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Surveillance and zoning for aquatic animal diseases

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PREPARATION OF THIS DOCUMENT

In an effort to determine what surveillance options can best support scientifically valid zonation frameworks for aquatic animal diseases, an Expert Consultation was organized by FAO, the Federal Department of Fisheries and Oceans Canada (DFO Canada) and the World Organisation for Animal Health (OIE) in October 2002. The objective of the Consultation was to provide recommendations for surveillance and zoning that will be useful for designing national programmes aimed at reducing the risks of diseases resulting from transfers of live aquatic animals. This document contains the collective expert opinion and recommendations made during the Consultation, aimed at providing scientific advice to member countries building national or regional aquatic animal health management infrastructures.

Distribution:
Editors
Expert Consultation Participants
Regional Fishery Bodies and Arrangements
FAO Fisheries Officers
FAO Members and associate members
FAO Fish Health Projects
Fish Health Agencies

ABSTRACT

The primary purpose of aquatic animal disease surveillance is to provide cost-effective information for assessing and managing risks associated with trade (intra- and international) in aquatic animals and products, animal production efficiency and public health. This statement of purpose is consistent with the World Organisation for Animal Health (OIE) Aquatic Animal Health Code and international perceptions of what disease surveillance is meant to achieve in both terrestrial and aquatic production systems. This document provides technical information and recommendations to the Competent Authorities of countries wishing to implement zonation to demonstrate that they have a "reliable system of disease control and surveillance" in place. However, the design and implementation of such systems under a wide range of aquatic situations has highlighted both technical and economic challenges for realistic and scientifically justifiable surveillance programmes. This is particularly complex for open-water marine environment zonation, but also poses problems for multijurisdictional freshwater and estuarine hydrographic areas. While recommending the establishment of zones for aquatic animal disease management, FAO and OIE recognize that most countries face significant challenges in the practical implementation of zonation. In addition to scientific capability, political will and economic support are required, and scientifically sound surveillance programmes are often costly investments. The economic benefits of such programmes have to be weighed against each country's aquaculture activities – especially live animal movements – where like-to-like transfers form the basis of most disease risk assessments. Both the regulatory jurisdictions of governments involved in aquaculture development and the protection of wild aquatic resources must be taken into account to ensure optimum partnership (stakeholder) activities cover disease management in its broadest ecological sense. This document is a result of an Expert Consultation jointly organized by FAO, the Federal Department of Fisheries and Oceans Canada (DFO-Canada) and OIE to determine what surveillance options can best support scientifically valid zonation frameworks.

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FROM THE EDITORS

The Expert Consultation held in Rome in October 2002 was aimed at developing a document to provide guidance and advice to a wide audience of experts and responsible authorities for developing surveillance and zonation programmes for aquatic animal diseases. Special account was made to address appropriate options to meet local needs in developing countries. The consultation was not intended to produce a set of standards for direct application to surveillance and zonation implementation, as it is clearly recognized that this mandate falls on the shoulders of regional expertise and experience. Furthermore, basic standards have to be flexible enough to adapt to local environmental and socio-economic conditions. This guide focuses on scientifically-valid options that may be used to assist the surveillance programme design – both at the implementation stage and for the ongoing review and revision of established programmes. The value, as well as limitations, of historic data and observations for this process was included during the consultation discussions. We believe this document will serve as a strong starting point, for both targeted (active) and general (passive) surveillance design.

Rohana P. Subasinghe
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CONTENTS

LIST OF ABBREVIATIONS AND ACRONYMS

ACIAR	Australian Centre for International Agricultural Research
ALOP	Appropriate Level of Protection
ALOR	Acceptable Level of Risk
AR	Attack Rate
BSE	Bovine Spongioform Encephalopathy
CA	Competent Authority
CCRF	Code of Conduct for Responsible Fisheries
CVO	Chief Veterinary Officer
DFO	Department of Fisheries and Oceans of Canada
DNA	Deoxyribonucleic Acid
EDTA	Ethylene Diamine Tetra-acetic Acid (Acetate)
EIFAC	European Inland Fisheries Advisory Commission
ELISA	Enzyme-linked Immunosorbent Assay
EUS	Epizootic Ulcerative Syndrome
FAO	Food and Agriculture Organization of the United Nations
FMD	Foot and Mouth Disease
FSW	Filtered Seawater
GAV	Gill Associated Virus
GMP	Good Management Practice
H&E	Haematoxylin and Eosin
ICES	International Council for the Exploration of the Sea
1G4F	1 percent glutaraldehyde and 4 percent formaldehyde solution
IHC	Immunohistochemistry
IHHNV	Infectious Hypodermal and Hematopoietic Necrosis Virus
IRA	Import Risk Analysis
ISH	*in-situ* hybridization
KHV	Koi herpes virus
MSX	Multi-nucleate sphere X
NACA	Network of Aquaculture Centres in Asia-Pacific
NC	National Coordinator (for aquatic animal health)
NHP	Necrotising Hepatopancreatitis
OIE	World Organisation for Animal Health (OIE)
PCR	Polymerase Chain Reaction
QA/QC	Quality Assurance/Quality Control
RD	Runt Deformity (IHHNV in shrimp)
RFLP	Restriction Fragment Length Polymorphism
RFTM	Ray Fluid's Thioglycolate Medium
RNA	Ribonucleic Acid
RR	Relative Risk
RT-PCR	Reverse Transcriptase-Polymerase Chain Reaction
SARS	Severe Acute Respiratory Syndrome
SE	Sensitivity
SEM	Scanning Electron Microscopy
SP	Specificity
SSO	Seaside Organism
TEM	Transmission Electron Microscopy
TSV	Taura Syndrome Virus
VNN	Viral Nervous Necrosis
WGPDMO	Working Group on Pathology and Diseases of Marine Organisms
WSD	White Spot Disease
WTO	World Trade Organization
WTO-SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization
YHD	Yellowhead Disease
YHV	Yellowhead Virus

RELEVANT DEFINITIONS FROM THE OIE AQUATIC ANIMAL HEALTH CODE[1]

Term	OIE Aquatic Animal Health Code.
Aquatic Manual	means the *Manual of Diagnostic Tests for Aquatic Animals*.
Competent Authority	means the National Veterinary Services, or other Authority of a Member Country, having the responsibility and competence for ensuring or supervising the implementation of the aquatic animal health measures recommended in this *Aquatic Code*.
Diagnosis	means determination of the nature of a *disease*. (see also "Diagnosis" under Additional Definitions Relevant To National Surveillance Programmes For Disease Control, below)
Disease	means clinical or nonclinical infection with one or more of the aetiological agents of the *diseases* listed in this *Aquatic Code*.
Disease agent[2]	means an organism that causes or contributes to the development of a *disease* listed in this *Aquatic Code*.
Diseases listed by the OIE	means *diseases* that fulfil the criteria outlined in Chapter 1.1.2 of this *Aquatic Code*. (Chapter 1.1.2 - http://www.oie.int/eng/normes/fcode/A_00004.htm) Note: change to single listing for both Notifiable and Other Significant Diseases in 2003 6th edition of the Code and 4th edition of the Manual.
Disease outbreak	means an occurrence of *disease* in an aquatic animal population.
Emerging disease	means a newly recognised serious disease, the cause of which may or may not yet be established, that has the potential to be spread within and between populations, for example by way of trade in *aquatic animals* and/or *aquatic animal products*.
Imported outbreak	means a *disease outbreak* introduced into a *territory* from another country.
Incidence	means the number of new *outbreaks of disease* within a specified period of time in a defined aquatic animal population.
Infected zone	means a clearly defined *zone* in which a *disease* of *aquatic animals* included in this *Aquatic Code* has been diagnosed. This area must be clearly defined and decreed by the *Competent Authority* in accordance with the environment, the different ecological and geographical factors, the epidemiological factors and the type of aquacultural activity being practised. Within and at the border of an *infected zone*, there must be official veterinary control of *aquatic animals* and *aquatic animal products*, their *transportation* and *slaughtering*. The time during which the infected zone designation remains in effect will vary according to the *disease* and to the sanitary measures and control methods applied.
International trade	means import, export or transit of *aquatic animals, aquatic animal products, biological products* and *pathological material*.
Laboratory	means a *laboratory* of high technical competence under direct supervision of a veterinarian or other person with competent biological training. Through quality controls and monitoring performance, the *Competent Authority* approves such a *laboratory* in regard to testing requirements for export.

[1] Italicized text refers to other definitions in the OIE Code. These may/may not be included in the list selected for this Consultation report.

[2] Disease is also caused by non-infectious agents or abiotic factors. However, for prevention of disease spread with live aquatic animal movements, the term 'disease' used in this report applies solely of those caused by infectious agents (infectious or contagious disease).

Term	OIE Aquatic Animal Health Code.
Prevalence	means the total number of infected *aquatic animals* expressed as a percentage of the total number of *aquatic animals* in a given aquatic animal population at one specific time.
Risk	means 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.
Risk assessment	means the processes of identifying and estimating the *risks* associated with the importation of a *commodity* and evaluating the consequences of taking those *risks*.
Risk communication	means 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.
Risk management	means the identification, documentation and implementation of the measures that can be applied to reduce *risks* and their consequences.
Susceptible species	means *aquatic animals* that are capable of being infected by a given *disease agent*.
Surveillance	means 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.
Surveillance zone	means a *zone* in which a systematic series of investigations of a given population of *aquatic animals* takes place.
Targeted surveillance	means *surveillance* targeted at a specific *disease* or *infection*.
Zone	means a portion of one or more countries comprising an entire catchment area from the source of a waterway to the estuary, more than one catchment area, part of a catchment area from the source of a waterway to a barrier, or a part of the coastal area, or an estuary with a precise geographical delimitation, that consists of a homogeneous hydrological system.
Zoning	means identifying *zones* for disease control purposes.

ADDITIONAL DEFINITIONS RELEVANT TO NATIONAL SURVEILLANCE PROGRAMMES

Term	Definition (in the sense of this Technical Consultation)
Appropriate level of protection (ALOP)	Actions designed to reduce the risk of an event occurring that is considered to present a level of risk that is unacceptable economically, socially, or environmentally, to an importing country, region or zone within a country. The level of protection, and actions associated with its implementation, must be commensurate with the level of risk and scientifically justifiable.
Acceptable level of risk (ALOR)	The level of protection deemed appropriate by a country in establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory (modified from WTO-SPS Agreement).
Assay	A test designed to isolate or detect evidence of an infectious agent.
Biosecurity measures	Appropriate measures or procedures in place to manage the probability of a biological organism or agent spreading to an individual, population of ecosystem and the harm that may result. Biological organism in this context includes a recognized disease agent, a new or novel disease agent, a recognized pest species that causes economic damage, or a species that would cause ecological degradation, reduce biodiversity or other adverse environmental effects.
Buffer zone	Zone between a positive and negative zone that requires stringent surveillance to prevent disease spread to negative zones, or ensure accurate definition of positive zone area.
Carrier or Reservoir host	A species that can carry an infectious agent without clinical sign of infection or evidence of development or proliferation, *and* which can transmit that agent to produce infections in either the known susceptible species or other carrier species.
Clinical infection	An infection that causes a subjective change in condition that reduces health, ranging from subtle signs to fatality.
Data	Data from disease surveillance activities: o *Primary* (raw) data is generally data where the precise source (farm, animal, etc.) is known. o *Secondary* data refers to aggregated data, such as the prevalence of disease in a given sample/series of samples/population.
Data management	Management of data from disease surveillance activities (i.e. general or non-specific; and targeted or disease-specific) that contribute to databases upon which zones are established and maintained, in such as way as to meet regional, national and scientific scrutiny/verification, as required.
Diagnosis	o Presumptive – Suspicion of an infection that requires additional analysis to confirm or refute. o Conclusive – Diagnosis of an infection that requires no further analysis. Also known as Confirmatory Diagnosis.
Epidemiology	o The study of the distribution and factors associated with disease establishment, levels and spread. o The study of the distribution and determinants of health-related states and events in populations and the control of health problems, the study of epidemic disease (Online Medical Dictionary, http://cancerweb.ncl.ac.uk/omd/). o The study of populations in order to determine the frequency and distribution of disease and measure risks.

Term	Definition (in the sense of this Technical Consultation)
Immunization	Enhancement of host defence capability by exposure or by administration of a vaccine preparation containing actual or substitute pathogen antigens.
Import risk analysis (IRA)	The process by which hazards associated with the movement of a particular commodity into a country are identified and mitigative options are assessed. Risk analysis incorporates risk assessment to identify possible risk mitigation options for evaluation in the socio-economic as well as ecological/habitat context of importation. See also OIE definitions for Risk, Risk Assessment, Risk Management and Risk Communication.
Intensity	The number of infectious agents present per infected host within a sample, expressed as a mean number, or qualitative rating.
Introduction	o Active introduction of a species to waters outside their current geographic range. o The human-assisted movement of an aquatic animal to an area outside its natural range (FAO/NACA 2001).
Koch-Henle's postulate	Application of Koch's postulates distinguishes a pathogenic from an adventitious microbe (Davis 1980). The criteria used are: (a) the organism is regularly found in the lesions of the disease; (b) it can be isolated in pure culture on artificial media; (c) inoculation of this culture produces a similar disease in experimental animals; and (d) the organism can be recovered from the lesions in these animals.
Monitoring	A systematic series of investigations of a given population of aquatic animals to detect changes in the prevalence and geographical distribution of disease, which may involve testing samples of a population. Collection and analysis of information necessary to detect changes in prevalence and intensity of infection (FAO/NACA 2001).
Outbreak (Disease)	A short term epidemic or a series of clustered (time or space) disease events that are new cases of a disease occurring at a higher frequency than expected, or due to a "new" disease.
Pathogen	An agent capable of causing clinical changes in a susceptible host may or may not be infectious. In the sense of this report, all pathogens are infectious. An infectious agent capable of causing disease (FAO/NACA 2001).
Risk estimation	The process of integrating the results of the release assessment, exposure assessment, and consequence assessment to produce overall measure of risks associated with the hazards identified at the outset (Arthur and Bondad-Reantaso 2003).
Resistance	The ability of an organism to prevent infection by being refractive (the agent never invades the host) or by having an immune/defence response that can detect and kill all the infectious agents entering the organism.
Sensitivity and specificity	The inherent characteristics of diagnostic test which must be taken into account when interpreting the results of that test. Sensitivity is the ability of the test to detect infections where present and is an important characteristic for screening for sub-clinical or carrier infections. Specificity is the ability of the test to distinguish between significant pathogens and closely related or morphologically similar pathogens of less/no significance.
Surveillance programme	A programme that incorporates General (Passive) and/or Targeted (Active) surveillance, and may incorporate monitoring activities, where the programme is aimed at control of a disease that is present in some areas/zones, but absent from others that contain susceptible populations.

Term	Definition (in the sense of this Technical Consultation)
Surveillance Types	o General (or passive) surveillance is the ongoing work, which maintains a continuous watch over the endemic disease profile of a population so that unexpected and /or unpredicted changes can be recognized. General surveillance includes all the routine disease investigation activities that may be used in a country. This is also known as scanning surveillance by Scudamore (2002). o Targeted (or Active) surveillance collects information about a specific disease or condition so that its level in defined population can be measured, or its absence reliably substantiated. This includes surveys and sentinel systems.
Susceptible	An individual or species that is incapable of defending itself against infection by a given disease agent, or group of related disease agents.
Syndrome	o A collection of signs and epidemiological factors that often occur together, and can be used to identify a disease. o A set of signs or a series of events occurring together that often point to a single disease or condition as the cause (Online Medical Dictionary, http://cancerweb.ncl.ac.uk/omd/).
Tolerance/ Tolerant	An individual or species that is susceptible to infection, but is capable of suppressing the infection to sub-clinical levels. Tolerance is usually acquired by survival of an initial exposure to infection, or generically by inheritance from parent stock that survived infection.
Transfer	o Active transfer of stocks of a species to waters within their current geographic range. o The movement of an aquatic animal to an area within or across political borders (international, state/provincial or regional boundaries) (FAO/NACA 2001).
Vertical transmission	o Transmission of an infectious agent from parents to offspring via intra-ovum infection (vertical transmission *sensu stricto*) or via contamination of gamete surfaces, zygotes or larvae. o The prenatal transmission (i.e. passed from parent to egg); may be either inside the egg (intra-ovum) or through external exposure to pathogens from the parent generation (Bondad-Reantaso *et al*. 2001).

EXECUTIVE SUMMARY

The fundamental basis for any decision to undertake surveillance under complex aquatic conditions is a clear understanding of the objective of such surveillance. The Expert Consultation (herein referred to as the Consultation) agreed that the primary purpose of aquatic animal disease surveillance is to provide cost-effective information for assessing and managing risks associated with:

- protection of wild and cultured aquatic resources and their ecosystems from preventable disease threats;
- trade in aquatic animals and products (intra- and international);
- animal production efficiency;
- public health.

This is consistent with international perceptions of what disease surveillance is meant to achieve in both terrestrial (OIE 2003a) and aquatic (OIE 2003b) production systems.

The objectives which define surveillance for aquatic animal diseases are:

- rapid detection of new and exotic infectious diseases in wild and cultured aquatic animals;
- provision of evidence of freedom from diseases relevant to domestic and international movement of aquatic animals and products;
- accurate description of the distribution and occurrence of diseases relevant to disease control and domestic and international movement of aquatic animals and products;
- assessment of control or eradication success for selected diseases and pathogens.

The Consultation also agreed that, although many types of surveillance exist, for the purpose of these guidelines and recommendations, only two are appropriate. The definitions for these are modified from Scudamore (2002):

General surveillance is an ongoing investigation or observation of the endemic disease profile of a population, so that unexpected and/or unpredicted changes can be quickly recognized. General surveillance includes all the routine disease investigation activities that may be used in a country which could detect the disease of concern if present. This is also known as passive surveillance or scanning surveillance by Scudamore (2002).

Targeted surveillance collects information about a specific disease or condition so that its presence in a defined population can be measured, or its absence reliably substantiated.

Fundamental principles are provided throughout this document to assist the design of scientifically sound surveillance programmes. However, users of the document must apply these with a clear understanding that there are no “fixed rules” or “recipe book” guidelines. General principles will always have to be adapted to fit the human and ecological factors faced within any given situation in order to establish and maintain effective zones.

The Consultation, organized by the Food and Agriculture Organization of the United Nations (FAO), the Federal Department of Fisheries and Oceans Canada (DFO Canada) and the World Organisation for Animal Health (OIE) to address such questions was held in October 2002 at the FAO Headquarters in Rome, Italy. Twenty-three participants were invited with expertise spanning global aspects of aquatic animal health management. Their input was

aimed at providing recommendations for surveillance and zonation that will be useful for designing national programmes to reduce the risks of diseases arising from live transfers of aquatic animals. The recommendations and guidelines are not intended for use as international trade standards (the remit of the WTO and OIE), but extends to a broader application aimed principally at aquatic food security and encompassing protection from high risk trade as well as surveillance to protect against impacts from endemic diseases.

Five working documents prepared by selected experts provided the basis for discussion and development of recommendations during the Expert Consultation. Four working documents addressed technical issues related to: (a) freshwater finfish; (b) marine and diadromous finfish; (c) crustaceans; and (d) molluscs. Capacity building, information access and technical requirements for developing countries wishing to implement aquatic animal disease surveillance and zonation formed a fifth, non-technical, discussion document.

The development of the guidelines and recommendations outlined in this document were based on a set of seven general Guiding Principles, along with a set of scientific principles, encompassing surveillance to establish and maintain zones as applied to animals in general and specifically for application to finfish, crustaceans and molluscs.

Zonation is the process of delineating infected and uninfected populations within a country or group of countries. “Infected zone” and “uninfected zone” usually applies to specific diseases, except on the rare occasion where a range of different diseases share common epidemiological characteristics or can be detected using common diagnostic (non-disease-specific) techniques. An uninfected zone can be established within a country using the health status of a susceptible host species for a specific disease within a particular geographic or hydrographic area. Zoning is particularly relevant to controlling aquatic animal diseases, since these do not readily respond to disease control measures used for isolation and containment in land-based facilities or for terrestrial animals.

INTRODUCTION

Aquaculture contributes significantly to affordable, high-quality, animal protein and other essential nutrients, especially for poorer segments of the world. However, disease is a serious constraint to the sustainable culture of many species, impeding socio-economic progress in many countries. As a result, aquatic animal health programmes based on surveillance and zonation for diseases of national and international trade significance have become a primary requirement for effective management of sustainable aquaculture development in many countries.

Outlines for aquatic animal health programmes are provided by the Aquatic Animal Health Code (OIE 2003b) and the Manual of Diagnostic Tests for Aquatic Animals (OIE 2003c) of the World Organisation for Animal Health (OIE), as well as by Asia-Pacific regional aquaculture health infrastructure support documents of the FAO and the Network of Aquaculture Centres of Asia-Pacific (NACA), including a Technical Guidelines and Implementation Strategy (FAO/NACA 2000), Manual of Procedures (FAO/NACA 2001) and an Asia Diagnostic Guide (Bondad-Reantaso *et al.* 2001). All documents take into full consideration the provisions of the World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (WTO-SPS Agreement) (WTO 2002), along with Article 9 (Aquaculture Development) of the Code of Conduct for Responsible Fisheries (CCRF) (FAO 1995).

The OIE Aquatic Code recommends that zones for diseases of concern to international trade be established to "internationally accepted standards with regard to terminology, boundaries, legal competence, duration of disease free periods, standards of surveillance, use of buffer zones, quarantine procedures and other aspects of regulatory control".

It is the responsibility of the Competent Authorities (CA) of countries wishing to implement zonation to demonstrate that they have a "reliable system of disease control and surveillance" in place. The design and implementation of such systems under a wide range of aquatic situations, however, has highlighted both technical and economic challenges for realistic and scientifically justifiable surveillance programmes. This is particularly complex for open-water marine environment zonation, but also poses problems for multijurisdictional freshwater and estuarine hydrographic areas.

In the context of this Expert Consultation, surveillance and zonation are applicable to diseases of concern to trade, to disease management and control within individual countries, as well as to management spanning a range of jurisdictional (provincial, state, territory) and geographic boundaries. In the latter situations, disease control frameworks have frequently used political boundaries, rather than epidemiological, climatic or hydrographic boundaries, to define "zones". These have proven ineffective and are subject to inconsistencies and unscientific decision-making. As more countries start to develop their own aquatic animal health programmes, it is important to define the process for listing the "diseases of concern". Without such definitions, the justification for the significant investment of resources and infrastructure required will continue to be argued among policy and decision makers.

While recommending establishment of zones for aquatic animal disease management, FAO and OIE recognize that most countries face significant challenges in the practical implementation of zonation. In addition to scientific capability, political will and economic

support are required. Scientifically sound surveillance programmes are often costly investments. The economic benefits of such programmes have to be weighed against each country's aquaculture activities – especially live aquatic animal movements. The regulatory jurisdictions of governments involved in aquaculture development, as well as protection of wild aquatic resources, must be taken into account to ensure optimum partnership (stakeholder) involvement in disease management in its broadest ecological sense.

In an effort to determine what surveillance options can best support scientifically valid zonation frameworks, the Federal Department of Fisheries and Oceans Canada (DFO Canada) in 2002 offered assistance to FAO in order to hold an Expert Consultation on the question of Surveillance and Zonation.

Objective: The objective of the Expert Consultation was to provide recommendations for surveillance and zonation that will be useful for designing national programmes aimed at reducing the risks of disease losses through live transfers of aquatic animals. These recommendations are aimed solely at providing scientific advice to member countries building national or regional aquatic animal health infrastructures. They are not intended for use as international trade guidelines or standards (the remit of the WTO and OIE).

Approach: The three levels of diagnostics (Levels I, II, III) used throughout this Technical Paper were developed for the Asia Regional Technical Guidelines, the Manual of Procedures and the Asia Diagnostic Guide to Aquatic Animal Diseases. These span all levels of aquatic disease experience, technology and related infrastructures.

Thematic organization: The Expert Consultation consisted of presentations and discussions in both plenary and sub-group sessions. Sub-groups consisted of experts in specific aquatic animal groups and habitats (duly noting that some diseases may span more than one habitat):

- Finfish – marine, freshwater, diadromous
- Molluscs – marine, estuarine
- Crustaceans – marine, freshwater, estuarine

Criteria taken into consideration were: type of disease and host(s); duration of production cycles; wild and hatchery-based production; production systems and marketing; sampling options (collection methods, transportation conditions, etc.); reporting options; and data management. These were discussed in light of scientific (confidence levels) and legal (transparency) challenges at the international level (assuming this will cover national/regional or local disease management objectives).

Scope and base-line assumptions: Consultation discussions were limited to surveillance and zonation strategies, despite obvious linkages to diagnostic methodology (sensitivity and specificity questions, field validation, etc.), quality assurance/quality control management of surveillance protocols, disease response/control mechanisms, and others. Such restriction in scope was necessary in order to focus on the basic design of sampling programmes, rather than on their technological or regulatory foundations. This required a clear understanding, and recognition, of several base-line assumptions. These should be considered by any aquatic animal health interests using the resulting recommendations of this Expert Consultation. These base-line assumptions are:

- screening technology used is effective for detection of the disease agent in question, under normal environmental and culture conditions[3] ;
- a Quality Assurance/Quality Control (QA/QC) programme is in place to monitor the effectiveness of the screening technology used;
- all diseases have a sub-clinical stage of development that can escape detection using optimum screening methodology;
- all susceptible and/or carrier species are unlikely to be known.

Procedure: Five working documents were prepared by selected experts and provided the basis for discussion and development of recommendations during the Consultation. Four working documents addressed the technical issues that required discussion for: (a) freshwater finfish, (b) marine and diadromous finfish, (c) crustaceans; and (d) molluscs. The capacity building, information access and technical requirements of developing countries wishing to implement surveillance and zonation for aquatic animal diseases formed a fifth, non-technical, discussion document.

Participants: Participants were selected on the basis of technical experience and knowledge of surveillance, zonation and epidemiology (See Appendix II). Representation from the agricultural disease control field was included to compare surveillance approaches used for terrestrial animal diseases. Every effort was also made to include representation from various regions of the world to cover the breadth of environmental and aquatic resource sectors faced in developing surveillance and zonation programmes.

Venue and date: FAO-UN headquarters, Rome, Italy, 14-16 October 2002. See Appendix III for the Consultation Work Programme.

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[3] Seasonal detection sensitivity was taken into account for collection scheduling.

GUIDING PRINCIPLES

The following principles were used to develop the guidelines and recommendations:

- Responsible movement of living aquatic animals within and across national boundaries is necessary and can lead to considerable economic, social, and development benefits.
- Transboundary movement of living aquatic animals poses varying risks of introducing exotic pathogens and/or increasing the distribution of enzootic (endemic) pathogens.
- The Expert Consultation is aimed at providing scientifically-based recommendations for surveillance and zoning assisting the development of effective national or regional disease management programmes for both cultured and wild stocks of aquatic animals that are susceptible to, or vectors of, viable infectious agents of concern.
- The "zero-risk" approach (i.e. no movement of live product between or within countries) is considered impractical. However, it is recognized that each country has the sovereign right to set its own appropriate level of protection (ALOP).
- Recommended surveillance programmes and zoning systems should be practical, cost-effective and capable of implementation using existing disease detection techniques, including provisions to cover variations in resource availability and technical capacity of individual countries. Where no disease detection capability exists (beyond recognition of dead animals), recommendations should include capacity building options.
- Surveillance and zoning are integral components of effective import risk analysis (IRA) for transboundary trade in aquatic animals. Other components of IRA are hazard identification, justification for protection, and identification and implementation of suitable control measures (such as surveillance and zoning). The objective is to provide countries with an ALOP that minimizes unnecessary disruption to trade.
- Pathogens/diseases that merit consideration as candidates for surveillance and zoning are primarily: infectious in aetiology; listed diseases of international trade significance (as defined by the OIE Aquatic Code); infectious diseases of regional, national or local significance; and newly emerging infectious diseases.

SCIENTIFIC PRINCIPLES FOR SURVEILLANCE TO ESTABLISH AND MAINTAIN ZONES

Principles applying to all types of animals are listed first, followed by those which are more specific to fish, crustaceans and molluscs.

Animals in general

- Both wild and farmed species are susceptible to infectious pathogens of disease concern.
- Risk analysis is the appropriate process to guide the selection of diseases that warrant establishment and maintenance of zones.
- In the process of establishing a zone free of a disease or pathogen of significance, there is no valid reason for requiring the testing of a species for which there is scientific evidence to demonstrate that the species is refractory to infection by the pathogen(s) to be tested for.
- There is no valid reason to test species in environments that fall outside of the physiological tolerance range or epidemiological transmission range of the pathogen being tested for.
- An appropriate sample size must be applied to demonstrate presence or absence of an infectious pathogen in a population (e.g. Cameron 2002).
- Some tests available for surveillance (e.g. biomolecular assays[4]) are only indicative of the presence of the particular pathogen and should be applied in conjunction with tests that visually demonstrate presence of the particular pathogen (e.g. bioassay, histology and culture techniques).
- Sampling procedures for OIE listed diseases and other pathogens of significance may be lethal to the host, therefore, any surveillance scheme must take into account lethal-sampling limitations, e.g. for limited numbers of susceptible stock, such as valuable broodstock, which present minimal disease transfer opportunities. Alternative, non-lethal, sampling methods may need to be used in these circumstances.
- Many pathogens of concern are known to be carried by clinically healthy hosts.
- Detection of viral pathogens in clinically normal specimens often requires the use of Level III technology (i.e. tissue culture, electron microscopy, PCR or other biomolecular-based diagnostic tools).
- There are no scientifically reliable methodologies to rid a carrier animal population of viral or other directly transmitted pathogens.
- Due to the low prevalence of certain significant diseases in healthy wild populations, the diversity of species in an open-environments, the lack of scientific knowledge on the susceptibility of most non-cultured species, and the difficulty in accurately establishing the health status of wild populations, untested populations should be considered suspect for carrying pathogens of significance unless environmental conditions or host susceptibility prove otherwise.
- Prevalence of infection in both wild and cultured animal populations is likely to be highly variable, ranging from one infected individual in several thousand animals to all individuals in a population being infected.

[4] PCR – polymerase chain reaction based molecular analyses of DNA and RNA.

Finfish

- Gametes obtained from broodstock infected with a viral disease should be suspect for the pathogen in question. Egg disinfection procedures greatly reduce the risk of vertical transmission of some viral pathogens; however, infectious viruses which are present inside the egg can persist post-disinfection.
- While disinfection of fertilized eggs can reduce the risk of infection, Level III technology is often required to demonstrate freedom from infection.
- Immunization against some diseases of salmonids exist, however, levels of protection vary.

Crustaceans

- Many significant viral diseases have a broad host species range in crustaceans. All crustaceans should be regarded as potential carriers unless clearly demonstrated to be refractory to infection, or environmental conditions are not conducive to pathogen transmission/virulence.
- Many viral pathogens of crustaceans are transmitted vertically through contamination of spawning fluids.
- Gametes from infected broodstock should be presumed to be infected unless scientific evidence has established otherwise. While disinfection of fertilized eggs may reduce the risk of infection, Level III technology is often required to demonstrate freedom from infection.
- No effective vaccines are currently available for enhancing tolerance of, or resistance against, significant diseases of crustaceans.
- No cell-lines are currently available for isolation and characterization of intra-cellular infectious agents (viruses, some bacteria) of crustaceans.
- Apparently healthy shrimp may harbour one or a number of pathogens which cannot be identified due to the absence of pathology and/or insufficiently sensitive detection tests.

Molluscs

- No vaccines are currently available for enhancing tolerance of, or resistance to significant diseases of molluscs.
- No cell-lines are currently available for isolation and characterization of intra-cellular infectious agents (viruses, some bacteria).
- Apparently healthy molluscs may harbour pathogens which cannot be detected or identified due to the absence of pathology and/or insufficiently sensitive/specific detection tests.
- Molluscs often provide substrate surfaces for a variety of micro- and macroscopic fouling organisms that may be factors in disease transmission, but are rarely included in routine disease surveillance methods that concentrate on soft-tissue pathology.

OVERVIEW OF SURVEILLANCE AND ZONING

What is disease surveillance?

Surveillance is a mechanism applied to collect and interpret data on the health of animal populations, to accurately describe their health status with respect to specific diseases of concern. This can be based on historic scientific evidence for absence, under certain circumstances, of clinical cases of a virulent disease of the susceptible species. Targeted surveillance to prove absence of infection by specific pathogens may be used to reinforce inconclusive general (passive) and/or historic evidence. As indicated in the definition section, the term surveillance is used for the detection of new or exotic diseases, while monitoring is aimed at detecting increases in established or endemic infection levels that may signal the recurrence of a disease outbreak. The term surveillance *programme* is often used to incorporate both surveillance and monitoring activities.

The concept of surveillance is shown diagrammatically in Figure 1. Stakeholders include people whose livelihoods depend on consistent aquatic animal productivity, government regulators with the responsibility for protection of trade and wild and cultured resources, and environmental protection interests. One of the most critical factors behind this overview is the feedback loop. Rapid and transparent communication between the stakeholders and surveillance managers is essential for data accuracy and effectiveness for disease control use. Many countries and international organizations make mandatory reporting of disease outbreaks a legal requirement to ensure diseases cannot occur and go unreported. Regardless of legislative support, however, it is in the interest of all stakeholders to report any health concern immediately, since the cost of delayed intervention always outweighs the cost of early intervention. In countries where mandatory reporting is not yet legislated, Good Management Practices (GMPs) at the farm level can be used to assist effective health management. Good Management Practices are particularly effective where farms operating under such programmes can command stronger market positions or site licensing costs. This can address “self-policing” concerns and promotes rapid voluntary reporting.

Figure 2 shows the relationships among the components of a surveillance program, including effective surveillance, host population and environmental factors.

Surveillance and monitoring require trained expertise, suitably equipped laboratories, legal support structures, transport and communication networks, etc. Effective application of this support infrastructure requires a good knowledge of susceptible/carrier host populations and their local environments. Building on this foundation are the various surveillance and monitoring activities which lead to accurate data and knowledge of the location and pathologic significance of pathogens of concern. Last, but not least, the information collected and analysed must be communicated to relevant stakeholders, including surveillance personnel. This completes the feedback required for reducing the risk of disease transfer with movements of live aquatic animals for all purposes.

Figure 1: Overview of disease surveillance.

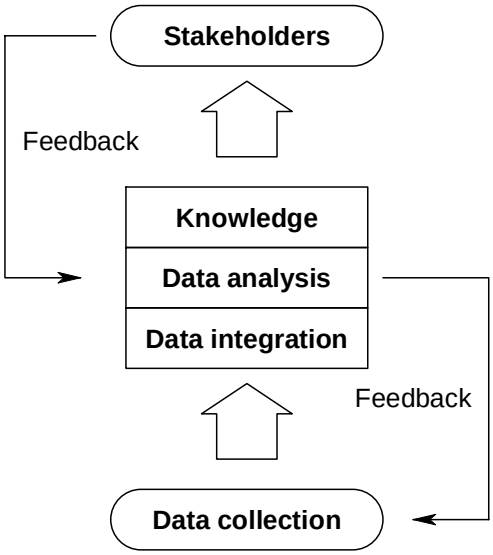
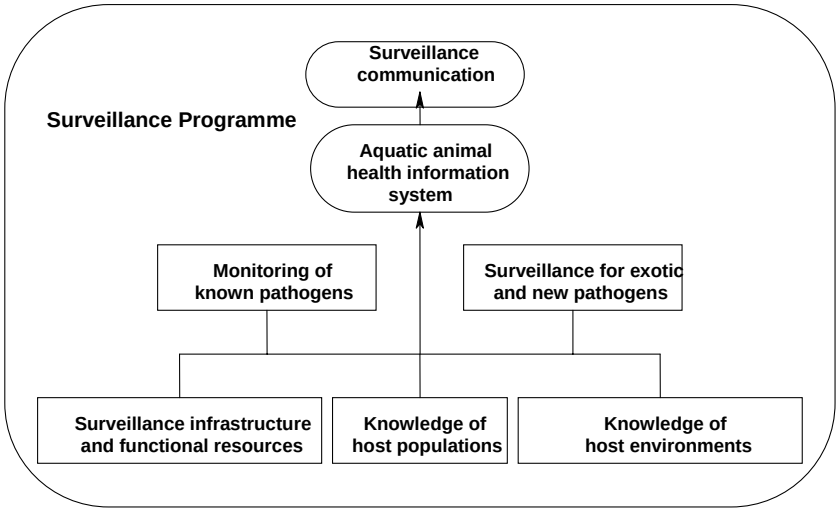


Figure 2: Relationships among different components of a surveillance programme.



Importance of disease surveillance

An ongoing problem for setting guidelines for low risk trade practices is that the disease situation is never static. A number of factors contribute to changes in disease status, proliferation and spread. These include:

Globalization: There is a continuing integration and inter-dependence of world markets and economies. This includes the current increase in trade of live animals, their products, animal feeds and related food items. Concomitant with faster and higher volume shipping,

transportation, and human travel, is a significant increase in opportunity for introduction of "new"[5] diseases and infections.

Increasing aquaculture production: Aquaculture is presently the fastest growing food sector in the world, with production almost trebling since 1990 to reach 45.71 million tonnes in 2000. Developing countries are providing the bulk of this increase in production. Pressures from continued growth at this rate raise the risks due to rapid changes in production systems and the emergence and spread of "new" diseases.

Microbial adaptation: Micro-organisms have a remarkable ability to adapt to changes in their environment. For example, the widespread use of antibiotics in the treatment of human and animal diseases has led to the appearance of problematic drug resistant organisms. Similarly, global warming and other climatic changes are beginning to show evidence of facilitating alterations in the geographical distribution of some pathogens and their vectors.

These issues suggest that the disease situation in aquaculture will continue to change in an unpredictable way. Some recent examples of diseases that have emerged as aquaculture has developed are shown in Table 1.

Table 1. Examples of important diseases that have emerged for finfish, crustaceans and molluscs.

Finfish	Crustaceans	Molluscs
1. Epizootic Ulcerative Syndrome (EUS) 2. Viral Nervous Necrosis (VNN) 3. Koi Herpes Virus (KHV)	1. White Spot Disease (WSD) 2. Yellowhead Disease (YHD) 3. Taura Syndrome (TS)	1. Multinucleate Sphere X (MSX) disease 2. Bonamiosis

Enhanced trade in aquatic animal commodities (live, fresh and frozen product) has lead to increasing scrutiny of the risks of spread of diseases along with this trade. This, in turn, has highlighted the need for more effective systems for investigating, reporting and responding to significant aquatic animal disease threats. Reliable evidence for freedom from particular diseases is a major challenge behind development of such programmes. Current international animal trade agreements (notably the WTO-SPS Agreement) require scientific justification for restrictions on trade on animal health grounds, such as a clear risk to the freedom of a country or territory from a particular disease or a potential threat to the effectiveness of an official control programme for the disease. Supporting international standards for aquatic animal diseases (OIE Aquatic Animal Health Code and OIE Manual of Diagnostic Tests for Aquatic Animal Diseases) recommend certain requirements for surveillance to support a country's declaration of freedom from a disease[6]. This is necessary for any country wishing to impose protective measures to prevent exposure via imports from countries where the disease of concern exists. In order for a country, regions or other zone, to make informed decisions on preventive or remedial actions, it is essential to have effective means of identifying and tracking diseases, as well as assessing their effects.

Disease surveillance is a fundamental component of any official aquatic animal health protection programme. Such surveillance forms the basis for early warning of imminent or emerging disease outbreaks; planning and maintaining disease control programmes; provision

[5] Previously unobserved, unreported or undocumented infections.
[6] See Chapter 1.1.4 "Requirements for surveillance for international recognition of freedom from infection"; OIE *Manual of Diagnostic Tests for Aquatic Animals*, 4th ed, 2003 - http://www.oie.int/eng/normes/en_amanual.htm

of sound (data-based) aquatic animal health advice to farmers and environmental interests; certification of exports; international reporting and verification of freedom from diseases of concern. Proactive surveillance, prior to any emergency disease outbreak, provides the data essential to respond immediately and effectively to isolate the source and identify the extent of the problem. Knowing the source and extent of a disease outbreak saves valuable time and effort in focusing control efforts on the areas most required.

Purpose and objectives of surveillance

A clear definition of objective(s) is of prime importance for effective surveillance. The following are summaries from Consultation discussions, along with pertinent reports on the issue.

The primary purpose of aquatic animal disease surveillance is to provide scientifically accurate, cost-effective, information for assessing and managing risks of disease transfer associated with trade (intra- and international) in aquatic animals and animal production efficiency and public health. This statement of purpose is consistent with the WTO-SPS Agreement, the OIE Aquatic Code, and international understanding of what disease surveillance is meant to achieve in both terrestrial and aquatic production systems.

Diseases that warrant surveillance programmes should be those that pose a significant threat to trade, productivity (wild or cultured) and/or public health. These may be diseases listed by the OIE, or other diseases of special concern within a country. The objectives which define surveillance for aquatic animal diseases are:

- rapid detection of new and exotic (to a zone or country) infectious diseases;
- provision of evidence of freedom from diseases within a defined geographical area or a specific population/stock relevant to domestic and international movement of aquatic animals and products;
- accurate delineation of the distribution and occurrence of diseases relevant to disease control and domestic and international movement of aquatic animals and products; and
- assessment of control or eradication success for selected diseases and pathogens.

These objectives define what surveillance is meant to achieve, whether undertaken to describe the distribution and prevalence of an important disease, to ensure that disease zones are maintained, or to assess success of eradication, fallowing or other disease control measures.

Types of surveillance

Many terms have been applied to describe different types of surveillance, reflecting the various objectives of surveillance. Terms such as passive surveillance, active surveillance, general surveillance, targeted surveillance and, more recently, scanning surveillance (Scudamore 2002) are used throughout the literature. Since they are frequently interchanged, or used without clear definition, a brief explanation for each is given below. A more complete discussion on passive and active surveillance is provided by Cameron (2002). A comprehensive surveillance programme can comprise of a combination of many approaches to the gathering of surveillance data.

Passive surveillance is the secondary use of data routinely collected for some other purpose. This specific disease information is a “by-product” of more general disease investigations, e.g.

routine gathering of information on disease incidents reported by farmers and field officers, or results from specimens submitted to diagnostic laboratories, or examined for research purposes. General surveillance is very useful for early detection of emerging diseases and often provides a general picture of the disease situation in a population. However, it provides negligible quantifiable data on infection levels, or reliable data on the full geographic distribution, of the disease. This type of surveillance cannot be used to reliably demonstrate absence of a particular disease from a given area. Because of this its broad non-specific nature, general surveillance is sometimes called "passive" or "scanning" surveillance.

Targeted surveillance involves planned collection of precise field data on the presence of a specific disease or pathogen within a defined population. Active disease surveillance programmes may be (i) "catch all" – aimed at detecting any significant disease occurrences; (ii) may target specific diseases; or (iii) may monitor the progress of specific disease control or eradication efforts. This kind of surveillance can provide the data required to prove that the specified populations are free of a specific disease. In order to maximize the value of targeted surveillance, it should be based on survey techniques which provide representative samples of the susceptible population of interest. Sampling techniques are aimed at maximizing the likelihood of pathogen detection, based on available epidemiological information.

Since general surveillance is not always completely "passive" and targeted surveillance can include activities other than planned active surveillance (e.g. investigation of disease outbreak reports), clear understanding of surveillance activities can be complicated and hybrid terms such as targeted active surveillance may appear. To avoid confusion in the context of this report, the definitions and terminology below are used throughout the rest of this document.

General surveillance can be used to develop targeted surveillance programs. For example, routine health checks of dying oysters in Atlantic Canada revealed the presence of MSX disease for the first time in Canadian waters. This then triggered a targeted surveillance programme to define the extent of the spread of the disease in Canadian oyster populations. The design of the programme was strongly based on historic data as well as current oyster transfers throughout the Atlantic region (Stephenson *et al.* 2003).

Box 1. General and targeted surveillance

General (passive) surveillance is an ongoing observation of the endemic disease profile of a susceptible population, so that unexpected and /or abnormal changes can be detected and acted upon as rapidly as possible. In addition, laboratory diagnostic data may be used to define a threshold level of undiagnosed syndromes which would trigger in-depth investigations to try and characterize them. For example, if gill disease in fish exceeded a given prevalence, this could trigger a diagnostic investigation to determine whether or not this is indicative of a "new" disease. Such surveillance of disease syndromes (common clinical signs) could also be collected by fisheries officers or harvesters/farmers.

Targeted surveillance collects information on a specific disease or condition so that its presence within a defined population can be measured, or its absence can be substantiated.

What is zoning and what are zones?

Disease zoning is a tool that can be used to facilitate domestic, as well as international trade, whilst preventing spread of diseases of concern. Zones defined by appropriate surveillance mechanisms as being free of such diseases (uninfected) may be used to facilitate trade and to protect against the introduction of their causative pathogens. Zones defined as having the presence of a specific pathogen may also have unrestricted transfers to zones positive for the same pathogen ("like-to-like" disease profiles). Thus, a zone which is positive for a disease is not, necessarily subject to cessation of trade, although it could necessitate mitigative conditions, such as movement of surface disinfected eggs only, to prevent spread of vertically-transmitted viral agents of diseases of concern to uninfected zones or countries.

Disease zoning is the process of delineating infected and uninfected populations within a country or group of countries. "Infected zone" and "uninfected zone" usually applies to specific diseases, except on the rare occasion where a range of different diseases share common epidemiological characteristics or can be detected using common diagnostic (non-disease-specific) techniques. An uninfected zone can be established within a country using the health status of a susceptible host species for a specific disease within a particular geographic or hydrographic area. The OIE provides an outline of the zoning concept in Chapter 1.4.4 of the Code, in the section on import risk analysis. Zoning is particularly relevant to control of aquatic animal diseases, since these do not readily respond to disease control measures used for isolation and containment in land-based facilities or for terrestrial animals.

Disease zones are usually clearly delineated geographical areas within a country; but they can also cross country borders. Catchment areas and rivers may be used to define continental zones, whereas coastal zones can be based on tidal and oceanographic water movements (that may span large areas). Coastal zonation for specific diseases is often further complicated by migratory hosts or poorly understood reservoir species. The tools used for delineation of zones must be relevant to the purpose of zoning, i.e., ability to detect infections early (sensitive), thereby

- reducing the risk of spread;
- increasing the chance of control; or
- accurately defining an area as being free from a given disease of concern.

As different diseases have different means of spread, effective delineation of a zone depends on applying tools that are relevant for the particular disease of concern.

Importance of zoning

Historically, the occurrence of a disease within a nation's borders has lead to suspension or restrictions on trade of that species (or products from it) from the whole country. Recently, however, geographical, hydrological and climatic barriers have been recognized as being just as effective in delineating and controlling the spread of disease from an affected area – effectively isolating it within a zone within a given country. Furthermore, recognition of the biological basis for variations in disease occurrence is a first step in the concept of zoning for aquatic animal health management. An effective zoning scheme can allow surrounding uninfected zones within the country to continue trading while the "infected" zone is placed under appropriate disease control measures, including trade or movement restrictions. Zoning

is equally applicable and effective for preventing spread and reducing economic losses due to diseases of concern within a country.

How are zone boundaries defined?

For terrestrial animals, an infected zone may simply be defined as an area of a specified radius around an infected property. For aquatic animals, however, delineation of zone boundaries is more difficult. The simplest freshwater zonation system is farms that obtain their incoming water from an unshared river system, an independent reservoir of surface water, spring or borehole supply. In such situations, zoning can effectively be facility-based, thus, animal transfers can continue even when neighbouring (unconnected hydrographically) facilities are infected. In inland situations, however, most aquaculture facilities are connected to common river systems or other shared waterways, through which the disease agent can be transmitted to wild aquatic animal populations, or to other farms located downstream. The minimum "zone" that can be applied to a freshwater aquatic animal disease, in such circumstances, would be the entire river system or water catchment area. Some massive water catchment areas, such as the Mekong Delta and Great Lakes often require consideration of multi-national and regional political jurisdictions. Disease management on one side of a shared water body, where none exists on the other side, may not be an effective way to manage disease. Therefore, political cooperation (intra- or international) is required.

Zoning in marine and estuarine areas is also complicated, depending on oceanographic characteristics, and vector/host distribution and characteristics, as well as, in many instances, shared political boundaries and unrelated human activities (recreational, shipping, etc.).

Types of zones

In a country wishing to establish zones for controlling a particular aquatic animal disease, the disease must be compulsorily notifiable. This is necessary to prevent "hidden" or "unreported" outbreaks of the disease detracting from the efficacy of surveillance and the disease response mechanisms associated with it. Both the WTO and OIE base their standards on the assumption that disease control is always more effective with rapid and open reporting from affected stakeholders. Where such notification is not compulsory, or clearly legislated, however, surveillance can still be initiated with stakeholders who agree with the objectives. In such an instance, "self-policing" provides a temporary balance until mandatory reporting, can develop legislative support. The reporting can also be built into good management practices (GMPs) or formal registration and licensing of farms/sites.

The size, location, delineation and management requirements for different types of zones vary with the disease they are meant to control. The extent of zones and their limits should be established by the CA of the country and enforced by national legislation, but also clearly delineated by natural, artificial or legal boundaries, which are scientifically justifiable. Strict conditions for disease surveillance and data management must be met to support the disease-free status, including mandatory reporting or equivalent mechanism that ensures all significant disease outbreaks are rapidly investigated by a laboratory capable of diagnostics that meet national or international standards (directly or though regional/national reference laboratories). This includes appropriate immediate reporting to the CA for aquatic animal disease management and control, when necessary.

Zones free of specific diseases

Aquaculture facilities – farms or establishments located within an infected zone, but having a protected independent water supply, and meeting other stocking conditions. Each facility can demonstrate freedom from the disease of concern, thus, can supply other farms free of the specific disease(s) within that country or in other countries officially free of the disease. Strict conditions for disease surveillance and data management must be met to support the disease-free status for aquaculture establishments within an area endemic for the disease. Facility-based zonation can be applied equally to diseases of national or regional concern within a country, but cannot be applied to facilities in open-estuaries or coastal waters, where isolation from wild populations or other cultured stocks is impossible.

Hydrographic areas – areas for within which susceptible aquatic animal populations (cultured or wild) can be demonstrated to be free of a specific disease of concern (national, regional or OIE listed) through targeted surveillance and protection from exposure to populations or stocks from "infected zones" (as described below).

Buffer zones for specific diseases

A zone – often referred to as a "surveillance zone" (somewhat confusingly, since all zones *de facto* require some degree/level of surveillance) – that is established in an uninfected zone surrounding an infected zone. Surveillance within this zone helps maintain accurate delineation of the uninfected zone. In a disease outbreak situation, a buffer zone can be established around an identified infected zone, to control spread of the disease while surveying for the actual extent of spread from the known infected area.

Infected zones for specific diseases

An "infected zone" is a zone where a specific disease:

- has been detected; or
- is established as an endemic infection of the local population (wild and/or cultured).

If eradication is possible, e.g. in an aquaculture facility; control measures to attempt to eradicate the infectious agent may be undertaken. The zone will maintain its "infected" status until eradication of the disease agent is proven through targeted surveillance appropriate for demonstration of disease absence. In open-water/flow-through situations where eradication is impossible, delineation of the infected zone is maintained by general surveillance of the zone and targeted surveillance of the surrounding buffer zone.

Movement of animals between zones

Ongoing management is essential to prevent live aquatic animals from being transported from infected to uninfected zones, including into buffer zones. Likewise, it is necessary to control shipments of other known vectors of the disease, e.g., genetic material, vaccines, pathological material and aquatic animal feedstuffs, between infected and uninfected zones.

Obviously, "susceptibility" can span the range of non-clinical carriers of the disease agent (disease tolerance), to true resistance (uninfected). This acknowledges that the same species may have disease resistant/tolerant stocks, as well as naïve, or vulnerable stocks. Thus,

targeted surveillance of individual populations is an essential pre-requisite for assessing true susceptibility. The general principle for movement between different zones is shown in Figure 3.

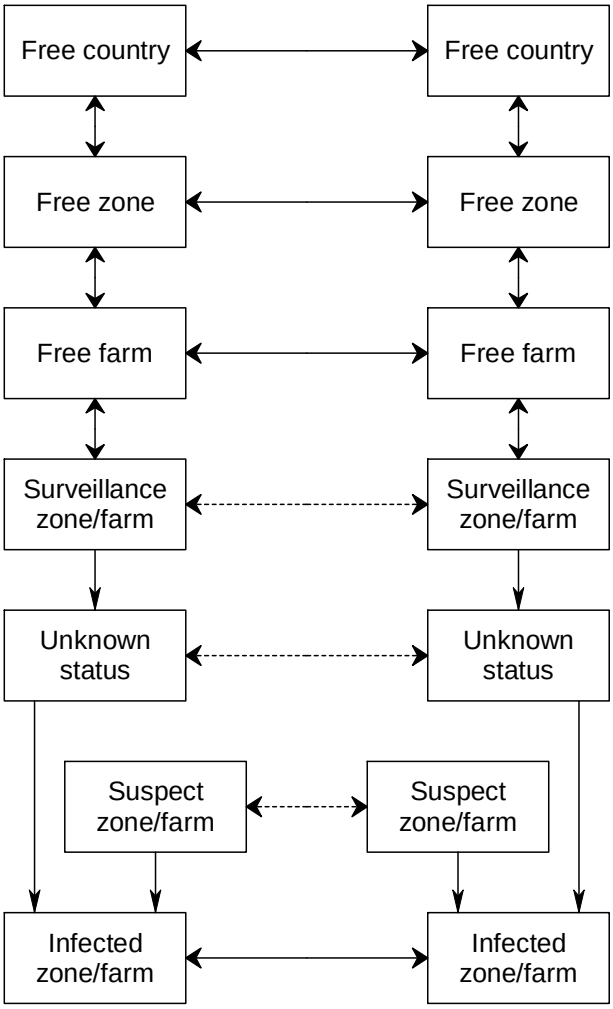
Relationship of surveillance and zoning to import risk analysis

Countries that are members of WTO are obliged to follow various multilateral agreements, including the WTO-SPS Agreement. The WTO-SPS Agreement recognises the OIE as the international organisation responsible for the development and promotion of standards applicable to international animal health recommendations affecting trade in live animals and animal products. The OIE Code provides guidelines for national CA's for addressing the principles laid out in the SPS Agreement for aquatic animal diseases of trade concern. Section 1.4 of the OIE Code provides a framework for analysing the risks of international transfer of disease deemed to be of trade significance by the OIE Aquatic Animal Health Standards Commission (AAHSC, formerly known as the Fish Disease Commission). Diseases that pose the highest assessed risk are those that: (a) are highly infectious to species (wild or cultured) of economic or ecological importance; (b) have few, if any, effective control options; and (c) have a high risk of establishing endemic infections either in susceptible and/or reservoir host species. The threat can be direct, causing significant disease loss, or indirect, affecting domestic or international markets for live or processed products. Arrows indicate the direction of low risk transfers consistent with general principles of disease control, while broken lines indicate movements that may have mitigative measure options to reduce disease risks, or risks posed by unknown disease status. Surveillance zone/farm = Buffer zone/farm[7].

Another, often underestimated, economic impact is that of devaluation of product value by consumer perception. That is that product from "diseased populations" is of poor/lower quality than that of "disease-free" sources, even where the disease has no human health or seafood quality significance.

[7] Anon. 2000. *Aquaplan Zoning Policy Guidelines*. Agriculture, Fisheries, Forestry – Australia, Canberra, Australia. 41 pp.

Figure 3. Transfers of live aquatic animals between countries, zones and farms of different health knowledge status (Diagram reproduced from Anon. 2000).



All these risk factors are of pivotal importance in selecting the diseases that warrant surveillance and zonation. The OIE Code lists several criteria by which a disease is assessed as being of sufficient risk to warrant listing in the Code (OIE 2003b). These criteria are:

- **Consequences** - Where it occurs, the disease has been shown to cause significant production losses due to morbidity or mortality ("morbidity" includes, for example, loss of production due to spawning failure) at a national or multinational (zonal or regional) level.
- Or the disease has been shown to, or is strongly suspected to, negatively affect wild aquatic animal populations that are shown to be an asset worth protecting.
- Or the agent is of public health concern.

- **Spread** - Infectious aetiology of the disease is proven.
- Or an infectious agent is strongly associated with the disease, but the aetiology is not yet known.
- And Potential for international spread, including via live animals, their products and inanimate objects.
- And several countries/zones are free of the disease based on the recommendations of the *International Aquatic Animal Health Code* and *Manual of Diagnostic Tests for Aquatic Animals.*

Diagnosis - A repeatable, robust means of detection/diagnosis exists.

In addition, the OIE Code provides criteria for urgent notification of aquatic animal diseases (OIE 2003b). They are:

A. For listed diseases:

- First occurrence or re-occurrence of a disease in a country or zone of a country, if the country or zone of the country was previously considered to be free of that particular disease; or
- Occurrence in a new host species; or
- New pathogen strain or new disease manifestation; or
- Potential for international spread of the disease; or
- Zoonotic potential;

B. For non-listed diseases:

Emerging disease/pathogenic agent if there are findings that are of epidemiological significance to other countries

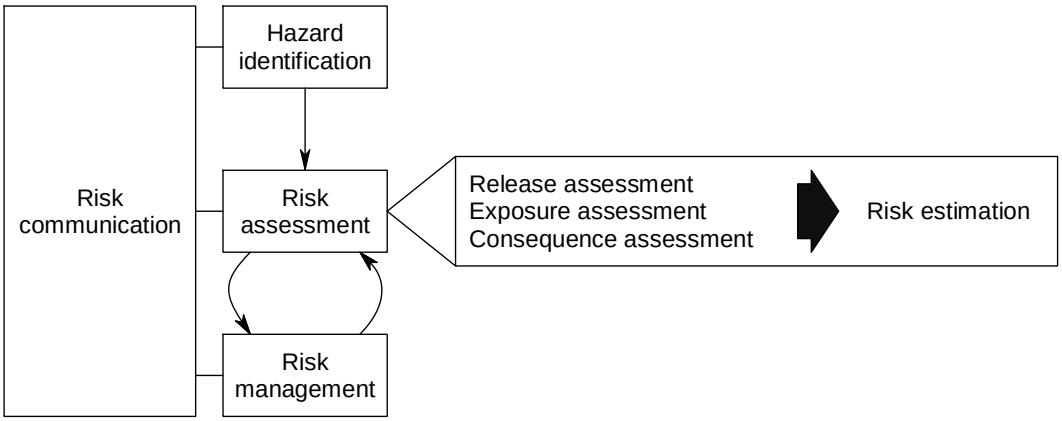
Under the OIE Code, risk analysis has four major components. These are:

- hazard identification;
- risk assessment; composed of the following:
    - release assessment (risk of pathogen release into aquatic environment);
    - exposure assessment (risk of pathogen contact with susceptible/reservoir hosts);
    - consequence assessment (risk of negative impact from host-pathogen exposure);
    - and risk estimation (level and scope of negative impact);
- risk management; and
- risk communication.

Hazard identification and risk assessment are most meaningful when based on an accurate understanding of the health status of the relevant aquatic animal populations in both importing and exporting waters (zones, regions or countries). This requires data from comprehensive and effective targeted and/or general surveillance programs. Likewise, the disease status for defining individual zones can only be established by accurate analysis and interpretation of the surveillance data. Once zones are established, some level of ongoing surveillance of uninfected zones is required to verify the uninfected status of the zone and ensure early detection of any change in that status.

The relationships among these components are shown in Figure 4.

Figure 4. Import risk assessment components and risk assessment steps.



GUIDELINES FOR SURVEILLANCE AND ZONING

Diagnosing disease

Before developing surveillance and zoning programmes, it is important to understand the principles behind surveillance of animal populations (Cameron 2002). Understanding different types of diagnosis and establishment of clear case definitions (criteria for an infection constituting a disease concern) are essential. Each of these is influenced by the nature of the disease under investigation, notably infection characteristics, local environmental factors influencing virulence, related human activities, and reliability (specificity/sensitivity) of available diagnostic tools.

Disease, in the classic medical sense, includes non-infectious diseases, but for most disease control programmes (national and international), infectious diseases are the focus of attention. Non-infectious disease management is generally the responsibility of farmers or local extension/field officers.

In the context of infectious disease control, animals may be considered as being “diseased” as soon as they become infected, even before clinical signs or pathological changes become evident. This is also true for carrier or reservoir hosts, that may carry and transmit viable infectious agents, but themselves exhibit no detectable pathology or signs of the disease in question. This means that case definitions are very important in the context of design of effective surveillance programs. For example, surveillance for clinical disease is significantly less complicated than screening healthy (non-clinical) infected or carrier hosts. However, in order to prevent disease or define the health status of aquatic animal populations as accurately as possible within defined zones, both clinical and non-clinical hosts need to be included.

The logistics of surveillance of healthy populations deemed susceptible to significant pathogens has recently come into question. The European Union (EU) and the OIE AAHSC are revisiting the cost-benefit of this all-inclusive effort under the assumption that, if the host population is indeed susceptible, and the disease agent is indeed highly virulent, then the first sign of the presence of the infection should be clinical disease. The debate over this assumption hinges on the fact that host-pathogen-environment interactions are complex, and some degree of risk of genetic or environmental suppression, is inherent in this assumption. Furthermore, clinical expression of disease may not be readily apparent, as is the case for many molluscan diseases. As epidemiological knowledge of significant diseases increases, however, the risk of missing or overlooking infected animals should be reduced.

Clinicians and pathologists devote substantial time and effort in arriving at the “correct” conclusive diagnosis when investigating disease. Competent investigators use judgment based on thorough knowledge of the literature, experience, diagnostic test results and, where appropriate, cross checks, as well as case-history observations (often provided by field personnel) to interpret their results and observations and reach an accurate diagnostic conclusion or result.

Table 2 lists a number of diagnostic methods that are applied to aquatic animal diseases. These may be used alone, or in combination, to arrive at a conclusive (confirmatory) diagnosis. All diagnostic methods, however, are subject to limitations. Random errors, due to

lack of precision and non-random errors, due to false negative and false positive results, must always be taken into account. Sample sizes and collection strategies are the most commonly used methods to minimize both random and non-random diagnostic errors. Accurate quantitative assessments of the level of infection within a population (prevalence, intensity, and incidence) require further statistical analysis and correction factors to deal with sensitivity/specificity errors in diagnostic methodologies. Where infection levels become significant, general monitoring of endemic diseases (within "infected zones") for levels exceeding a pre-defined tolerance threshold should trigger disease control action.

Table 2. Diagnostic methods routinely applied to aquatic animal diseases.

Field information	**Laboratory techniques**	**Experimental techniques**
o history (recurrent losses, abnormal losses, stocking and related husbandry activities) o economics (measure of losses due to sub-optimal production performance, or direct mortality) o behaviour o clinical signs o physical examination (autopsy or gross observations) o epidemiology (population disease dynamics) o response to therapy (mainly finfish, some bacterial crustacean diseases)	o microbiology o tissue smears o histopathology o serology (immunological assays) (finfish) o ultrastructural examinations (TEM, SEM, negative stain) o tissue culture (cell-lines for certain finfish diseases only due to the current lack of cell lines for other groups) o biomolecular analyses (PCR, ISH, etc.)	o physiology challenges (stress testing) o transmission tests (bioassay infection challenges to assess host susceptibility)

Each investigation will yield information that can be applied to overall surveillance data gathering, and diagnosis with varying levels of certainty, depending on the complexity of the disease(s) of concern. In some instances, the investigation may not result in a conclusive diagnosis, but be limited to describing a "disease incident" (e.g. in terms of morbidity, mortality, duration of the problem, clinical signs, appearance of gross lesions). This is particularly common with aquatic animal diseases, many of which (especially microbial) are still "new" to science.

The level of diagnostic certainty will be largely determined by the investigator's ability to recognize the characteristics of specific diseases, as well as whether or not the report needs to be followed up with a more detailed investigation by specialist expertise. In most instances, the highest level of diagnostic certainty for internationally recognized diseases is achieved when positive results are confirmed by an internationally accredited reference laboratory (usually a laboratory recognized with a high diagnostic capability in terms of facilities, staff expertise, experience and peer-reviewed scientific publications concerning a particular disease). For local or regional diseases, the same applies to confirmation by laboratories with adequate diagnostic facilities and recognized expertise on that disease.

Most first-time diagnoses of “new” or “emerging” diseases require confirmation by an independent reference laboratory with established expertise in the suspect pathogen or group of pathogens. Back up confirmation is an essential pre-requisite for any diagnosis that has significant zonation, disease control or trade implications. Even internationally recognized laboratories rely on cross-checks for diagnoses falling outside their area of specialization (e.g. exotic diseases). Thus, it is necessary to include an assessment of the diagnostic certainty (suspect, presumptive or confirmatory) with each record of a disease investigation.

Three levels of diagnosis have been defined to assist in the safe trans-boundary movement of aquatic animals and surveillance and control of their disease in the Asia-Pacific Region, however, these apply equally well to other areas of the world involved in aquatic animal disease diagnosis, since all laboratory diagnostics (whether Level II or III in technical complexity) benefit from Level I (field) information. The three levels of diagnosis are as described by Bondad-Reantaso *et al.* 2001 are summarized in Table 3. Level I diagnosis can be made for certain diseases at the field site without any laboratory confirmation. Most Level I information, however, is used to reinforce Level II diagnosis that requires some laboratory support. Level III diagnostic techniques require advanced laboratory infrastructure and training and are usually reserved for confirmation of diagnoses that remain presumptive at Levels I and II.

Establishing a case definition

It is important when investigating disease at a population level, that consistency of diagnosis is maintained, regardless of the diagnostic method(s) used. This involves developing a case definition, as well as undergoing field validation of the diagnostic techniques and developing a quality assurance/quality control system to ensure diagnostic consistency between diagnostic and field facilities. Failure to do so can lead to bias (non-random error) and inaccuracies in the surveillance programme. Such inaccuracies can cause significant errors in zonation and disease control decision-making, with significant disease or economic impacts.

> A ***case definition*** *is a set of standard criteria for deciding whether an individual study unit of interest has a particular disease or other outcome of interest. The study unit may be an individual animal or a group of animals such as a pond of shrimp, a cage of fish, a shellfish bed or an entire estuary.*

For example, the investigator may be interested in comparing the occurrence of a particular disease in farmed fish in two different countries. Care is needed in such a comparison if one country uses microbiological screening techniques while the other country used observation of gross pathology alone to diagnose the same disease.

An optimal case definition depends on criteria that can be applied to any potential case in the source population. In many instances, it is difficult to define a set of criteria that includes all true cases of the disease of concern and exclude all similar, but unrelated, conditions. Few cases show the complete range of criteria attributed to a disease and there are always some “non-cases” which show clinical signs similar to those of the particular disease being investigated. This is particularly true for aquatic animal diseases, where clinical signs are rarely pathognomonic (i.e. specific to a single disease). A useful approach to development of a case definition is given by Stephen and Ribble (1996).

Table 3. Three levels of diagnostic information, associated requirements and responsibilities (Bondad-Reantaso et al. 2001).

Level – Activities	Skills and equipment	Responsibility	Requirements
Level I – Activities Observation of animal and the environment; Clinical examination; Gross pathology	Knowledge of normal (feeding, behaviour, growth of stock, etc); Frequent/regular observation of stock; Regular, consistent record-keeping and maintenance of records - including fundamental environmental information; Knowledge contacts for health diagnostic assistance; Ability to submit and/or preserve representative specimens.	Farm Workers/Managers; Fisheries Extension Officers; Field Veterinarians; Local Fisheries Biologists.	Field keys; Farm record keeping formats; Equipment list; Model clinical data sheets; Pond-side check list; Protocols for preservation and transport of samples.
Level II – Activities Parasitology Bacteriology Mycology Histopathology	Laboratories with basic equipment and personnel trained/experienced in aquatic animal pathology; keep and maintain accurate diagnostic records; Preserve and store specimens; knowledge of/contact with different areas of specialization within Level II Knowledge of who to contact for Level III diagnostic assistance.	Fish biologists; Aquatic Animal Veterinarians; Parasitologists; Mycologists; Bacteriologist; Histopathologists; Technicians.	Model laboratory record-keeping system; Protocols for preservation/transport of samples to Level III; Model laboratory requirements an equipment and consumable lists; Contact information for accessing Level II and Level III specialist expertise; Asia Diagnostic Guide to Aquatic Animal Diseases; OIE Manual of Diagnostic Tests for Aquatic Animals; Regional General Diagnostic Manuals.
Level III – Activities Virology Electron Microscopy Molecular Biology Immunology	Highly equipped laboratory with highly specialized and trained personnel; Keep and maintain accurate diagnostic records; Preserve and store specimens; Maintenance of contact with people responsible for sample submission.	Virologists; Ultrastructural histopathologists; Molecular biologists; Technicians.	Model Laboratory requirements, equipment, consumable lists; Model job descriptions skills for requirements; Contact information for reference laboratories; Protocols for preservation of samples for consultation and validation; OIE Manual of Diagnostic Tests for Aquatic Animals; General molecular and microbiology diagnostic references; Asia Diagnostic Guide to Aquatic Animal Diseases.

Some examples of case definitions of use for investigating White Spot Disease (WSD) in shrimp are given in Table 4. The choice of a particular case definition depends on the objectives for the investigation and, no matter which case definition is used, it will not be perfect. For example, shrimp in some outbreaks of WSD can show no evidence of white spots in their carapaces, so use of the first case definition in Table 4 would produce false negative

results for individual animals or stocks. False negative results are due to inadequate detection sensitivity, while false positive results are due to inadequate specific identification.

It is often necessary to define "suspect" cases, as well as confirmed cases. This is especially useful where it may take some time (e.g. weeks) to achieve diagnostic confirmation. Where a previously unrecognised and potentially serious disease is found, it is advisable to use a broad scope case definition to capture all possible cases. The definition, and associated surveillance and diagnostic protocols can be revised as more information is obtained.

Table 4. Examples of case definitions for white spot disease (WSD)[8] in shrimp.

Study Unit	Case definition
Animal	A shrimp with one or more visible, discrete white patches on the inside of the carapace.
Animal	A shrimp which yields positive PCR result for white spot syndrome virus.
Pond	A pond where one or more shrimp have one or more visible, discrete white patches on the inside of the carapace.
Pond	A pond where one or more shrimp yield a positive PCR result for white spot syndrome virus.
Pond	A pond subject to emergency harvest because, in the opinion of the manager, there is a risk of mass mortality from white spot syndrome.
Population (possible source of wild post-larvae)	A wild population where one or more shrimp have one or more visible, discrete white patches on the inside of the carapace.
Population	A wild population where one or more shrimp yield return a positive PCR result for white spot syndrome virus.
Population	A wild population subject to mass mortality from white spot syndrome.

Examples of presumptive (suspect) and confirmatory case definitions are given for epizootic ulcerative syndrome (EUS) in Table 5. All of the case definitions in Table 5 are legitimate for EUS, spanning the most pathogen specific, but least sensitive (first definition) to the most sensitive, but least specific (fourth definition) for individual animals.

Although still subject to debate, the consensus among experts is that EUS is a specific condition involving tissue damage due to the fungal agent, *Aphanomyces piscicida*/*invadans*, regardless of the pre-disposing factors.

Although the disease could be called aphanamycosis, implying *Aphanomyces piscicida*/*invadans* infection as the cause, other *Aphanomyces* spp. fungi can also cause fish lesions and disease with symptoms similar to EUS. Thus, caution is required in using genus-based "-osis" nomenclature. A classic human example of this is use of *Herpes*, which is now recognized to span a wide range of diseases and pathologies.

[8] In the OIE Aquatic Animal Health Standards Commission's view, a PCR signal alone does not provide confirmation of the presence of viable and transmissible agents.

Table 5. Possible case definitions for epizootic ulcerative syndrome

Study Unit	Case definition
Animal	A fish with degeneration and hardening of the tissues of the eye-ball (necrotizing, glaucomatous dermatitis) and/or muscle tissue inflammation (myosistis) and/or localised blood cell aggregations (granulomas) in internal organs associated with the presence of *Aphanomyces piscicida*/*invadans*.
Animal	A fish with one or more granulomas with *Aphanomyces piscicida*/*invadans* in the lesion.
Animal	A fish with any lesions containing *Aphanomyces piscicida*/*invadans*.
Animal	A fish with one or more surface lesions which could be described as a "red spot".
Pond	A pond with one or more fish meeting the descriptions above.
River	A river with one or more fish meeting the descriptions for individual animals.

The surveillance objective dictates the specificity or sensitivity of the case definition selected:

(i) Early detection is required because the disease has never been reported in an area and it presents a significant disease threat. Thus, any fish that may represent a case is important, and the most sensitive case definition is required - in this case "red spot". Laboratory confirmation of the presence of *Aphanomyces piscicida/invadans* would be required to confirm (or refute) the presumptive diagnosis.

(ii) If an area is endemic for EUS, determining the prevalence of the condition would be important for monitoring for potential EUS outbreaks, and a more specific case definition required, particularly if there were other diseases present which produced similar "red spot" lesions.

Investigating disease outbreaks

The basis of all good surveillance is the ability of Competent Authorities and aquatic animal disease diagnostic services to investigate outbreaks of unusual disease events efficiently.

An outbreak investigation should be aimed at systematic identification of the cause(s) and source(s) of the infection, in order to:

- control spread of the existing epidemic, and
- prevent exposure to new infections in the future.

In most situations, the primary objective of a disease outbreak investigation is to determine the cause and to identify ways of preventing further transmission (spread) of the disease agent. An infection from an exotic introduction usually shows a point-source "focus" of infection. Emergence of pathogenic levels of endemic diseases may centre on the most vulnerable groups within a susceptible population, or show more sporadic infections (chronic or random acute) increasing in frequency. It is the role of the investigating team to record and analyse these patterns to help meet the primary objective of preventing spread to unaffected susceptible populations. Disease outbreak investigations include the following activities.

Disease outbreak investigation

- Establish or verify the diagnosis.
- Define a "case" (surveillance for exotic pathogen(s) = most sensitive definition; monitoring of endemic infections = acceptable level of infection/mortality level definition).
- Confirm that an outbreak is actually occurring – presumptive/confirmatory diagnosis.
- Characterize the outbreak in terms of time, animal/stock/population, and place.
- Analyse the data from field observation, tracking animal movements and design appropriate sampling programs to define geographic range of outbreak.
- Formulate working hypotheses in an attempt to identify the possible source and mechanism of transmission.
- Undertake follow-up investigations to identify high risk activities and stocks and practical mitigative measures where there are high risks of further outbreaks.
- Implement appropriate control and preventive measures.
- Report the findings of the investigation with recommendations for containing, eradicating and/or preventing future outbreaks of the same disease.

Outbreak Step 1 - The Diagnosis. The initial “presumptive” diagnosis of an outbreak is usually made on: clinical signs; crude patterns of infection, environmental and human activities associated with morbidity or mortality; and gross pathology. Whenever possible, laboratory tests should be undertaken as quickly as possible to verify the presumptive diagnosis. Since some laboratory procedures may require weeks, the implementation of control measures should be based on the presumptive diagnosis of significant diseases of concern.

Because any group of aquatic animals is likely to contain a range of pathogens and, even where there is a specific primary pathogen, there may be secondary infections, it is vital that a full range of specimens be taken from a number of animals at different stages of disease development – especially from any healthy animals in the vicinity of the outbreak, so comparative diagnostic observations can be made. When selecting healthy animals for examination, it is important to obtain them from at least two sources; (i) site(s) which appear(s) to be experiencing the particular problem, and (b) one or more sites in the same area, which have stocks showing no evidence of the disease problem. The geographic range of the latter will depend on the severity of the presumptive diagnosis and distribution of susceptible populations exposed directly, or indirectly, to the site of initial disease detection.

Outbreak Step 2 - Define a Case. Where large numbers of animals are dying rapidly, a case can simply be a recently dead (preferably moribund for microbial infections) animal.

As described above under “establishing a case definition”, where the disease aetiology is initially obscure, it is better to have a fairly broad case definition to ensure that all possible causes are included in the investigation. The case definition can be refined as more information becomes available and the data re-analysed accordingly.

Outbreak Step 3 - Confirm the Outbreak. This step may seem unnecessary but, in situations where a related disease is endemic, or where environmental extremes may cause physiological stress-based mortalities, such a confirmation is essential. For monitoring purposes (rather than surveillance-based zonation), a certain level of infection may be normal, however, any increase could lead to severe production losses if not identified quickly and accurately. Distinguishing a disease outbreak due to an increase in endemic infection levels, rather than a new/exotic disease outbreak is, therefore, critical.

Outbreak Step 4 – Characterize Outbreak. It is important to try and pin-point the time, population/stock and place associated with a disease outbreak where the cause is initially obscure. This is necessary for identifying possible source(s), mode(s) of transmission and chances of establishment of the infection:

(a) Time:

- When did the outbreak first appear? Anecdotal reports of decreased production, unreported mortalities, failed spawning, etc., can all be useful for estimating the period of appearance of the outbreak. Such reports should be corroborated, however, or treated with due caution, before using as the basis for management decisions.
- Given a presumptive or confirmed diagnosis, what is the probable period of exposure to the infectious agent based on known transmission cycles?
- Does the outbreak indicate a point source, or a broad/random transmission distribution?

(b) Animal:

- Are there any characteristics about the animals affected that may indicate variations in susceptibility?
- Which stocks, age-groups, spawning stages, and/or seed/egg sources, show the highest and lowest, apparent susceptibility?

(c) Place:

- Are there any significant geographical/hydrographical patterns in the distribution of the disease or infection (e.g. stock transfer linkages, shared environmental factors, other human activities)?
- What site factors are common to high and low prevalence of pathology, or absence of infections?

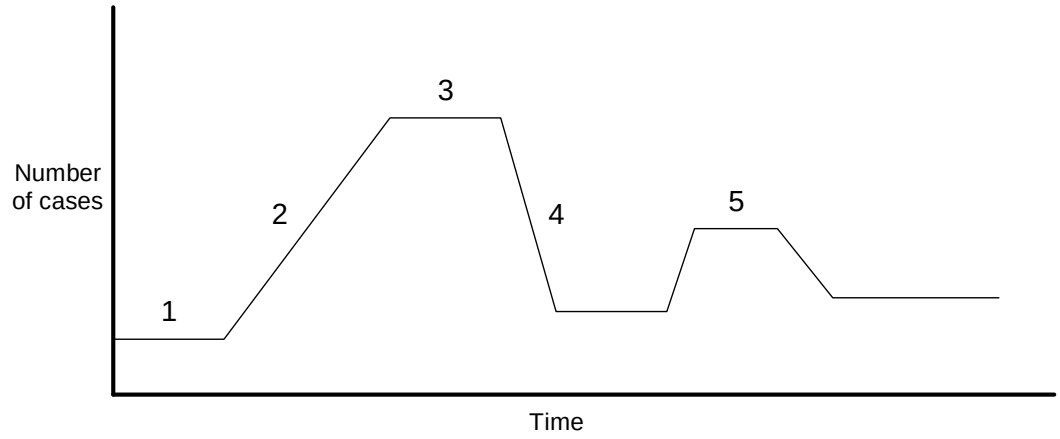
(a) Time. For infectious diseases, identifying the index case is valuable for identifying the source of the outbreak (assuming it is a point source). The index case may be an individual animal, pond, farm, or stock (wild or farmed). One method of tracking an index-borne disease outbreak is to map an epidemic curve. This may have four or five segments; (1) the endemic level (where an infection is established), (2) an ascending branch, (3) a peak or plateau, (4) a descending branch, and (5) a secondary peak (Figure 5).

The duration of any epidemic is influenced by:

- the number of susceptible animals that become infected;
- the period of time susceptible animals are exposed (cumulative or acute);
- the minimum and maximum incubation periods of the disease; and
- environmental factors related to transmission.

The slope of the ascending branch (2) can indicate the type of exposure. If transmission is rapid and the incubation period short, as with a significant infectious disease, then the ascending branch will be steeper than if transmission is slow or if the incubation period is long.

Figure 5. Segments of an epidemic curve.



The length of the plateau (3) and slope of the descending branch (4) indicate depends on the factors described for the duration of the epidemic, i.e. stocking densities, transmission mechanisms, and levels of susceptible stocks/reservoirs. Secondary peaks (5) are usually due to the introduction of new susceptible animals, a change in the mode of transmission, or temporary seasonal suppression of pathogenic proliferation (e.g. overwinter).

The choice of sampling frequency required to follow an epidemic curve is important. Appropriate time intervals may vary from several hours (e.g. some acute microbial infections) to months or years for slower progressing diseases, or diseases relying on seasonal intermediate host availability. Subtle differences in temporal patterns are missed, if sampling frequency is too far apart, e.g. secondary peaks (5) from animal-to-animal transmission, seasonal suppression of intermediate/carrier hosts or free-living infective developmental stages. Since the incubation period of most aquatic animal pathogens is highly variable and subject to the vagaries of hydrographic and climate conditions, at least one or two seasonal cycles (whether tropical or temperate) should be included. This is consistent with the OIE (OIE 2003b) standard of a minimum of two years before any facility/zone/country can be declared free of a listed disease.

In general, the OIE recommends an approach that is more flexible and disease-specific. The OIE Manual of Diagnostic Tests for Aquatic Animals (OIE 2003c) stipulates that the number of units to be sampled from a population should be calculated using a statistically valid technique that takes at least the following factors into account: the sensitivity and specificity of the diagnostic test, or test system; the design prevalence; and the level of confidence that is desired of the survey results. The specific sampling requirements will need to be tailor-made for each individual disease, taking into account its characteristics and the specificity and sensitivity of the accepted testing methods for detecting the disease agent in host populations[9].

[9] See Chapter 1.1.4 "Requirements for surveillance for international recognition of freedom from infection"; OIE *Manual of Diagnostic Tests for Aquatic Animals*, 4th ed, 2003 - http://www.oie.int/eng/normes/en_amanual.htm

In the case of exotic pathogens, exposure of a naïve host population will usually produce an epidemic curve similar to Figure 5. The initial exposure indicates rapid transmission within a defined water body or dense population, with large numbers affected over a short period of time. Survivors of the initial epidemic, may undergo subsequent outbreaks, as the disease establishes a cyclical infection pattern and environmental and host tolerance factors come into play.

In the short-term, rapid and accurate diagnosis have greatest priority. However, for effective, long-term, controls for diseases that cannot be eradicated, require understanding of the factors influencing the epidemic curve.

(b) Animal. The term "animal" is used for stocks, populations, sites, etc. Age, sex, geographical origin and genotype are frequently associated with varying susceptibility to disease impacts. However, infection patterns are also linked to the physiological and ecological characteristics of the infectious disease agent.

One method to analyse disease infection patterns within an outbreak, is measurement of attack rate (AR). Attack rate is the number of cases of a specific disease divided by the number of animals at risk at the beginning of the outbreak, e.g., EUS appears to affect small fish to a greater extent than large fish within in a given pond. In this case, the following calculations would be necessary:

Small fish, AR1 = $\frac{\text{No. with EUS}}{\text{Total no. of small fish}}$	Large fish, AR2 = $\frac{\text{No. with EUS}}{\text{Total no. of large fish}}$

If there were 1000 small fish in the pond and 300 had EUS, and there were 1000 large fish of which 100 had EUS during an outbreak, the AR's would be 30 percent (AR1) and 10 percent (AR2), respectively. This indicates that small fish are three times more susceptible to EUS than large fish. Likewise this evaluation process could also be used to test the hypothesis that nutritionally stressed fish are more susceptible to infection than well-fed fish (Table 6).

Table 6. Attack Rate (AR) for EUS-infected fish with and without nutritional stress.

	With nutritional stress			**Without nutritional stress**				
Factor	EUS	Total	AR (%)	EUS	Total	AR (%)	AR Diff (%)	RR
Small	30	100	30%	35	500	7%	23%	4.3
Medium	20	200	10%	45	400	11%	-1%	1.1
Large	15	300	5%	50	300	17%	-12%	0.3

In Table 6, ARs are expressed as percentages. The second last column (AR Diff) is the difference in attack rates between groups. The column "relative risk" (RR), gives the ratio of EUS found in fish with, and without nutritional stress. The higher the values for AR Diff and RR, the more significant the factor being analysed is in increasing the risk of disease. In this example, small fish are three times more likely to develop EUS than medium-sized fish, and six times more likely than large fish. Medium-sized fish are twice as susceptible as large fish.

This example also supports the hypothesis that nutritional stress is a factor in EUS size-related susceptibility.

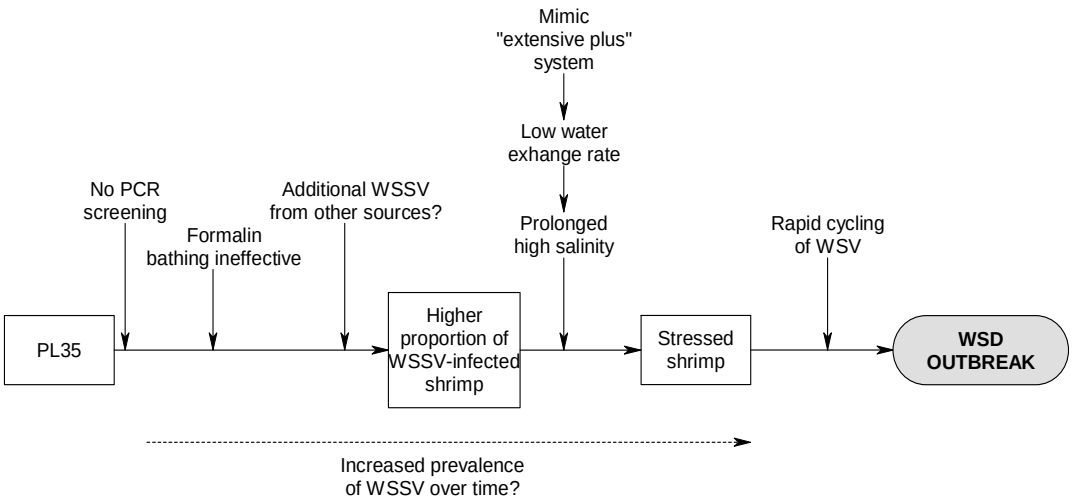
In the context of surveillance and zonation, it is important to determine the relative importance of as many of the possible contributory factors (e.g. sudden acidification of the water for EUS) as possible. This will help focus surveillance efforts, whether aimed at early detection of endemic outbreaks, or surveillance to prove freedom from the disease. All surveillance programmes must focus on the most vulnerable sectors of the susceptible population as possible.

(c) Place. Defining the exact source of an outbreak can be helped by mapping an affected site/area or facility, recording the dates when cases were detected, and the stage of development of the infection. Such a map can indicate whether or not an outbreak is due to an infectious point-source, or other, source. Surveillance aimed mapping the extent of an outbreak should work inwards towards an apparent point-source. Such an approach reduces the risk of spread by surveillance activities radiating outward from a known infected farm/area/site.

Surveillance should also focus on neighbouring sites with documented (or undocumented) disease losses, and links to point-source waters or stocks though seed/broodstock or market-relay transfers. This will help develop accurate preliminary maps of the disease distribution. Negative results are as useful as positive results in tracking suspect highly virulent disease outbreaks, although more difficult to map as conclusively as positive results. Such maps are particularly important for aquatic animal diseases, since direct observation of infected animals can be difficult, requiring fishing, diving, specialized boat equipment, etc.

Outbreak Step 6 – Formulate hypothesis(es). Based on the analysis of time, place and animal data, options for controls and priorities for further investigation are developed. Any hypothesis must be compatible with the confirmed data and related epidemiological information. Control options can be developed based on such hypotheses, e.g. investigation of a WSD outbreak in two ponds at a research station led to the hypothesis of the sequence of events that contribute (Figure 6) to an outbreak of WSD in 70 day old post-larval shrimp.

Figure 6. Sequence of events leading to a WSD outbreak



Outbreak Step 7 - Intensive follow-up. Follow-up studies require analysis of available data, checking for cases that may be present at other locations (downstream or linked by stock transfers), examination of movement of stocks, feedstuff, or any other human activities associated with the affected stocks. Feeding or other challenge trials could be required where non-infectious agents are suspected. Transmission experiments, to establish infectious agent aetiology, where this is in doubt (Koch-Henle's Postulate), may also be required.

Outbreak Step 8 – Implement control and prevention measures. An effective investigation will help define effective control options that reduce the risk of recurrence of similar outbreaks. Investigations may, however, indicate that the possibility of re-infection is inevitable, e.g., in open-water circumstances where, once established in susceptible or carrier/reservoir populations, eradication of the pathogen is not possible or economically feasible. In such instances, control measures are aimed at minimizing exposure to the established pathogen in affected waters and preventing spread to unaffected, susceptible, populations.

Outbreak Step 9 – Report findings and recommendations for dealing with future outbreaks. For isolated farms experiencing disease outbreaks, recommendations may take the form of a brief discussion with the farm manager, outlining the actions required for surveillance in order to prevent future outbreaks. A written report of the information, data and recommendations developed from the outbreak, provides a useful reference. For broader outbreaks, findings should be published in peer-reviewed scientific literature and, depending on the disease, reported to the OIE to ensure transparent reporting to trade partners. Reports of investigations of serious outbreaks should include: case-history background; methods applied to diagnostic and epidemiological investigations; results; hypotheses; financial and ecological impacts (as appropriate) and recommendations for control.

DISEASE SURVEILLANCE

Surveillance should be an integral component of all official aquatic animal health management programmes. This ensures that activities are in place that support early warning of diseases of concern, contingency planning and monitoring of disease control measures. Likewise, surveillance provides the basis for sound aquatic animal health advice for farmers, processors and other stakeholders involved in the handling of live aquatic animals; and accurate certification of exports, international health status reporting and verification of freedom from diseases. Surveillance is particularly important for effective aquatic animal emergency disease preparedness.

Both general and targeted surveillance are necessary. Solely targeted programmes are not cost effective, and can only be applied to a few selected diseases. General surveillance is useful for detection of new and exotic diseases, as well as for monitoring outbreaks of endemic diseases. General surveillance increases farmers' (and other field personnel's) awareness of disease, and establishes working links to expertise providing clinical and preventive health care. General surveillance can also reassure farmers and other stakeholders that disease monitoring is not an automatic trigger for emergency disease responses that can mean stock destruction or transfer/trade controls. Conversely, such surveillance can provide the evidence required for those nervous of such activity that proactive management can reduce negative economic or productivity impacts. Surveillance can also serve as an indirect consumer/business value-enhancement "label" where competitors may not have embraced proactive health management or related good management practices. Initial efforts, especially where resources or infrastructure are under development (or limited), should focus on facilities, sites or aquatic populations at greatest risk of exposure to known pathogens/diseases of concern.

Basic requirements for implementing a surveillance programme

Investigations of suspected disease occurrences, or to prove freedom from those diseases, require:

- appropriately trained and dedicated personnel;
- standardised field and laboratory methods supported by quality control systems; and
- access to manuals and ongoing training opportunities.

The basis of effective surveillance programmes is observant and skilled people, who understand normal health patterns, are alert to changes, and can describe the abnormalities they see. The precise design and structure of a surveillance programmes vary with their exact purpose, but all share some basic common features:

- clearly stated objective(s);
- a list of diseases of concern;
- the capability to recognize a disease outbreak with general surveillance activities to the required level of diagnostic certainty;
- specified protocols for collection of the information required; and
- a system to record and collate the data collected, as well as report findings.

Clearly stated objectives

The following outline the approach to meeting the four general objectives of surveillance:

1. Rapidly detect new and exotic infectious diseases in aquatic animals.

As a minimum requirement, all countries should have a system in place that gives early warning of new and exotic aquatic animal diseases. Such surveillance is based on comprehensive general surveillance activities aimed at spotting endemic pathogen problems. If this system is working well, new or exotic disease can be detected using Levels I and II diagnostic methods, although many diseases will require first time confirmation using Level III methods and/or confirmation by a reference laboratory.

Once a new or exotic pathogen is detected, targeted surveillance will be required to define its distribution and the magnitude of the problem, track its spread, assess feasible control options and, where appropriate, demonstrate successful eradication.

2. Provide evidence of freedom from diseases relevant to domestic and international movement of aquatic animals and products.

The existence of comprehensive general surveillance activities, which have the ability to diagnose the pathogen(s) of interest, provide the initial evidence of freedom from diseases of national/international concern. Historical records may be used to reinforce the hypothesis of freedom being tested by the current surveillance program, or to develop preliminary surveillance programs. It should be recognised, however, that environmental conditions or human activities may have changed host susceptibility since historic records were collected. At present, there are no specific guidelines on how to quantify historic evidence, but methods of analysis are currently being developed. A combination of Levels I to III diagnostic methods may be necessary, depending on how characteristic the signs of the particular disease are, and whether or not sub-clinical carriers are suspected. This is because Level I can rarely provide conclusive evidence of freedom of an exotic disease, and Level II and III diagnostic tests frequently require validation from Level I observations.

For significant diseases (high risk), targeted surveillance may be required in addition to general surveillance in order to prove freedom from the causative agent. Cameron (2002) describes various methods that can be used to enhance comprehensive and scientifically-justifiable coverage of aquatic animal populations.

3. Describe the distribution and occurrence of diseases relevant to disease control and domestic and international movement of aquatic animals and products.

Defining the geographic distribution of specific diseases can often be done using general surveillance, provided it is sufficiently comprehensive to include adequate sample sizes from all geographical areas where susceptible host populations occur. Such surveillance, however, does not delineate the precise geographic distribution of the disease agent, nor infection levels present. This information requires targeted surveillance and specific diagnostic techniques (usually Levels II and III).

4. Assess progress in control or eradication of selected diseases and pathogens.

Having undertaken a surveillance program, and delineated a positive zone where control or eradication of the disease is possible, it is important to know how successful the control or eradication measures are. Without this capability, redefining the zone as negative, or accurately protecting surrounding negative populations from spread of the disease is impossible. A necessary prerequisite for any control or eradication measure to be successful is complete participation by all affected stakeholders (farmers, commercial harvesters, processors, and regulatory authorities). If one or more sites within a zone do not participate, controls within the zone as a whole may be jeopardised. In addition, the cost of disease control measures (on top of losses to the disease itself) means that non-compliance by some stakeholders may be a catalyst for conflict.

Assessment of control of spread requires targeted surveillance of the "buffer" zone surrounding the affected area. The buffer zone must include the susceptible host species and lie outside the immediate hydrographic influences of the zone containing the infected stocks. As long as the populations in the buffer zones remain uninfected, the disease has been successfully contained within the positive zone. If the disease spreads to the buffer zone, and cannot be eradicated, the positive zone will need to be expanded to include the affected populations. A new buffer zone is then established to protect the next neighbouring susceptible populations. Once again, hydrographic influences on the expanded positive zone need to be taken into account for selecting the new buffer zone.

Assessment of success in eradicating a disease from a positive zone can be challenging and there are few examples for aquatic animal diseases. Scotland successfully suppressed clinical infections of Infectious Salmon Anaemia (ISA) with early intervention, salmon stock depopulation, fallowing and stringent biosecurity measures. However, eradication of the causative agent from the affected area is not assured, so biosecurity measures have been maintained, along with close monitoring for any disease reoccurrence. Norway attempted to eradicate the salmon ectoparasite *Gyrodactylus salaris*, using chemical sterilisation of entire river ecosystems. Although successful, such an extreme measure requires serious cost-benefit analysis.

Where eradication has potential for success, and measures to remove the disease agent are undertaken, surveillance can be impeded by the fact that all susceptible animals have to be removed to break the infection cycle (fallowing). In such cases, a small number of susceptible animals could be used to test the area, following the fallowing period. If the disease does not appear in these animals, more intense stocking with disease-free animals can be considered. If the disease does occur in the test animals, the fallowing period may need to be extended, or the area may have to be zoned as positive. In the latter instance, efforts would then concentrate on controlling disease spread, rather than on its eradication.

List of diseases

Each country will have its own specific diseases of concern. A minimum list would be those notifiable to the OIE which are relevant to the particular country's aquatic resources, or trade interests, or other infectious diseases of regional concern. OIE listed diseases have been identified as posing a risk with trade in susceptible aquatic species, therefore, demonstration

of freedom or equivalent infection status may be necessary for trade with countries that also have susceptible populations.

Capability and capacity

A model plan for the development of disease surveillance capabilities and capacity at national and regional levels is provided in Appendix I.

Information specifications

Basic Information

In the event of an emergency disease outbreak, the following information is required:

- the disease(s) suspected;
- the exact geographical location(s)/extent of the outbreak(s);
- contact information for affected growers or sites, responsible authorities (aquaculture leasing/management; wild resource/fisheries protection);
- species and life-history stages affected;
- approximate numbers (estimated percentages) of sick and dead animals, where this can be calculated. Other measures of the extent of disease impact can be used, e.g. number of ponds or cages affected;
- brief description of history, clinical signs and lesions observed;
- date(s) when the disease was first noticed at the initial outbreak site as well as at any subsequent sites;
- details of movements of susceptible animals to or from the affected site(s)/facility(ies);
- any other key epidemiological information, such as temperature, salinity, turbidity, disease status of surrounding wild populations, abnormal environmental events (floods, drought, pollutant contamination), and possible vectors (birds, human activities); and
- initial disease control actions taken.

All exotic and other significant aquatic animal disease emergencies should be reported immediately to the national authority responsible for aquatic resources within that country. This requires a communication network to be in place that ensures that a fishery resource user or aquaculturist has access (direct or indirect) to the national authority. In some countries this is achieved through mandatory reporting legislation or policy. This requires diagnostic laboratories or field veterinarians and extension officers to report specific diseases or mortalities fitting specified criteria to the national authority immediately upon detection. In other countries, this may be achieved through education of the resource users, rather than legislation, but this has a higher risk of delayed or non-reporting, than legislated reporting. Even with immediate reporting, most aquatic animal diseases are difficult to eradicate from open water or flow-through sites, so delayed reporting renders the option of eradication even more challenging (if not impossible).

For endemic diseases, reporting may be limited to recording presence or absence of disease events within a particular area or, in more sophisticated systems, recording estimates of prevalence of the particular disease for specified time periods (e.g., annually or quarterly).

Data management and reporting

To provide access to surveillance findings, some form of information repository is required, from which various reports can be produced. This can be at a national or regional level, as required.

A national disease data management system is necessary to collect, store, and use the data needed to establish and maintain zones for diseases of national or trade concern. As a minimum, this should include presence/absence data for reportable diseases within the country. Data required for risk analysis or epidemiological research, may be stored at a regional or local aquatic animal support facility (veterinary, government, or research). In general, corporate or individual client information is retained by the direct aquatic animal health service provider (extension officer, local veterinarian or government aquatic animal health services). This can be independent of, or linked to, the data repositories used for zonation. Where such information is kept separate from the national database, some form of communication network must be in place to ensure that client or local information can be accessed quickly when a disease emergency arises.

Aquatic animal health information systems may range from information gathered by stock-owners, passed by word of mouth, recorded on local, regional or national computerized data bases, or managed via networks linking a broad number of government agencies and diagnostic laboratory resources.

Transparency and disease reporting

Effective disease management requires transparent declaration of significant disease problems. Historic establishment of many aquatic animal diseases has undoubtedly been due to inadequate surveillance, but more recent history indicates another reason that is more difficult to address. Some stakeholder believe that rapid reporting of disease losses (regardless of diagnosis) poses a significant risk of immediate market loss, devaluation of product and related disease management credibility issues. In addition, disease reporting is often linked to stock destruction – especially for detection of exotic diseases. Such beliefs are easy to understand, in light of terrestrial disease examples, such as Foot and Mouth Disease (FMD) and Bovine Spongioform Encephalopathy (BSE). However, reticence to report poses significant challenges to effective disease control in open-water and flow-through aquatic systems. This is why mandatory reporting is an OIE requirement for both terrestrial as well as aquatic animals. It assists accurate pin-pointing of disease incursions, and provides credible trade certification status. If a disease breaks out post-import and the country has a surveillance system with transparent reporting and associated export certification, that importation can be examined and (where appropriate) ruled out as the source of the infection. This is covered by the chapter on “veterinary ethics” in the OIE Code.

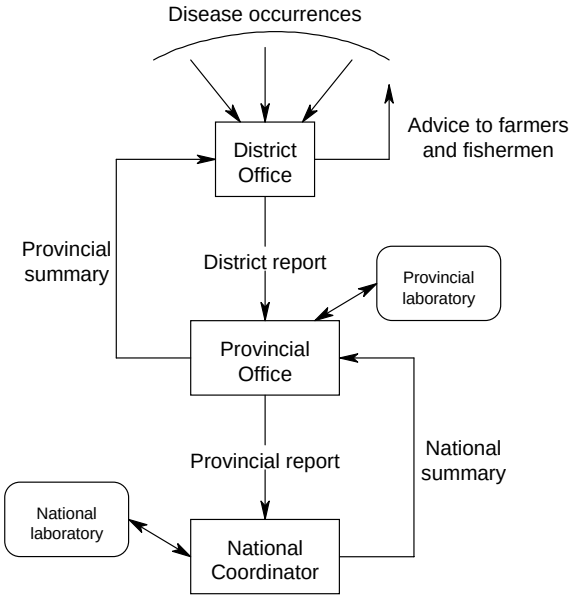
National disease reporting

Special emergency disease reporting mechanisms must be in place for serious disease outbreaks or suspect cases. These reporting mechanisms (usually part of a more comprehensive contingency plan) must allow critical information (as outlined under the first 4 bullets under “Basic Information” above) to be transmitted quickly and accurately to the national authorities responsible for aquatic animal disease control (preferably, the same day of

detection/presumptive diagnosis). This means that field and laboratory staff, who are involved in surveillance, need to have the necessary contact information (with a list of alternatives) so emergency disease reports can be acted upon with minimal delay. Mandatory reporting is useless if information required to pinpoint the outbreak is inaccessible[10].

A national disease reporting system should be based, where possible, on the day-to-day disease investigation activities of field officers and diagnostic laboratories. Such a reporting system, by necessity, requires feedback loops, as shown in Figure 7. Routine data collection is aimed at helping the industry stakeholder with any disease problems, so only a small proportion of the field information is required by the next administrative level, and likewise "up the line". Some kind of tracking system is required, however, to permit rapid feedback, when required.

Figure 7. Example of information flows in a national disease reporting system



International disease reporting

There are various international levels of formal reporting, the most important for aquatic animal diseases of trade significance being through the OIE. The NACA/FAO and OIE Quarterly Aquatic Animal Disease Reporting System provide similar reporting programs for geographic regions such as Asia-Pacific countries. The North Atlantic countries report to the International Council for the Exploration of the Sea (ICES) and European countries provide reports to the European Inland Fisheries Advisory Commission (EIFAC).

World Organisation for Animal Health (OIE). The OIE has disease reporting requirements for member countries that need to be addressed within any national aquatic animal disease control program. A staff member in the national office of the Competent Authority for each country should be delegated the official responsibility of preparing international disease reports, which are submitted to the OIE by the national delegate (usually the Chief Veterinary Officer [CVO]) of the OIE Member Country. The same person can prepare reports for other

[10] Client confidentiality is protected except where action is required to prevent exotic disease spread to surrounding wild resources or neighbouring farm animals.

organizations with aquatic animal disease interests, e.g. NACA/FAO, ICES, EIFAC, but these do not require submission via the CVO for the country.

Obligations of the OIE Aquatic Code require notification to be sent to the OIE Central Bureau within 24 hours of confirmation of any of the following events:

- for diseases listed by the OIE, the first occurrence or re-occurrence of a disease in a country or zone of the country, if the country or zone of the country was previously considered to be free of that particular disease; or
- for diseases listed by the OIE, if the disease has occurred in a new host species; or
- for diseases listed by the OIE, if the disease has occurred with a new pathogen strain or in a new disease manifestation; or
- for diseases listed by the OIE, if there is potential for international spread of the disease; or
- for diseases listed by the OIE, if the disease has newly recognised zoonotic potential; or
- for diseases not listed by the OIE, if there is a case of an emerging disease or pathogenic agent should there be findings that are of epidemiological significance to other countries.

Thereafter, monthly reports outlining the disease situation are sent to the OIE, until the disease has been eradicated, or the situation has been brought under control, e.g. by surveillance supported zonation.

Annual disease status reports are sent to the OIE from member countries with presence/absence records, information on changes in status of diseases listed by the OIE, or findings of epidemiological importance to other countries for diseases that are not listed by the OIE. These reports are aimed at providing information on significant changes in the status of infected zones that are of relevance to trade partners or neighbouring countries with confluent hydrographic boundaries.

Regional organizations. Regional Inter-Governmental Organizations (IGOs) with a mandate for aquatic animal health management could be used to assist international cooperation on aquatic animal health issues and development of infrastructure to reduce risks associated with trade in live aquatic animals and their products (e.g. the European Commission, Council Directive 91/67/EC, its amendments, or related Directives and Commission Decisions, and the ICES Code of Practice on the Introductions and Transfers of Marine Organisms (ICES 1995a)). These mechanisms may include diseases of significance to the region, which are not included in the OIE list. The NACA/FAO and OIE Quarterly Aquatic Animal Disease Reporting System is an example of such cooperation in the Asian region. The NACA/FAO and OIE list includes the OIE listed diseases and other diseases of significance to Asia-Pacific Region trade. Since aquatic animal diseases do not respect borders, close collaboration between neighbouring countries is required. This includes early warning, rapid and transparent sharing of information on new disease occurrences, the spread of existing epidemic diseases to areas with shared water bodies, and information on related control strategies. This information should be shared by: (i) respective Competent Authorities; (ii) responsible government agencies; (iii) local district, provincial or regional management offices and laboratory personnel/scientists; as well as (iv) industry associations along shared borders.

Mechanisms to ensure rapid and transparent flow of disease information between the responsible government agencies of major trading partner countries, is also essential for effective disease control in aquatic animals and their products.

Implementing a basic surveillance programme

Most countries can conduct basic surveillance using existing communication networks but this should be reinforced, where necessary, by a system of formal reporting and record keeping. Use of existing communications systems ensures that historical records, even if qualitative, are available for back-up information. Such historical data is also useful for setting interim zones until targeted data can be generated to either confirm the zone or identify where the zone may need to be revised. Potential sources of qualitative surveillance information are listed in Table 7.

Table 7. Potential sources of surveillance information on aquatic animal diseases.

o Farm/Lease Workers o Villagers o Village Elders/Chiefs o Industry Associations o Hatcheries o Buyers/Brokers o Markets o Processors/Exporters	o Post-Larvae/Fry/Seed Salesmen o Salesmen/Delivery Men o Material Suppliers o Fisheries Officers o Extension Officers o Consultants	o Research Workers o Research Institutes o Government/Private Laboratories o Research Literature o Grey Literature

A diversity of information sources may be included in the surveillance system, and may span anecdotal information, farm records, hatchery records, private and government laboratory reports, certification records, research investigation and fishery stock assessment data. Such diversity inevitably includes varying levels of reliability and quality. All the information is valuable but, less reliable data will require some degree of verification before it can be used to make management decisions. Basic principles behind use of variable sources of surveillance information are given below.

Scenario 1

In Country A, the occurrence of sudden mass mortalities is noted in mussel farms located in a single lagoon within a single province. This information, along with other related observations, is communicated to the National Coordinator (NC) for aquatic animal health who immediately notifies authorities in neighbouring provinces. If the NC is not the Competent Authority (CA) for aquatic animal health for the country, the NC also will notify the CA. At the same time the NC requests information from any mussel/mollusc disease specialists in other institutes on any similar occurrences in mussel populations elsewhere. An "affected zone" is established, based on the initial reports, which is the area delineated by human activity and hydrographic links to the mussel stocks known to be affected (e.g. the lagoon). If human activities create links to more distant locations, these must also be investigated.

Once the disease or pathogen is identified, and confirmed as being a new/exotic infectious threat to mussel stocks in the country, surveillance is critical for delineating the actual geographic distribution of infection, this is reported to the NC who then notifies the fisheries officials responsible for mussel culture and processing and requests that they implement controls that will prevent transfer or spread of the infection out of the affected area. At this point the CA should be informed of the disease situation and control measures implemented. If a reportable disease, the appropriate authorities should also be informed within the required time period (for OIE listed diseases, this is 24 hours). More intensive surveillance is undertaken to ensure no sub-clinical infections have been missed in the initial surveillance for clinical infections. Any samples that are uninfected but within the positive zone (delineated by positive cases and hydrographic continuity) can be managed as "uninfected" sub-zones if controls can be put in place that isolate the site from infected sites.

Scenario 2

A fisherman in a small village notices an unusually high number of dead crabs in the creek where he normally fishes. He tells a friend who informs a rural crop extension worker who visits the village every three months. As a result of a government information initiative, the extension worker knows he should communicate information on unusual losses or diseases of aquatic animals to the district fisheries office.

When the district fisheries officer gets the information, he sends a note to his supervisor who, in turn, submits it to the National Coordinator (NC) for aquatic animal health. If the NC is not the Competent Authority (CA) for aquatic animal health for the country, the NC will include this information in their regular report to the Competent Authority (CA), and bulletin reports to other district fisheries offices. The NC will also check records and request information on any similar occurrences from other district fisheries officers .

(i) No further incidents occur since the initial incident. The NC includes this information in his next report to the CA and the next disease surveillance bulletin distributed to other district offices.

or

(ii) In the next two weeks, similar occurrences are reported in other creeks in the original district, as well as in neighbouring districts. The CA is notified of the increasing problem and an investigative team is sent from the nearest Institute with crab health expertise to help the district fisheries officers take samples of moribund and healthy crabs for analysis. The district officers in both affected and neighbouring or linked non-affected areas are informed of the disease situation. All are also asked to look for sick crabs and collect samples wherever possible for testing. Guidelines for collecting, labelling, transporting and/or preserving specimens for optimal laboratory analysis are included with these requests.

At the same time, movement of live crabs from affected areas to markets in nearby provinces for use as bait, comes under regulatory prohibition. District fisheries officers in the affected and neighbouring provinces are also asked to distribute notices informing local communities of the situation and request that alternative types of bait be used until further notice.

Surveillance to support zoning

Surveillance to establish zones: National surveillance programmes entail significant investment in the required support infrastructure[11], so it is recommended that diseases for such programs be selected by a thorough risk analysis. Criteria for OIE listed diseases are provided in the Code (OIE 2003b).

Evidence of freedom: Evidence of freedom from infection may be based on a number of different sources, including:

- structured surveys using one or more tests for the presence of the agent;
- knowledge of physiological tolerance limits of the infectious agent;
- history of no imports of potentially infected material;
- existence of appropriate biosecurity measures;
- evaluation of historic or general surveillance data by the Competent Authority;
- structured, non-random surveillance (e.g. sentinel sites, accreditation programmes, etc.); or
- any other sources that provide evidence that lowers the probability that infection is present.

For diseases listed in the OIE Code, the general requirements for surveillance for recognition of freedom from infection are presented in the OIE Aquatic Manual, Chapter 1.1.4[12]. In brief, these requirements differ depending on the previous infection status of the country, zone or aquaculture establishment, namely absence of susceptible species; historically free; last known occurrence within the previous 25 years; or previously unknown infection status.

To maintain evidence of freedom from a disease, a surveillance system that ensures early detection and pathogen identification is required. This system should be managed or coordinated through the Competent Authority and include:

- representative coverage of susceptible populations by fishery or aquatic veterinary services capable to detecting, investigating and reporting disease incidents;
- access to laboratories capable of diagnosing the disease of concern;
- training for fish health specialists to ensure they can detect and identify the disease agent; and
- import requirements to prevent the introduction of disease/infection into the country or zone, from known infected areas.

[11] Dedicated human resources (field and laboratory), including legal or policy frameworks for mandatory reporting, diagnostic quality management systems, intergovernmental or jurisdictional policy agreements, etc.

[12] See Chapter 1.1.4 “Requirements for surveillance for international recognition of freedom from infection”; OIE *Manual of Diagnostic Tests for Aquatic Animals*, 4th ed, 2003 - - http://www.oie.int/eng/normes/en_amanual.htm

Surveillance questions

The decision to invest in surveillance depends on whether or not there is a risk of introduction or spread of the disease of concern. Some basic questions behind assessing this risk are:

1. Are susceptible species present?

Where a species is present that is known to be susceptible to an infectious disease of concern, the risk from exposure to the disease agent needs to be evaluated. If there is no history of unexplained mortalities and no detection of the infectious agent through general surveillance (where present), it may be assumed that the populations present are naïve and at risk. The degree of risk depends on whether or not human activities expose the populations present to stocks from areas where the disease is known to occur. Likewise, current or potential trade with other countries, or zones within the country, that are considered or proven to be free of the disease, also needs to be taken into consideration.

If the species is present, and likely to be exposed to risk, targeted surveillance to confirm the presumed negative status is required. Before embarking on such a program, it is recommended that susceptibility be confirmed. This is necessary to ensure that the populations present are truly susceptible, as opposed to being tolerant or resistant to infection. In the latter case, no surveillance for protection may be required, although surveillance for sub-clinical infections would be needed. In some cases, countries have undertaken challenge experiments using animals from the presumed negative zone, in collaboration with countries where the disease of concern is endemic.

2. Can the pathogen of concern survive the environmental conditions present in the area being proposed for zonation?

Many of the most significant aquatic animal pathogens are serious because of their ability to cause disease outbreaks in susceptible hosts over a broad geographic range. Timing and duration of infections may be affected by temperature and salinity differences, but most diseases are suppressed, rather than eradicated under extremes in environmental conditions. Some tropical pathogens may show a limited distribution, but where the host species is/are cultured outside their natural geographic range, culture conditions usually replicate the optimum temperatures and salinities for growth, that will be conducive to pathogen proliferation if present.

3. Do susceptible stocks straddle political borders (national or provincial/state)?

Before embarking on targeted surveillance to define zones containing susceptible populations, it is necessary to ensure that these zones cover the entire ecological range of the species. Where this range straddles political borders (internal or international), zonation will only be effective if all jurisdictions participate or support the surveillance efforts.

4. Is data available to define zones?

Data from general surveillance activities that include the susceptible populations can provide a strong foundation for establishing preliminary zones. These can then be refined as data from

targeted surveillance is generated. General surveillance can be especially useful for providing evidence of freedom, where the diagnostic tests required to detect infection are not pathogen-specific. Such data normally requires reinforcement from targeted surveillance, where the objective is to prove (certify) freedom from infections within the zone.

Where there is insufficient data to establish a preliminary zone, targeted surveillance of susceptible populations can be started. Consideration should be given to prioritising those stocks or populations at greatest risk, selecting samples of the most susceptible size/age group from discrete populations, and timing collections to match the season of peak outbreaks in endemic zones.

5. What sample sizes are required?

Statistical tables require samples sizes close to 100 percent if 0 percent prevalence (disease absence) is assumed. Since this would defeat the purpose of zonation, most surveillance programmes work towards samples giving 95 percent confidence of detecting a single infection at 2 percent prevalence (n = 150 for populations >1 000 000). Any sub-sampling of widespread but homogenous stocks needs epidemiological review (Cameron 2002). Also, some stocks may be too valuable or rare for intense sampling, so non-lethal sampling or lower confidence levels may need to be considered, possibly over a longer period.

Smaller samples (n = 30–60) can be collected from any stocks experiencing abnormal growth or mortalities during the period of establishing the zone, in addition to the targeted surveillance samples.

At least two representative samples per year, over a two year period, from each discrete population, is considered by the EU and other individual countries to be the minimum amount of data required to define the zones applicable to those populations. The OIE Aquatic Manual stipulates that the number of units to be sampled from a population should be calculated using a statistically valid technique that takes at least the following factors into account: the sensitivity and specificity of the diagnostic test, or test system; the design prevalence; and the level of confidence that is desired of the survey results. The specific sampling requirements will need to be tailor-made for each individual disease, taking into account its characteristics and the specificity and sensitivity of the accepted testing methods for detecting the disease agent in host populations[13]. The sample size calculations are performed using the *FreeCalc* software (FreeCalc–Cameron, A.R. Software for the calculation of sample size and analysis of surveys to demonstrate freedom from disease). Available for free download from http://www.ausvet.com.au).

6. Surveillance within established zones

Positive Zones – If eradication is determined to be unfeasible, minimal surveillance is required, except to monitor for recurrent outbreaks that require management intervention to minimise losses.

Buffer Zones – Similar to surveillance in free zones, but with samples concentrated on susceptible populations closest to, or with human activity links to, positive zones.

[13] See Chapter 1.1.4 "Requirements for surveillance for international recognition of freedom from infection"; OIE *Manual of Diagnostic Tests for Aquatic Animals*, 4th ed, 2003 - - http://www.oie.int/eng/normes/en_amanual.htm

7. Assessment of risk associated with movements of other species out of a positive zone

The question of host specificity of the pathogen is becoming increasingly important as more species and greater number of animals get transported live for aquaculture, processing and marketing. This is especially pertinent to molluscs and crustaceans that have serious pathogens with broad host-specificities. The ability to accurately assess the potential of other species to act as carriers or reservoirs of infection is, therefore, essential for effective zonation. This may be achieved by using historic evidence of transfers of other species, with no associated spread of disease, or it may require targeted challenge experiments.

Accurate risk assessments are essential for identifying true risks of pathogen transfer, versus suspected risk of carrier transfer. Suspicion of potential carrier species must focus on links to naïve susceptible populations; otherwise the scope of surveillance or challenge experiments required could encompass all species within an infected zone. Although this may be logistically challenging when resources are focussed on controlling the disease impact on the recognised host species, protection of surrounding vulnerable populations may necessitate impacting other resource users until a risk analysis can be done.

A basic assumption for any diagnostic analysis of potential carrier species is that the characteristics of infection in the primary susceptible host are unlikely to be present in the carrier/transport host. Visual inspections, such as histology are, therefore, of limited use for checking carrier status of other species in positive zones. Vertebrates can be screened for serious finfish viruses using sensitive fish cell-lines, but no such tools are currently available for invertebrate pathogens. Recent development of molecular probes, however, has significantly increased our ability to screen potential sub-clinical carriers.

In 1995, the question of assessment of carrier species was raised by the ICES Working Group on Pathology and Diseases of Marine Organisms (WGPDMO) (ICES 1995b). More recently, FAO hosted a workshop to discuss the use and interpretation of molecular-based diagnostics, which included discussion of sensitivity-specificity field validation for screening potential carrier/reservoir hosts, as well as sub-clinical infections in the normal host species (Walker and Subasinghe 2000).

General considerations recommended by the WGPDMO for assessing whether or not other species pose a risk of transfer of a significant pathogen from a positive zone to a negative zone are as follows:

- Determine the geographic range of pathogen “A” in known susceptible host species
- Determine which species within that range is/are likely to be transferred live to other areas that have uninfected susceptible species populations present.
- Examine these species for the presence of pathogen “A”, using diagnostic tools known to be sensitive and specific for the pathogen, and sample sizes appropriate for detection of low level, sub-clinical, infections.
- If evidence of pathogen “A” is detected, assess the viability of the pathogen in the alternate host. If tests are molecular assays, can the pathogen be isolated in tissue samples using *in situ* hybridisation? Is there any evidence of pathogen proliferation?
- Assess the transmissibility of the infection from the suspect carrier species to the known susceptible host, using e.g. laboratory-based challenges where susceptible hosts are held in contact with the suspect carriers. Although useful for validating

laboratory challenges, especially for pathogens with unknown intermediate hosts, field exposure of naïve host species and suspect carriers is not recommended. Such experiments are difficult to control and risk raising infection loads in open-water.

- If the results from the challenge experiment are positive, then the alternate species presents a high risk for transfer of the pathogen out of the infected zone. The species should be reported to the national authority as being a carrier of viable disease agent, so appropriate control measures can be put in place.

The WGPDMO further recommended that simple inoculation-based challenges not be used alone to assess alternate host susceptibility. Proximity challenges and pathogen viability also need to be examined.

SURVEILLANCE AND ZONATION – A PRACTICAL CASE STUDY

There are many surveillance and monitoring programs underway around the world that are aimed at specific diseases of concern. In Europe several countries monitor for specified diseases under the European Council Directive 91/67/EEC and associated amendments, as well as the European Commission Decision 96/240/EC. Likewise, Australia has an extensive surveillance programme for specific reportable diseases under their AquaPlan (AquaPlan 2000). Most recently, Canada had to implement a surveillance programme to address the first time detection of an OIE listed molluscan pathogen, *Haplosporidium nelsoni*, the causative agent of MSX disease. Coincidentally, this outbreak occurred at the same time as the Expert Consultation in Rome in October, 2002, and necessitated the early departure of Dr. McGladdery who was in charge of coordinating the contingency plan response. Since much of the Expert Consultation discussions up to that point were brought immediately to bear in addressing this disease emergency, it was considered appropriate to include the outbreak history and controls based on the surveillance that was implemented (and is ongoing) as a case-study (Atlantic Canadian oyster disease surveillance) for this report.

Atlantic Canadian oyster disease surveillance

Historic reference data

Traditionally, Canada's east coast native oyster species, *Crassostrea virginica*, has been considered to be free of the diseases that have impacted the same species along the mid-eastern Atlantic coast of the United States. In the late 1980s a shellfish health programme was initiated with the objective of compiling a disease database that could be used to assess the risk of moving oysters between the four Atlantic Provinces and three hydrographic water bodies. The database comprised of histopathology information and a reference slide collection.

Between 1988 and 2002, over 8 000 oysters were examined histologically as part of disease and aquaculture development research projects (variable sample sizes), health checks for licensed stock transfers (for depuration relay and seed/broodstock for culture purposes) (sample size n = 60), and investigation of reports of abnormal mortalities, growth or spawning events (variable sample sizes). During this period, no OIE listed pathogens of oysters were detected, and annual reports to OIE were based on these observations.

In 1998, the data generated from this general surveillance was used to establish zones within Atlantic Canada for use by government introductions and transfers committees, as well as for teaching purposes. Based on like-to-like health profiles, all oysters in the southern Gulf of St. Lawrence were considered to be homogenous, while those in Cape Breton were considered to be distinct, based on experimental demonstration of ongoing susceptibility to Malpeque Bay Disease, which is present at subclinical levels in oysters throughout the southern Gulf of St. Lawrence and southwestern Nova Scotia.

Detection of suspect OIE listed disease

Suspicious observations were found by the shellfish health laboratory in October 2002 in a sample of oysters submitted from Cape Breton due to heavy mortalities. The histology was sent to the OIE reference laboratory for molluscan diseases at the Virginia Institute of Marine

Sciences. Duplicate samples from the suspicious case were process for scanning and transmission electron microscopy, as well as for PCR using OIE published primer for MSX and SSO ("seaside organism") parasites.

At the same time, additional samples were received from Cape Breton independently from other stakeholders. Protocols for enhanced record-keeping and sign-off were initiated for laboratory personnel to track samples being sent for "second opinion"; for electron microscopy; and for PCR analysis in Moncton and Virginia (PCR done blind on all samples).

A contingency plan was developed with two stages:
(i) Actions required on Presumptive diagnosis of a significant infectious agent; and
(ii) Actions required on Confirmation of a significant infectious agent.

Stage (i) involved alerting local and national authorities of suspicion of a serious infection, as well as the oyster growers who submitted the samples and the provincial authorities. A communications plan was also developed with scenarios to cover "something new" killing oysters in Cape Breton, as well as first time detection of an OIE reportable pathogen.

Confirmation of MSX disease in Canada

On 18 October 2002, confirmation of the infection being *Haplosporidium nelsoni*, the parasite responsible for MSX disease in *Crassostrea virginica*, was received from the OIE reference laboratory. The Chief Veterinary Officer for Canada was notified immediately and he notified the OIE General Secretariat. Canada was no longer considered to be an MSX-free country.

The contingency plan prepared for confirmation of MSX was implemented and a meeting held in Cape Breton on 21 October 2002 with affected leaseholders and First Nations food fishery stakeholders, along with federal and provincial authorities and fish health veterinary services. This meeting was used to:

(a) Identify priority sites for sampling to map out extent of MSX infections in Atlantic Canada. Sites selected were those reporting mortalities, at neighbouring sites, with direct oyster transfers from the positive site over the preceding 18 months, with indirect links to the hydrographic area containing the infected site, and with no links to the affected site.

(b) Establish interim control measures to prevent spread while samples were collected, analysed and results produced for feedback. This included voluntary cessation of the native food fishery, closure of leases (harvest fishery closed for conservation reasons), and development of harvest protocols for lease-holders to help get product out of the water and to market live with no intermediate washing or resoaking that could spread MSX.

Surveillance to determine the geographic extent of MSX infection of Atlantic Canadian oyster populations

The sampling protocols were developed in consultation with provincial extension officers familiar with all oyster industry stakeholders in the area. One site per day was visited and two teams of two personnel were deployed. Disinfection of clothing and equipment was undertaken pre- and post- each site visit and oysters were collected by the biologists, using farm equipment and wet-gear. The approach used was to start at the sites furthest removed from the known positive area and work inwards from there.

At the same time samples were received from the two neighbouring provinces. These were from sites that had reported observations of mortalities over the summer, but did not consider them abnormal at the time. They were also sites with indirect links to Nova Scotia oyster processors with live-holding capability.

Laboratory examinations

On receipt of the oysters at the laboratory, they were logged into a special log with code numbers which were used for blind samples for PCR and cross-checking histology readings. All initial samples received were processed using sterile flaming between oysters. This was to ensure that any PCR results received could be tracked back to individual oysters.

Sample sizes were 60. Thirty of the oysters were processed immediately for histology and tissues preserved for PCR. The remaining 30 were fixed, but not processed further for immediate histology, and tissues fixed for PCR examination, as required.

Protocols for reading slides included a sweep for obvious clinical infections – noting whether or not there was spore development. As soon as a positive slide was confirmed, the entire sample was recorded as positive and examination moved to the next sample. It was considered more important at this stage of surveillance to map presence/absence than prevalence. Negative samples following the sweep and high power "search and rescue" examination of the entire tissue section were flagged for processing the remaining 30 animals. Any suspicious but inconclusive histological observations were flagged for PCR examination.

Subsamples of tissue sections from each sample of 30 were flagged for analysis by a second slide-reader. This included slides with anything suspicious but inconclusive.

Other species

Mussels from the positive area were also submitted for examination due concerns over proposed transfers to mussel growing sites outside the area. These were processed for histology, but also analysed using MSX-PCR.

Preliminary results

The surveillance period (November-December) is not recommended for detection of subacute infections by MSX, however heavy infections were found in oysters from the Bras d'Or Lakes area of Cape Breton with direct transfer links to the affected site. Other sites outside the Bras d'Or Lakes system showed no clear evidence of MSX or related pathology. However, a couple of oysters from the southern Gulf of St. Lawrence contained low numbers of plasmodia with no evidence of proliferation or pathology. These were subsequently identified as SSO, a related parasite, previously thought to be absent from Canadian oysters. The salinity range in the southern Gulf is not considered normal for SSO, and the patchy, light, and subclinical infections detected subsequently indicated a diffuse, ubiquitous distribution, rather than the point-source heavy infection profile found for MSX within Bras d'Or Lakes.

Follow-up sampling to address establishment questions

The direct transfer links to the positive site raised the question of how long the parasite may have been present in Cape Breton oysters and if it had established infections in surrounding wild populations. Additional samples were collected in late November-December that indicated that the disease had spread to oysters on neighbouring beds that were not subject to handling or seed transfers.

Preliminary zonation for mapping

Bras d'Or Lakes as a whole were zoned as positive for MSX, despite the presence of some sites that showed no evidence of infection. This was because they could not be isolated from positive sites hydrographically or from routine human activities within Bras d'Or Lakes.

A preliminary Buffer Zone was delineated around the outer coast of Cape Breton where results showed no evidence of MSX and despite there being seed transfers from the affected area of Bras d'Or Lakes in early summer 2002.

The remaining east coast oysters were designated as being in MSX-negative areas, although analysis of these negative samples was continued over the winter.

Zonation for management strategies

The presence of spores, indicative of advanced infections and potential for release of MSX sporoplasm into the water, along with detection of plasmodia in neighbouring wild oyster samples, indicated the strong possibility that MSX had established an infection process in affected waters. Although observations suggested the disease outbreak was recent, this may have had an incubation period dating back to the previous fall to permit infections of neighbouring oysters. These observations, along with the fact that MSX cannot be transmitted directly between oysters in the laboratory, indicated that some reservoir, other than oysters, had become involved in MSX transmission in the Bras d'Or Lakes ecosystem.

All these facts suggested that any attempt to remove oysters in order to eradicate MSX from the system would likely be futile. Thus, emphasis was placed on defining zones within which MSX could effectively be contained. Results from ongoing surveillance in 2003 continue to indicate that MSX is confined within Bras d'Or Lakes and all transfer controls are based on this remaining a positive zone.

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APPENDIXES

Appendix I. A model plan for strengthening national and regional capabilities in disease surveillance

Introduction

Containment, control and eradication of major diseases of aquatic animals in any area of the world require a coordinated regional approach. Countries within a region, or areas within a country, that have lower socio-economic standards, are liable to fall behind their more developed neighbours in disease control.

The majority of the populations in most developing countries are involved in smallholder agriculture. This also represents one of the poorest sectors of developing country society. In addition to food and draft power, livestock and aquatic animals represent an important income system within the village economy. Losses due to disease related mortalities and decreased production, therefore, cause a proportionately greater impact on these rural sectors. Strengthening aquatic animal health support of developing countries is therefore an efficient, well targeted approach to improving the overall livelihood of the rural poor on a national, regional and global basis.

The key to a coordinated regional disease control programme is the free exchange of reliable, compatible disease information between countries, and the harmonization of reporting and disease control procedures. Encouraging this approach will help significantly in control and eradication of many preventable aquatic animal diseases.

The objective of integrated control is use of a vertically managed approach to improve collection, analysis and use of aquatic animal health information for disease control. This can be achieved by addressing weaknesses at each level of the information chain – from farmers and fishermen to regional associations and organizations. The long term goal is to enable aquatic animal health services to control and eradicate major diseases successfully and in an environmentally sustainable manner.

The current difficulties experienced by poorer countries in control of significant aquatic animal diseases is the lack of internally funded, and dedicated programmes aimed at aquatic animal diseases – certainly in comparison with other livestock production sectors. Such programmes will establish a skill-base that can develop experience with local growing systems and environmental conditions. Such experience is not readily extrapolated from outside expertise (especially on an on-going basis). These skills can then be used to tackle other diseases of importance that may emerge as aquatic production intensifies and diversifies within the region. Commencing a disease eradication project without investing in preparedness (contingency planning, surveillance and zonation) is likely to result in expensive failure, and repeated disease outbreaks.

All effective disease control measures need sound information on the distribution and nature of significant diseases. This information can only be generated through a well-planned disease surveillance program. The following is a generic plan for strengthening disease surveillance capabilities at a national and regional level. It is particularly aimed at developing countries, but is also applicable to regions within developed countries that are expanding and diversifying aquaculture production.

Objectives directed at developing an effective and comprehensive surveillance capability

The following are relatively generic objectives which need to be met if a country is to successfully develop a national aquatic animal disease surveillance program. By clearly defining these objectives, necessary activities and support requirements can be more effectively identified.

Objective 1: Improve the collection of aquatic animal health information
Objective 2: Ensure sustainable laboratory support
Objective 3: Implement an information management system
Objective 4: Establish national and regional analysis and reporting systems

Outputs and activities

In this section, the required outputs and activities are briefly summarized for each objective stated above.

Objective 1: Improve the collection of aquatic animal health information

General surveillance

Improve disease reporting and specimen submission by farm owners, lease-holders, village or municipality representatives, district and provincial government authorities. General surveillance gathers information on disease outbreaks and identifies samples that require diagnostic laboratory analysis. Under-reporting in general surveillance systems means that the data collected is unrepresentative of the aquatic resources in general and, therefore, are of little use for developing disease control strategies or minimizing the impact from disease outbreaks. In countries where laboratory facilities are limited, the key personnel in the chain of reporting are the district officers who are responsible for submitting primary disease reports.

Activity 1.1.1: Training of provincial and district government staff

Highly targeted training to district staff should be provided to equip them with the skills to carry out effective disease investigations, collect disease history information, capture and examine aquatic animals, collect appropriate specimens, and submit these in optimum condition for laboratory analysis. Training should be provided in two-stages, starting with provincial staff, who receive detailed technical training, as well as appropriate methods to pass on to district staff (“train the trainer”). Training of the district staff should be audited, as soon as practical, to ensure training objectives are met and passed on successfully.

Activity 1.1.2: Provision of specimen collection kits

District staff need to be issued with basic sample collection kits (including capture equipment, specimen collection equipment, transport containers, appropriate preservatives, culture media, disinfectants, etc.), along with data recording forms and laboratory submission sheets.

Activity 1.1.3: Provision of ongoing support for district staff

After being trained, district staff need to be supported by provincial staff in carrying out field disease outbreak investigations, as they arise, as well as in the development of emergency disease outbreak response plans (contingency plans).

Activity 1.1.4: Monitoring staff activity

The activity of provincial and district staff in disease outbreak investigations, disease reporting and submission of specimens can be monitored with the assistance of an information management system of some type, preferably computerized. Provinces and districts that fail to submit health reports, report disease outbreaks or losses, or submit specimens for diagnostic analysis can be identified, and the reasons for this lack of activity investigated. Further training and support may be required. Information management systems need to address the needs of the aquatic animal health authorities and as well as existing information systems. A good example is the information system used by the Philippines Bureau of Animal Industries (BAI) for control of Foot and Mouth Disease (FMD) in bovine livestock.

Activity 1.1.5: Establishment of specimen transport and feedback systems

Systems for efficient transport of specimens to the diagnostic laboratory, information feedback to provinces, districts and villages, are required. This includes maintenance of capture equipment, and submission materials (packaging, labels, preservatives and/or ice, etc.) where required. To assist laboratories with feedback to the districts and villages, simple information sheets on common diseases are very useful. They serve a double purpose of informing the field observers, as well as providing reference material to distinguish abnormal from common disease outbreaks.

Activity 1.1.6: Continuing aquatic animal health education for provincial and district staff

Provincial staff should be invited to attend periodic “refresher courses” on commonly encountered diseases or control issues, run by national counterparts. This will ensure maintenance of up-to-date field diagnostic skills and knowledge on new or emerging diseases. Trainees should be provided with reference materials and required to present the same information to district staff at regular (e.g. annual) provincial meetings.

Activity 1.1.7: Public awareness campaigns for small-scale farmers

Encouraging the support of small-scale farmers in disease reporting can be achieved through the development of appropriate public awareness and education materials in the local language and at a level consistent with local education levels.

Activity 1.1.8: Establish links with village-level agricultural projects

Links should be established with agricultural development projects working at the village level (e.g. via NGOs) to include this message in their work and distribute educational material.

Targeted surveillance

Targeted surveillance to collect reliable, population-based information on key diseases, and to monitor the progress of control campaigns is an essential complement to general surveillance.

Activity 1.2.1: Training of provincial and district staff in survey techniques

Where there is existing knowledge on specific diseases of concern to a country, province or district, surveillance information may be available to assist in the design of appropriate surveillance strategies for the stocks the authorities and industry wish to protect.

Activity 1.2.2: Implementing field disease surveillance

Training should include field exercises to give staff practical opportunities to assess the environmental constraints on theoretical surveillance strategies. For example, 30 animals every 4 months may not be feasible in some monsoon months, or when production stocks have been marketed. Likewise surveillance of certain size-classes may only be feasible at certain times of the year, month, etc.

Activity 1.2.3: Development of a targeted surveillance program

In collaboration with national staff, a coordinated programme of targeted surveillance should be established for priority diseases. This would initially aim at gathering baseline data on disease presence/absence and, where relevant, prevalence. Trained staff should be involved in these survey activities as part of their normal general aquatic animal disease surveillance responsibilities.

Activity 1.2.4: Use of targeted surveillance to support disease control programmes

Surveillance activities for priority areas should be maintained to ensure effective decision-making in response to disease outbreaks as well as development of informed and feasible control options.

Ancillary data

Training a range of personnel in reporting and data collection techniques relevant to their responsibilities is vital to ensuring that ancillary data which supports disease control is properly recorded, analysed and reported.

Activity 1.3.1: Train personnel in the collection of ancillary data

Personnel from industry cooperatives or associations, district offices, provincial offices and laboratories, as well as national agencies should receive basic training in the use of reporting forms and data/information collection necessary for disease surveillance and zonation. These include (but are not limited to):

- production and administration data;
- aquatic animal transfers and introductions;
- disease surveillance data;
- use of vaccines and chemotherapeutants;

- aquatic animal population data for the district waters; and
- pertinent environmental and human activity information.

Socio-economic data

Activity 1.4.1: Train national-level staff in the collection of socio-economic data

National-level staff should receive training in the collection of relevant socio-economic information. This should be combined with targeted surveillance activities, and be aimed at providing statistical support for priority setting in disease control programme implementation activities.

Objective 2: Ensure sustainable laboratory support

A vital component of any surveillance programme is competent and reliable diagnostic laboratory support that is fully integrated into the overall disease surveillance and control programmes. This approach has been used successfully in the Philippines for control of foot and mouth disease in livestock.

Effective laboratory support for field activities

Laboratory and field services should be coordinated to ensure optimum use of the expertise of both disciplines.

Activity 2.1.1: Provision of specimens to provincial and national laboratories

Regular submissions of specimens (diseased or healthy) from the field to diagnostic laboratories are required to ensure diagnosticians maintain their ability to detect abnormalities. Sporadic samples can result in loss of such skills and production of unreliable results. Thus, field surveillance should routinely include specimen collections for submission to government and/or private diagnostic support laboratories. Such collections should be planned to provide useful information, such as stock production cycles, seasonal variations, or other relevant environmental factors. Such surveillance efforts must be designed in collaboration with diagnostic laboratory personnel and managers.

Activity 2.1.2: Provision of diagnostic reagents to laboratories

In addition to maintaining staff skills, the sustainability of diagnostic laboratories depends on a reliable supply of diagnostic reagents. Essential reagents and other laboratory materials must be available to support diagnostic testing. Samples may perish and valuable information lost if they have to be stored pending delivery of requisite materials.

Activity 2.1.3: Development of systems for local production of key diagnostic reagents

In some instances, (especially in tropical climates with limited refrigeration/cool storage capacity) it may be necessary to produce some short-lived reagents locally, or from basic compounds within the laboratory. Reagents suitable for local production should be identified, staff trained and systems set up for their sustainable production.

Activity 2.1.4: Train laboratory staff in new diagnostic techniques as appropriate

Techniques such as PCR have been developed to assist the diagnosis of several significant aquatic animal diseases. These require expensive equipment and short-lived, costly, reagents. In addition, these molecular techniques require highly trained expertise. For some priority diseases, additional more simple and rapid tests exist. Where appropriate staff should be trained who can be dedicated to these techniques. The rapid evolution of these techniques, and the materials that support their use in diagnostics, does not make them appropriate for part-time responsibility.

Objective 3: Implement an information management system

A useful information system should be simple to use, inexpensive, and adaptable to a wide range of changing aquatic animal health information. Ideally such a system should include specialized epidemiological analytical capability, but these can also function as an independent data processing system, as appropriate. With modern technology and networking capability, systems can now be developed which meet the needs of all levels of aquatic animal health personnel, and which can operate within the various organizational structures of different countries. A wide range of report formats can be incorporated including automated disease mapping where base maps are available.

Efficient management of aquatic animal health information

Observation and recording of disease events is most reliable where a human and data management system is in place that can archive, analyse, interpret and communicate the data, as appropriate.

Activity 3.1.1: User analysis needs and database designs

Experience suggests that databases may need to be work within a specific administrative or organizational structure within a particular country. However, modularized systems are more flexible and can be tailored to meet the needs of specific countries.

Activity 3.1.2: Development and translation of user manuals

Comprehensive user manuals should be developed and translated for each data/information management system. A core manual prepared in English could provide the basis for all data management manuals, being modified solely where individual countries have specific requirements, and then translated. Bilingual versions should be available in each country.

Activity 3.1.3: Training of staff in the use of systems

Inputs into information systems come from many different areas within the government services of a country. Roles and responsibilities should be clearly defined, and appropriate training provided on a regular basis or whenever the system is updated. A small specialized core of national epidemiological data management staff should be trained in the detailed operation and programming of the system.

Activity 3.1.4: Phased implementation

Where required, systems should be phased-in, running in parallel with any existing systems until training and data transfer (where appropriate) onto the new system is completed. It may be necessary to archive back-dated data that cannot be readily transcribed to the new system (time-wise or programme-wise). Where possible, data management systems should be implemented at least the provincial and national levels.

Objective 4: Establish national and regional analysis and reporting systems

Because of the ease of movement of aquatic animals and diseases from one country, province or zone to another containing susceptible resource, disease control requires a regional approach. National staff needs to develop the skills to analyse data, and summaries results that can be used to establish cooperative regional approaches to disease control.

Improved ability of national staff to analyse and interpret animal health information

National staff require substantial investment in ongoing training in order to ensure they keep up to date on the rapid evolution of aquatic animal disease knowledge that is relevant to protection of national aquatic resources (wild and farmed).

Activity 4.1.1: Training of national staff in data analysis

Epidemiological expertise should work in collaboration with diagnostic personnel to ensure accurate interpretation of national disease information. This can include field and contingency planning exercises, as well as quality control exercises such as blind “ring tests” to ensure consistency of results between laboratories and between epidemiology-based surveillance programs. On-the-job training should be encouraged through exchanges with neighbouring provincial or national laboratories or disease control offices. Subregional workshops for national aquatic animal disease control personnel should be conducted to provide more consistent epidemiological training, data analysis and interpretation, and development of effective disease control options.

Activity 4.1.2: Language training

National level staff from countries where the primary language of communication is not an international language should receive ongoing language support where it is required. This should be reinforced by their contact with foreign project staff. This will increase their ability to participate fully in regional meetings, prepare publications and reports, access international literature and many aquatic animal health specialists and use many software programmes.

Improved regional communication and coordination of disease control activities

Regional activities should be conducted in close collaboration with international expertise.

Activity 4.2.1: Establishment of a regional disease outbreak database

A regional geo-referenced database should be established to facilitate collation and analysis of aquatic animal health information. Contributing countries could access to up-to-date information on the disease status of neighbours, in order to help prevent accidental cross-border spread of diseases with live aquatic animals and product trade.

Activity 4.2.2: Regional data analysis

Regional coordination with national staff and regional organizations would be required to analyse regional data collected through general surveillance, targeted surveillance, socio-economic studies, and aquatic animal movement records, and maintain an effective disease reporting system.

Activity 4.2.3: Country coordinators' meetings

Where regional programmes are instituted, country coordinators and their regional counterparts need to maintain close and open communication. In addition to correspondence, there should be regular meetings rotating through each of the regional countries. These meetings will serve to exchange the experiences with aquatic animal disease surveillance and zonation in different countries, as well as facilitate open discussion of resource and any data reporting issues.

Activity 4.2.4: Economic group member coordination meetings

Links should be established with formal trading group committees to institutionalize regional information sharing and disease control activities. In addition to working with formal committees, a series of technical meetings could be called to:

- develop a comprehensive manual of standard definitions and rules for disease reporting, and disease control options for priority diseases in different areas of the region. These standards should be based on the OIE Aquatic Animal Health Code guidelines.
- develop standards for information exchange and reporting between countries in the region, including minimum datasets, communication exchange formats, geo-referencing systems, etc.

Activity 4.2.5: Short-term attachments

Staff from regional participating countries could be involved in short-term attachments or exchanges to the relevant services in different countries in the region. Epidemiologists from developed countries would have an opportunity share their experiences in light of environmental and aquatic animal production infrastructure differences that constitute the aquatic resource responsibilities of less developed neighbours. Conversely, exchanges between personnel from less developed countries would permit them to examine developed country disease surveillance systems and assess their applicability to their home country.

Activity 4.2.6: Newsletter

If formulated as a series of regional projects, it may be useful to distribute a newsletter to all countries in the region, focusing on practical and technical aspects of disease surveillance and zonation as a means of disease management and control, as well as providing an informal format for information communication.

Personnel

The implementation of a program, such as that described above, requires development of regional business plans and the involvement of a core number of personnel. In addition to an overall programme manager, regional coordinators would be required, as well as full-time national aquatic animal disease management advisers. Regional coordinators should be people with experience in aquatic animal disease control within the region, as well as with inter-jurisdictional project management experience. Each regional coordinator would be based in a convenient capital city within the region and would be responsible for overall project management, country coordinator support, and regional activities.

A country coordinator should be present in each participating country, and be responsible for day to day running of project activities. Each country coordinator should have interest in aquatic epidemiology, good interpersonal and management skills, and cultural sensitivity. In particular, they should have well developed training and communication skills (they may be required to address public or media concerns in the face of emergency disease outbreaks). One key core (national/government) staff member should be identified within each participating country in a region to support the work of the country coordinator. The country coordinators' positions could be phased out after the first two years, with key core staff-member taking over full responsibilities. Short term expert consultants may be required for a variety of tasks, including computer programming, development of public information materials, economic analyses, laboratory diagnostic techniques, etc.

Potential collaboration

Implementation of a programme such as that described in 4.5.3 would require the cooperation of a number of agencies. Potential donor agencies would need to be identified during the planning phase and the programme developed with their collaboration

Main financial needs

The main items which would require financing include; core project personnel, ongoing technical support for national government services, training of provincial and district staff, support for field surveillance activities, and support for regional cooperation networks. Training and personnel costs are, therefore, likely to make up the most significant part of the budget. Some specific items which will need to be considered in developing business plans include:

- provincial staff training courses;
- district staff training courses;
- ancillary staff training courses;
- active surveillance field activities;

- general surveillance activities
- specimen collection equipment;
- vehicles;
- project personnel;
- office and computer equipment;
- data management training, programming and computerized database networks;
- laboratory staff training;
- materials and supplies for surveillance and diagnostics;
- regional exchanges and short-term attachments;
- regional meetings;
- travel;
- project management costs;
- administrative support costs.

Activities and outputs by administrative level

Region	Participation in regional meetings Establishment of standard definitions and rules for disease reporting Forging links with appropriate regional bodies and committees Institutionalizing regional cooperation Regional analysis of disease, and animal movement patterns Establishment of regional disease outbreak databases
Subregion	Harmonized disease surveillance and reporting systems Sharing of disease information for improved ability to prevent cross-border movement of animals
Nation	Improved general surveillance systems Establishment of effective active surveillance systems Improved understanding of priority diseases Short-term attachments and exchanges between countries Support and development of laboratory capabilities
Province	Training in general and targeted surveillance Improved skills in disease outbreak investigation and response
District	Training in general and targeted surveillance Improved reporting of aquatic animal demographics Improved reporting of aquatic animal movements
Village/ municipality	Increased awareness of the need to report and control diseases

Example of a project activity schedule

The GANTT[14] chart below outlines how a project to deliver the required outputs might be delivered.

Year	**Year 1**				**Year 2**				**Year 3**			
Quarter	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***
Objective 1: Improve the collection of animal health information												
Output 1.1: General surveillance												
Activity 1.1.1: Training of provincial and district staff												
Activity 1.1.2: Provision of specimen collection kits												
Activity 1.1.3: Provision of ongoing support for district staff												
Activity 1.1.4: Monitoring staff activity												
Activity 1.1.5: Establishment of specimen transport and feedback systems												
Activity 1.1.6: Continued training for provincial and district staff												
Activity 1.1.7: Public awareness campaigns for farmers												
Activity 1.1.8: Establish links with village level agricultural projects												
Output 1.2: Targeted Surveillance												
Activity 1.2.1: Training of provincial and district staff in survey techniques												
Activity 1.2.2: Implementing field disease surveillance												
Activity 1.2.3: Development of a targeted surveillance programmes												
Activity 1.2.4: Use targeted surveillance to support disease control programmes												

[14] The Gantt chart is a two axis graphical chart with the vertical axis used for a list of related tasks or project stages and the horizontal axis representing the passage of time on a linear scale. The duration of each task or project stage on the chart is represented by a horizontal bar. The Gantt chart is one of the foundations of modern Project Management. The chart is named after the early scientific management pioneer Henry Lawrence Gantt (1861-1919) who first developed it.

Continued...

Year	**Year 1**				**Year 2**				**Year 3**			
Quarter	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***
Output 1.3: Ancillary Data												
Activity 1.3.1: Train staff in the collection of ancillary data												
Output 1.4: Socio-economic Data												
Quarter	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***
Activity 1.4.1: Train national staff in the collection of socio-economic data												
Objective 2: Ensure sustainable laboratory support												
Output 2.1: Effective laboratory support for field activities												
Activity 2.1.1: Provision of specimens to national laboratories												
Activity 2.1.2: Provision of diagnostic reagents to laboratories												
Activity 2.1.3: Sustainable local production of key diagnostic reagents												
Activity 2.1.4: Train laboratory staff in new diagnostic techniques as appropriate												
Objective 3: Implement information management system												
Output 3.1: Efficient management of aquatic animal health information												
Activity 3.1.1: User needs analysis and database design												
Activity 3.1.2: Development and translation of users' manuals												
Activity 3.1.3: Training of staff in the use of the system												
Activity 3.1.4: Phased implementation												
Objective 4: Establish national and regional analysis and reporting system												
Output 4.1: National staff able to analyse and interpret animal health information												
Activity 4.1.1: Training of national staff and data analysis												
Activity 4.1.2: English language training												

Continued...

Year	**Year 1**				**Year 2**				**Year 3**			
Quarter	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***	***1***	***2***	***3***	***4***
Output 4.2: Improved regional communication and coordination												
Activity 4.2.1: Establishment of regional disease outbreak database												
Activity 4.2.2: Regional data analysis												
Activity 4.2.3: Country managers meetings												
Activity 4.2.4: Regional member coordination meetings												
Activity 4.2.5: Short term attachments												
Activity 4.2.6: Newsletter												

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Appendix III. Consultation work programme

Date	Time	Activity
Monday, 14 October 2002	09.00 – 09.30	▪ Welcome remarks ▪ Election of Chair
	09.30 – 10.00	▪ Introduction to Consultation ▪ Rationale and Goals
	10.00 – 10.30	▪ Coffee
	10.30 – 11.00	▪ Presentation of Working Document I – Freshwater Finfish – Barry Hill
	11.00 – 11.30	▪ Plenary discussion
	11.30 – 12.00	▪ Presentation of Working Document II – Marine and Diadromous Finfish – Kevin Amos
	12.00 – 12.30	▪ Plenary discussion
	12.30 – 14.00	▪ Lunch
	14.00 – 14.30	▪ Presentation of Working Document III – Molluscs – Sharon McGladdery
	14.30 – 15.00	▪ Plenary discussion
	15.00 – 15.30	▪ Coffee
	15.30 – 16.00	▪ Presentation of Working Document IV – Crustaceans – Peter Walker
	16.00 – 16.30	▪ Plenary discussion
	16.30 – 17.00	▪ Presentation of Working Document V – Wild stock surveillance – Sharon MacLean
	17.00 – 17.30	▪ Plenary discussion
	17.30 – 16.00	▪ Presentation of Working Document VI - Establishment of Surveillance and Zoning: Developing Countries – Michael Phillips (in lieu of Melba Reantaso)
Tuesday, 15 October 2002	09.00 – 10.00	▪ Breakout Working Groups ▪ Working Group I – Freshwater finfish ▪ Working Group II – Marine and diadromous finfish ▪ Working Groups III – Molluscs ▪ Working Group IV – Crustaceans ▪ Working Group V – Wild stock surveillance
	10.30 – 11.00	▪ Coffee
	11.00 – 12.30	▪ Working Group discussions continue
	12.30 – 14.00	▪ Lunch

Date	Time	Activity
	14.00 – 15.30	▪ Working Group discussions continue
	15.30 – 16.00	▪ Coffee
	16.00 – 17.30	▪ Working Group discussions continue
Wednesday, 16 October 2002	09.00 – 10.30	▪ Working Group discussions continue
	10.30 – 11.00	▪ Coffee
	11.00 – 12.30	▪ Working Group discussions continue
	12.30 – 14.00	▪ Lunch
	14.00 – 15.30	▪ Plenary presentation of Working Group findings – Groups I and II followed by discussion
	15.30 – 16.00	▪ Coffee
	16.00 – 17.30	▪ Plenary presentation of Working Group findings – Groups III and IV followed by discussion
Thursday, 17 October 2002	09.00 – 10.30	▪ Plenary presentation of Working Group findings – Groups V followed by discussion
	10.30 – 11.00	▪ Coffee
	11.00 – 12.30	▪ Continue plenary discussion of Working Group presentations – issues applicable to I-V
	12.30 – 14.00	▪ Lunch
	14.00 – 15.30	▪ Plenary discussion on developing country needs
	15.30 – 16.00	▪ Coffee
	16.00 – 17.30	▪ Breakout to revise and finalize discussion papers and recommendations by the Working Groups
Friday, 18 October 2002	09.00 – 10.30	▪ Plenary presentation of working group recommendations – Working Groups I and II – followed by discussion
	10.30 – 11.00	▪ Coffee
	11.00 – 12.30	▪ Plenary presentation of working group recommendations – Working Groups III and IV – followed by discussion
	12.30 – 14.00	▪ Lunch

Date	Time	Activity
	14.00 – 15.30	▪ Plenary presentation of Working Group V recommendations, followed by discussion ▪ Plenary presentation of recommendations on developing country needs - followed by discussion
	15.30 – 16.00	▪ Coffee
	16.00 – 17.00	▪ Final plenary discussions
	17.00 – 17.30	▪ Closing remarks

This document provides recommendations for surveillance and zoning that will be useful for designing national programmes aimed at reducing the risks of diseases resulting from transfers of live aquatic animals. It contains the collective expert opinion and recommendations made during an expert consultation, jointly organized by FAO, the Federal Department of Fisheries and Oceans Canada and the World Organisation for Animal Health (OIE), to determine what surveillance options can best support scientifically valid zonation frameworks. These recommendations are aimed at providing scientific advice to countries building national or regional aquatic animal health management infrastructures.

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