions

1.2.2 Course content

WG Exercises

- **WG Exercise 1 (Resource Document 1.1) –** Identifying issues and potential risks in proposals for species translocations for aquaculture development
- **WG Exercise 2 (Resource Document 2.1) –** Identifying current risk analysis frameworks and procedures
- **WG Exercise 3 (Resource Document 3.1) –** Pathogen risk analysis – Scoping to hazard identification
- **WG Exercise 4 (Resource Document 4.1) –** Determining an appropriate level of protection (ALOP)
- **WG Exercise 5 (Resource Document 5.1) –** Risk assessment (release, exposure and consequence assessment, risk estimation); Risk management (risk evaluation)
- **WG Exercise 6 (Resource Document 6.1) –** Risk management (option evaluation, implementation, monitoring and review)
- **WG Exercise 7 (Resource Document 7.1) –** Implementing risk analysis: identification of needs and recommendations

and transfers in all sectors and their knowledge of national values and priorities, participants are asked to reach a consensus as to what the national ALOP is (or should be).

- **WG Exercise 5 (Resource Document 5.1) – Risk assessment (release, exposure and consequence assessment, risk estimation); Risk management (risk evaluation):** Continuing in their assigned WGs, the participants follow their commodities through the pathogen risk analysis process. A simple qualitative risk assessment procedure is used to familiarize them with the use of scenario trees and pathways analysis. They are asked to calculate risks of exposure, release and consequence and an overall risk estimate. They then begin risk management by determining if the estimated risk is within the Appropriate Level of Risk (ALOR).

- **WG Exercise 6 (Resource Document 6.1) – Risk management (continued from WG Exercise 5) (option evaluation, implementation, monitoring and review):** Participants continue the risk analysis process by taking their assigned commodity through the remainder of the risk management process. They will prepare a short list of possible management options for one of the identified hazards and consider their likely effectiveness and feasibility. They will then recalculate a new risk estimate for this hazard and determine if the ALOP has been met. They are then asked to briefly consider some practical aspects of implementation and monitoring and review.

- **WG Exercise 7 (Resource Document 7.1) – Implementing risk analysis: identification of needs and recommendations:** This concluding exercise asks participants to consider current risk analysis procedures and capacity in their country, identify areas that can be improved, and suggest ways to achieve the required expertise and capacity. The outputs of the WGs can later be synthesized by the trainers into a list of recommendations for future development of national risk analysis capacity.

1.2.2 Course content

The contents of the supporting lectures (presented as ppt presentations) contained on the accompanying **CD-ROM** are listed below:

- **Part I – Course introduction:** Information on course resource personnel, course goals and limitations, course overview and course outline. **(14 slides)**

- **Part 2 – Overview of trade in aquatic animal commodities:** Why trade is "risky", the global growth of aquaculture and trade in aquatic products and the driving forces, and the nature of the trade. **(20 slides)**

- **Part 3 – Overview of risks in aquaculture:** The nature of risk and the types of risk inherent in aquaculture development, the seven risk sectors, the invasive species problem, overview of genetic risks, balancing the risks and benefits of aquaculture. **(37 slides)**

- **Part 4 – Overview of risk analysis:** What is risk?, important terms, protection vs. free trade; What is risk analysis?; Who uses risk analysis?; Relation of risk analysis and national biosecurity; National biosecurity actions; Why do countries need to be able to conduct risk analysis?; Two sides of the coin – risks to and from aquaculture; The four risk analysis questions; Approaches to risk analysis; Simplified risk analysis process; The World Organisation for Animal Health (OIE) framework (risk communication, hazard identification and the concept of hazard, risk assessment, risk management); Examples of risk analysis frameworks for various risk sectors; Simplified process for pathogen risk analysis.**(60 slides)**

- **Part 5 – Relevant international treaties, agreements and guidance:** Key treaties and agreements; World Trade Organization Sanitary and Phytosanitary (WTO SPS) Agreement main regulatory instruments; Key guidance (voluntary guidelines, guidance manuals, completed pathogen risk analyses, global and farm-level guidelines); Online resources. **(21 slides)**

1.2.2 Course content

Introduction to the Use of Risk Analysis in Aquaculture presented as powerpoint presentation

- **Part 1 –** Course introduction
- **Part 2 –** Overview of trade in aquatic animal commodities
- **Part 3 –** Overview of risks in aquaculture
- **Part 4 –** Overview of risk analysis
- **Part 5 –** Relevant international agreements, treaties, memberships and guidance
- **Part 6 –** Pathogen risk analysis – Transboundary aquatic animal diseases, introduction and preliminaries
- **Part 7 –** Pathogen risk analysis – Hazard identification
- **Part 8 –** Pathogen risk analysis – Risk assessment
- **Part 9 –** Pathogen risk analysis – Risk management
- **Part 10 –** Risk communication
- **Part 11 –** Concluding session

1.2.2 Course content

- **Part 6 – Pathogen risk analysis – Transboundary aquatic animal diseases (TAADs), introduction and preliminaries:** Examples of TAADs: koi herpesvirus, white spot syndrome virus, epizootic ulcerative syndrome; Estimates of losses due to disease; What is pathogen risk analysis?; What is import risk analysis?; Historical aspects; Summary of completed formal risk analyses; Major risk factors; The risk analysis process; The risk analysis team and its duties; How risk analyses are initiated; The proposal to import; The risk analysis working group; Scoping a risk analysis (including an example from an actual risk analysis); Special issues and problems. **(59 slides)**

- **Part 7 – Pathogen risk analysis – Hazard identification:** Screening criteria; Summary of procedure; Summary of hazards identified from completed risk analyses, giant river prawn as an example. **(18 slides)**

- **Part 8 – Pathogen risk analysis – Risk assessment:** Overview; Qualitative versus. quantitative methods; Use of scenario trees and pathways analysis; Release assessment; Exposure assessment; Consequence assessment; Risk estimation; Practical example using giant river prawn. **(36 slides)**

- **Part 9 – Pathogen risk analysis – Risk management:** Overview; Risk evaluation; ALOP/ALOR; Practical example using giant river prawn; Possible outcomes of risk evaluation; Summary of results from completed risk analyses; Options evaluation; Summary of risk management measures from completed risk analyses; The precautionary principle and its application to pathogen risk analysis; Practical example using giant river prawn; Implementation; Monitoring and review; Reporting and report preparation. **(44 slides)**

- **Part 10 – Risk communication:** Overview; Purpose; Strategies; Identifying stakeholders; Risk communication methods; The risk analysis report **(15 slides)**

1.2.2 Course content

- **Part 11 – Concluding session:** Some universal principles of risk analysis; What is needed to implement risk analysis?; Risk analysis and developing countries; Characteristics of risk analysis that support good governance; Regional approaches; Constraints; Evaluating your country's current situation. **(26 slides)**

1.2.3 How to use this material

It should be emphasized that while the material presented in this manual could be directly used to provide training on risk analysis, it is presented with the expectation that it will be **adapted to the specific circumstances of the training being planned.**

This includes:

- the number of days allotted to the workshop;
- the backgrounds, expertise and experience of the participants;
- the specific aquaculture risk sector(s) of interest/importance to the participants;
- the regional or national situation with regard to aquatic species whose introduction/transfer is being considered or is likely to be proposed; and
- the national and/or regional disease situation for the key commodities, including pathogens likely to be of high concern.

1.2.3 How to use this material

In this regard, the preparation of one or more **"case studies"** prior to each workshop is quite valuable. **Case studies** can provide an in-depth examination of a proposed or probable introduction or transfer of a live aquatic animal of direct relevance to the country (or region) in which the risk analysis training will be conducted.

Example Case Study
Mangrove crab
(Scylla serrata)
to Kosrae State,
Federated States of Micronesia

The case studies can include a brief expert assessment of the issues that should be considered during evaluation of a proposal to move a specific aquatic species (commodity). They thus can provide background material for use in species movement scenarios, aquatic species profiles, pathogen lists, etc. that will be used by the participants during the **WG Exercises.**

By presenting the results of case studies towards the end of the workshop and after the participants have completed their exercises, the participants can compare their work and the resulting conclusions with that of an experienced risk analyst.

Although not risk analyses, the case study(ies) can provide background information and guidance that can be used by participants to initiate specific risk analyses following completion of the workshop.

An example of such a case study (prepared for the FAO national workshop that was held in Pohnpei, Federated States of Micronesia), which supports some of the example documents used in this manual is given as **Annex 1** (see page 125).

1.2.3 How to use this material

Prior to each workshop, **relevant specific supporting materials will need to be prepared or revised,** as appropriate.

These may include, for example:

- Any "lead in" presentations designed, for example, to orient participants to the national and/or regional situation (e.g. history, present status, future trends) with regard to aquaculture development, introductions and transfers of aquatic animals, current legal procedures, experiences with invasive species, etc. (see, for example, **Presentations 1 to 6** as given in the example Workshop Programme presented in **Table 1**; see page 7);
- WG exercises and their supporting lectures;
- Aquatic species translocation scenarios (see **Resource Document 1.2**; see page 51);
- Aquatic species profiles (see **Resource Document 1.3**; see page 53);
- Example abbreviated lists of pathogens for the relevant aquatic species (see **Resource Document 3.3**; see page 73);
- Pathogen information sheets (see **Resource Document 3.4**; see page 74);
- Information relevant to determining national ALOP; and
- Relevant case studies (see example case study given in **Annex 1**; see page 125).

For **WG Exercises**, the course facilitators can **divide the participants into working groups of four to eight members** based on participants' knowledge, experience and interest in the various species translocation scenarios that have been specifically developed for the individual workshop.

1.2.3 How to use this material

In general, each WG works independently on each WG Exercise, the composition of the WGs remaining the same throughout the entire workshop and each WG following its assigned commodity through the simplified risk analysis process used during the workshop.

Some WG Exercises, such as identifying current risk analysis frameworks and procedures **(WG Exercise 2)**, discussion of national ALOP **(WG Exercise 4)** and implementing risk analysis: needs and recommendations **(WG Exercise 7)** are best conducted in plenary.

At the end of each WG Exercise, the participants reconvene in plenary to present and discuss their findings. Where possible, it is often best to designate one of the participants to act as discussion moderator.

The use of flip charts, post-it notes, white board, projector, etc. (facilitation materials) to present findings, draw pathways and organize and frame participants' contributions is recommended.

1.2.3 How to use this material

Course facilitators should act to guide WG and plenary discussions, clarify thinking, organize outputs and provide technical information and expert opinion, when requested to do so.

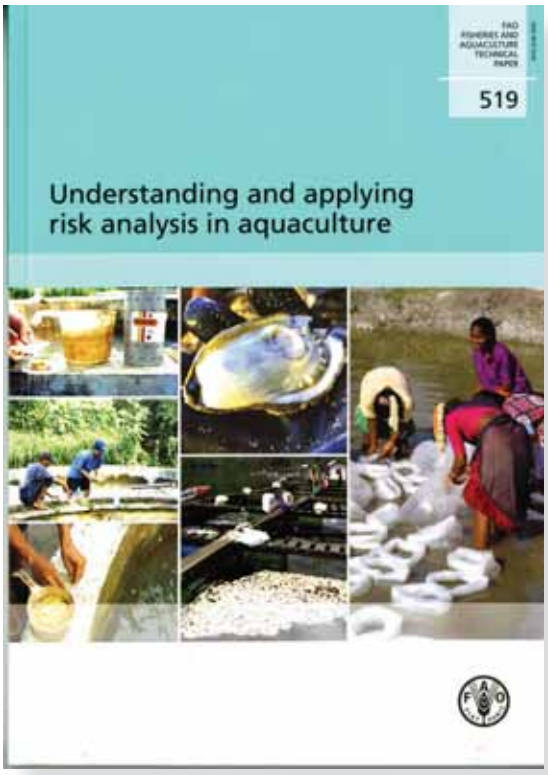
1.3 Background to risk analysis

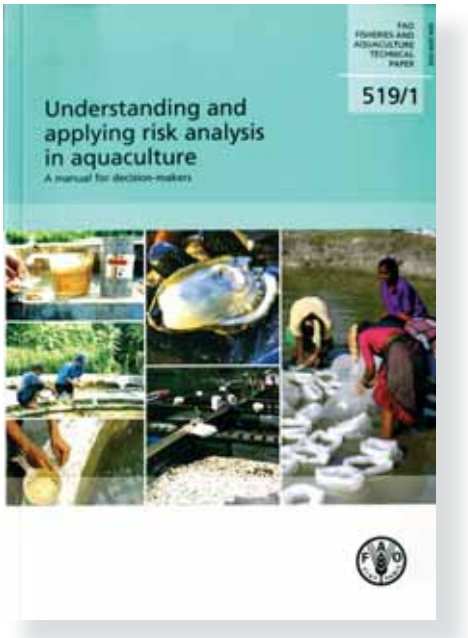
1.3 Background to risk analysis

Governments and the private sector must often make **decisions based on incomplete knowledge and a high degree of uncertainty.** Such decisions may have far-reaching social, environmental and economic consequences.

Risk analysis is a process that provides a flexible framework within which the risks of adverse consequences resulting from a course of action can be evaluated in a systematic, science-based manner.

The risk analysis approach permits a defendable decision to be made on whether the risk posed by a **particular action or "hazard"** is acceptable or not, and provides the means to evaluate possible ways to reduce the risk from an unacceptable level to one that is acceptable.





1.3.1 The concept of risk

The concept of **"risk"** varies somewhat depending on the sector. Most definitions incorporate the concepts of:

- uncertainty of outcome (of an action or situation),
- probability or likelihood (of an unwanted event occurring), and
- consequence or impact (if the unwanted event happens).

Thus **"risk"** is the potential for realization of unwanted, adverse consequences to human life, health, property or the environment. Its estimation involves both the likelihood (probability) of a negative event occurring as the result of a proposed action and the consequences that will result if it does happen.

As an example, taken from pathogen risk analysis, the Aquatic Animal Health Code (OIE, 2010) defines risk as:

"... the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health".

While some sectors incorporate consideration of potential benefits that may result from a **"risk"** being realized (e.g. financial risk analysis), others specifically exclude benefits from being taken into account (e.g. pathogen risk analysis).

1.3.2 What is risk analysis?

"Risk analysis" is usually defined either by its components and/or its processes. The Society for Risk Analysis (http://www.sra.org/) offers the following definitions of "risk analysis":

- a detailed examination including risk assessment, risk evaluation and risk management alternatives, performed to understand the nature of unwanted, negative consequences to human life, health, property or the environment;
- an analytical process to provide information regarding undesirable events;
- the process of quantification of the probabilities and expected consequences for identified risks.

It can also be defined as:

An objective, systematic, standardized and defensible method of assessing the likelihood of negative consequences occurring due to a proposed action or activity and the likely magnitude of those consequences, or, simply put, it is "science-based decision making".

1.3.3 The risk analysis process

In simple terms, a **risk analysis** typically seeks to answer **four questions:**

- What can go wrong?
- How likely is it to go wrong?
- What would be the consequences of its going wrong?
- What can be done to reduce either the likelihood or the consequences of its going wrong? (see MacDiarmid, 1997; Rodgers, 2004; Arthur *et al*., 2004).

The general framework for risk analysis typically consists of **four major components:**

- **Hazard identification** – the process of identifying hazards that could potentially produce consequences;
- **Risk assessment** – the process of evaluating the likelihood that a potential hazard will be realized and estimating the biological, social and/or economic consequences of its realization;
- **Risk management** – the seeking of means to reduce either the likelihood or the consequences of it going wrong; and
- **Risk communication** – the process by which stakeholders are consulted, information and opinions gathered and risk analysis results and management measures communicated.

1.3.3 The risk analysis process

The **risk analysis process** is quite flexible.

Its structure and components will vary considerably depending on:

- The sector (e.g. technical, social or financial),
- The user (e.g. government, company or individual),
- The scale (e.g. international, local or entity-level) and
- The purpose (e.g. to gain understanding of the processes that determine risk or to form the basis for legal measures).

It can be:

- Qualitative (probabilities of events happening expressed, for example, as high, medium or low) or
- Quantitative (numerical probabilities).

1.3.4 The concept of "hazard"

All **risk analysis** sectors involve the assessment of risk posed by a threat or **"hazard"**. The definition of **"hazard"** depends on the sector and the perspective from which risk is viewed (e.g. risks **to** aquaculture or risks **from** aquaculture).

A hazard can thus be:

- **a physical agent having the potential to cause harm, for example:**
  - ♦ a biological pathogen (pathogen risk analysis);
  - ♦ an aquatic organism that is being introduced or transferred (genetic risk analysis, ecological risk analysis, invasive alien species risk analysis);
  - ♦ a chemical, heavy metal or biological contaminant (human health and food safety risk analysis, environmental risk analysis); or
- **the inherent capacity or property of a physical agent or situation to cause adverse affects, as in:**
  - ♦ social risk analysis;
  - ♦ financial risk analysis; and
  - ♦ environmental risk analysis.

1.3.5 Risk analysis terminology

The terminology used by some **risk analysis sectors** is well established (e.g. pathogen risk analysis, food safety, environmental risk analysis), and there is often **considerable differences** in how individual terms are defined.

An attempt at **cross-sectoral standardization of terms** is thus probably **futile**, and it is thus important that that **terms** used by the various risk analysis sectors be **fully defined at the outset**.

1.3.6 Some general principles

Some basic principles that appear to be common to all types of risk analysis are presented below.

These involve the broader concepts of common sense, uncertainty, precaution, objectivity, transparency, consistency, scientific validation, stakeholder consultation, stringency, minimal risk management, unacceptable risk and equivalence (see Arthur, 2008).

- **The principle of common sense** – In assessing risks, the use of "common sense" should prevail. In many cases, the outcomes of a risk analysis are obvious and uncontroversial, and a decision can be made without resulting to a full risk analysis, which can be a lengthy and expensive process.

- **The principle of uncertainty** – All risk analyses contain an element of uncertainty. A good risk analysis will seek to reduce uncertainty to the extent possible.

- **The principle of precaution** – Those involved in the aquaculture sector have a responsibility to err on the side of caution, particularly if the outcomes of a given action may be irreversible. If the level of uncertainty is high, the **Precautionary Principle** can be applied to delay a decision until key information is obtained. However, steps must be taken to obtain the information in a timely manner.

- **The principle of objectivity** – Risk analyses should be conducted in the most objective way possible. However, due to uncertainty and human nature, a high degree of subjectivity may be present in some risk analyses. A risk analysis should clearly indicate where subjective decisions have been made.

- **The principle of transparency** – Risk analyses, particularly those conducted by public-sector agencies, should be fully transparent, so that all stakeholders can see how decisions were reached. This includes full documentation of all data, sources of information, assumptions, methods, results, constraints, discussions and conclusions.

1.3.6 Some general principles

Some General Principles

- The principle of common sense
- The principle of uncertainty
- The principle of precaution
- The principle of objectivity
- The principle of transparency
- The principle of consistency
- The principle of scientific validation
- The principle of stakeholder consultation
- The principle of stringency
- The principle of minimal risk management
- The principle of unacceptable risk
- The principle of equivalence

1.3.6 Some general principles

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- **The principle of consistency** – Although risk analysis methodology continues to evolve, it is important that decisions, particularly those made by government, are reached via standardized methods and procedures. In theory, two risk analysts independently conducting the same risk analysis should reach roughly similar conclusions.

- **The principle of scientific validation** – The scientific basis of a risk analysis and the conclusions drawn should be validated by independent expert review.

- **The principle of stakeholder consultation** – If the results of a risk analysis are likely to be of interest to, or impact upon others, then stakeholder consultations should be held. This is accomplished by risk communication, the interactive exchange of information on risk among risk assessors, risk managers and other interested parties. Ideally, stakeholders should be informed/involved throughout the entire risk analysis process, particularly for potentially contentious risk analyses (e.g. ecological, genetic and pathogen risk analyses for the introduction of new aquatic species).

- **The principle of stringency** – The stringency of the risk management measures to be applied should be in direct proportion to the risk involved.

- **The principle of minimal risk management** – Risk management measures that impinge on the legitimate activities of others should be applied only to the extent necessary to reduce risk to an acceptable level.

- **The principle of unacceptable risk** – If the level of risk is unacceptable and no effective or acceptable risk management measures are possible, then the activity should not take place.

- **The principle of equivalence** – Risk management measures proposed by trading partners that meet the acceptable level of risk should be accepted by the importing country.

1.4 Use of risk analysis in aquaculture development

1.4 Use of risk analysis in aquaculture development

As a food-producing sector, aquaculture has surpassed both capture fisheries and terrestrial farmed meat production in terms of average annual growth rate.

However, a number of biosecurity concerns pose risks to sustainable aquaculture development and to the broader aquatic environment and society.

Aquaculture faces risks similar to those of the agriculture sector. As aquaculture is very diverse in terms of species, environments, systems and practices, the range of hazards is broad and the perceived risks are complex.

Multiple objectives are driving the application of risk analysis to aquaculture. Foremost is for resource protection (human, animal health

1.4 Use of risk analysis in aquaculture development

and welfare aquaculture; wild fisheries and the general environment) as embodied in international treaties, memberships, agreements and informal guidance.

Of equal importance, the other drivers of risk analysis are: (i) food security; (ii) trade; (iii) consumer preference for high-quality and safe products; (iv) production profitability; and (v) other investment and development objectives.

Recently, **seven major risk sectors in aquaculture** have been identified (Bondad-Reantaso, Arthur and Subasinghe, 2008).

These are:

(i) pathogen;

(ii) food safety and public health;

(iii) ecological (pests and invasives);

(iv) genetic;

(v) environmental;

(vi) financial; and

(vii) social risks.

While the hazards and risks in some of the sectors are clearly recognized (i.e. pathogens and food safety) and methodologies (as well as standards) for their assessment have been developed and applied, the hazards and risks in many of these areas of concern are still vaguely understood and methods for their assessment are not yet clearly defined. Nevertheless, **all these sectors** are **inextricably linked** and pose serious biosecurity threats if their risks are not managed responsibly.

1.4 Use of risk analysis in aquaculture development

Risk analysis has wide applicability to aquaculture.

To date, it has been mainly applied in assessing risks to society and the environment posed by hazards created by or associated with aquaculture development **(Box 1)**. These include the risks of environmental degradation; introduction and spread of pathogens, pests and invasive species; genetic impacts; unsafe foods; and negative social and economic impacts.

The use of risk analysis can provide insights and assist in making decisions that will help to avoid such negative impacts, thus helping aquaculture development to proceed in a more socially and environmentally responsible manner.

Risk analysis is less commonly used to achieve successful and sustainable aquaculture by assessing the risks to aquaculture posed by the physical, social and economic environment in which it takes place **(Box 2)**. These include reduction of environmental risks (e.g. due to poor siting or severe weather events), biological risks (infection by pathogens via transfer from native stocks, predation by seals and sharks, red tides, etc.), operational risks (poor planning, work-related injuries), financial risks (market changes, currency fluctuations, emergence of new competitors, etc.) and social risks (negative image and resulting product boycott, lack of skilled manpower, competition from other sectors).

There exists, therefore, considerable scope to develop and expand the use of risk analysis for the benefit of aquaculture and the social and physical environments in which it takes place.

An integrated approach to risk analysis will assist the aquaculture sector in reducing risks to successful operations from both internal and external hazards and can similarly help to protect the environment, society and other resource users from adverse and often unpredicted impacts. This could lead to improved profitability and sustainability of the sector, while at the same time improving the public's perception of aquaculture as a responsible, sustainable and environmentally friendly activity.

1.4 Use of risk analysis in aquaculture development

Box 1: Examples of risks to society from aquaculture[1]

- **Environmental risks**
  - ♦ pollution from feeds, drugs, chemicals and wastes
  - ♦ alteration of water currents & flow patterns
- **Biological risks**
  - ♦ introduction of invasive alien species, exotic pests and pathogens
  - ♦ genetic impacts on native stocks
  - ♦ destruction/modification of ecosystems and agricultural lands (mangrove deforestation, salination of ricelands)
- **Financial risks**
  - ♦ failure of farming operations
  - ♦ collapse of local industry/sector
- **Social risks**
  - ♦ displacement of artisanal fishers
- **Human health risks**
  - ♦ food safety issues

[1] Source: **Arthur, J.R., Bondad-Reantaso, M.G. Campbell, M.L. Hewitt, C.L. Phillips M.J. & Subasinghe, R.P.** 2009. *Understanding and applying risk analysis in aquaculture. A manual for decision-makers.* FAO Fisheries and Aquaculture Technical Paper No. 519/1, Rome, FAO, 113 pp.

1.4 Use of risk analysis in aquaculture development

Box 2: Examples of risks to aquaculture from society and the environment[1]

- **Environmental risks**
  - ♦severe weather patterns
  - ♦pollution (e.g. agricultural chemicals, oil spills)

- **Biological risks**
  - ♦pathogen transfer from wild stocks
  - ♦local predators (seals, sharks, etc.)
  - ♦toxic algal blooms, red tide

- **Operational risks**
  - ♦poor planning
  - ♦poor design
  - ♦workplace injuries

- **Financial risks**
  - ♦market changes
  - ♦inadequate financing
  - ♦currency fluctuations
  - ♦emergence of new competitors

- **Social risks**
  - ♦negative image/press
  - ♦lack of skilled manpower
  - ♦competition for key resources from other sectors
  - ♦theft, vandalism

[1] Source: **Arthur, J.R., Bondad-Reantaso, M.G. Campbell, M.L. Hewitt, C.L. Phillips M.J. & Subasinghe, R.P.** 2009. *Understanding and applying risk analysis in aquaculture. A manual for decision-makers.* FAO Fisheries and Aquaculture Technical Paper No. 519/1, Rome, FAO, 113 pp.

1.4 Use of risk analysis in aquaculture development

For more than 15 years, the Food and Agriculture Organization of the United Nations (FAO), through its Fisheries and Aquaculture Department, has been assisting FAO Member countries in developing risk analysis capacity. During this period, numerous workshops and trainings have been conducted at the regional and national levels in various parts of the world. One of the most significant of these was the FAO/NACA Expert Workshop on Understanding and Applying Risk Analysis in Aquaculture, held in Rayong, Thailand from 7 to 11 June 2007 (Bondad-Reantaso, Arthur and Subasinghe, 2008).

A major accomplishment of the workshop was the commissioning of practical manual on "Understanding and applying risk analysis in aquaculture: a manual for decision-makers" (Arthur *et al*., 2009) which provided a unified overview of the application of risk analysis in the seven aquaculture risk sectors mentioned above.

This manual draws particularly on:

(i) A series of **Working Group (WG)** exercises and supporting materials (including case studies) that were developed as part of the FAO/FSM Department of Resources Development "National Workshop on Risk Assessment in Aquaculture Development" which was held in Pohnpei, Federated States of Micronesia from 24 to 27 May 2010; and

(ii) A series of **powerpoint lecture presentations** on risk analysis prepared by Drs Richard Arthur and Melba Reantaso on various national and regional training workshops on risk analysis in aquaculture and aquatic animal health management organized by FAO.