

WORLD ORGANISATION FOR ANIMAL HEALTH

Protecting animals, preserving our future

**AQUATIC ANIMAL
HEALTH CODE**

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FOREWORD

The OIE Aquatic Animal Health Code (the Aquatic Code) sets out standards for the improvement of aquatic animal health and welfare of farmed fish worldwide, and for safe international trade in aquatic animals (amphibians, crustaceans, fish and molluscs) and their products. The health measures in the Aquatic Code should be used by the Competent Authorities of importing and exporting countries for early detection, reporting and control of agents pathogenic to aquatic animals and to prevent their transfer via international trade in aquatic animals and their products, while avoiding unjustified sanitary barriers to trade.

The standards in the Aquatic Code have been formally adopted by the World Assembly of OIE Delegates, which constitutes the organisation's highest decision-making body. This 18th edition incorporates modifications to the Aquatic Code agreed at the 83rd General Session in May 2015.

*This edition includes an updated version of the table of contents, user's guide and glossary, and revised text in the following chapters: diseases listed by the OIE, import risk analysis, control of pathogenic agents in aquatic animal feed, general obligations related to certification, certification procedures, infection with *Batrachochytrium dendrobatidis*, infection with ranavirus and infection with *Perkinsus olsenii*. In addition, the text in Articles X.X.7. and X.X.11. of disease-specific chapters has been merged, and some amendments have been made in Articles 10.4.4. and 10.4.6.*

This edition also includes two new chapters: Recommendations for surface disinfection of salmonid eggs (4.4.) and Risk analysis for antimicrobial resistance arising from the use of antimicrobial agents in aquatic animals (6.5.).

The development of these standards and recommendations is the result of the ongoing work by the OIE Aquatic Animal Health Standards Commission (the Aquatic Animals Commission). This Commission, which comprises six elected members, meets twice yearly to address its work programme. This Commission draws upon the expertise of internationally renowned specialists to prepare draft texts for new articles of the Aquatic Code and to revise existing articles. The views of OIE National Delegates are routinely sought through the twice yearly circulation of new or revised texts. The Aquatic Animals Commission collaborates closely with other Specialist Commissions of the OIE, including the Terrestrial Animal Health Standards Commission, the Biological Standards Commission and the Scientific Commission for Animal Diseases, to ensure that the recommendations contained in the Aquatic Code are based upon the latest scientific information.

The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) formally recognises the role of the OIE as the international standard setting organisation for animal health and zoonotic diseases. According to the SPS Agreement, WTO Members should align their import requirements with the recommendations in the relevant standards of the OIE. Where there are no OIE recommendations or if the country chooses a level of protection requiring measures more stringent than the standards of the OIE, these should be based on an import risk analysis conducted in accordance with Chapter 2.1. The Aquatic Code is thus a key part of the WTO legal framework for international trade.

The Aquatic Code is published annually in the three official OIE languages (English, French and Spanish). The Aquatic Code may be viewed and downloaded from the OIE Web site at <http://www.oie.int>.

The User's Guide, which follows the foreword, is designed to help Competent Authorities and other interested parties to use the Aquatic Code.

We wish to thank the members of the Aquatic Animals Commission, Delegates and the experts participating in ad hoc Groups and other Specialist Commissions for their expert advice. My thanks go to the staff of the OIE for their dedication in producing this 18th edition of the Aquatic Code.

*Dr Bernard Vallat
Director General
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June 2015

USER'S GUIDE

A. Introduction

- 1) The OIE *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) provides standards for the improvement of aquatic animal health worldwide. The *Aquatic Code* also includes standards for the welfare of farmed fish and use of antimicrobial agents in aquatic animals. The purpose of this guide is to advise the Competent Authorities in OIE Member Countries on how to use the *Aquatic Code*.
- 2) Competent Authorities should use the standards in the *Aquatic Code* to develop measures for early detection, internal reporting, notification and control of pathogenic agents in aquatic animals (amphibians, crustaceans, fish and molluscs) and preventing their spread via international trade in aquatic animals and aquatic animal products, while avoiding unjustified sanitary barriers to trade.
- 3) OIE standards are based on the most recent scientific and technical information. Correctly applied, they protect aquatic animal health during the production and trade in aquatic animals and aquatic animal products as well as the welfare of farmed fish.
- 4) The absence of chapters, articles or recommendations on particular pathogenic agents or commodities does not preclude the application of appropriate sanitary measures by the Competent Authorities, provided they are based on risk analyses conducted in accordance with the *Aquatic Code*.
- 5) The complete text of the *Aquatic Code* is available on the OIE website and individual chapters may be downloaded from: <http://www.oie.int>.

B. *Aquatic Code* content

- 1) Key terms and expressions used in more than one chapter in the *Aquatic Code* are defined in the Glossary. The reader should be aware of definitions given in the Glossary when reading and using the *Aquatic Code*. Defined terms appear in italics. In the online version of the *Aquatic Code*, a hyperlink leads to the relevant definition.
- 2) The term '(under study)' is found in some rare instances, with reference to an article or part of an article. This means that this part of the text has not been adopted by the World Assembly of OIE Delegates and the particular provisions are thus not part of the *Aquatic Code*.
- 3) The standards in the chapters of Section 1 are designed for the implementation of measures for the surveillance and notification of pathogenic agents. The section includes the criteria for listing aquatic animal diseases, the diseases which are listed by the OIE, procedures for notification to the OIE, and criteria for listing species as susceptible to infection with a specific pathogen.
- 4) The standards in the chapters of Section 2 are designed to guide the importing country in conducting import risk analysis in the absence of OIE standards. The importing country may also use these standards to justify import measures which are more stringent than existing OIE standards.
- 5) The standards in the chapters of Section 3 are designed for the establishment, maintenance and evaluation of Aquatic Animal Health Services, including communication. These standards are intended to assist the Competent Authorities of Member Countries to meet their objectives of improving aquatic animal health and welfare of farmed fish, as well as to establish and maintain confidence in their international aquatic animal health certificates.
- 6) The standards in the chapters of Section 4 are designed for the implementation of measures for the prevention and control of pathogenic agents. Measures in this section include zoning, compartmentalisation, disinfection, contingency planning, fallowing, disposal of aquatic animal waste and control of pathogenic agents in aquatic animal feed.
- 7) The standards in the chapters of Section 5 are designed for the implementation of general sanitary measures for trade. They address certification and the measures applicable by the exporting, transit and importing countries. A range of model international aquatic animal health certificates is provided to facilitate consistent documentation for international trade.
- 8) The standards in the chapters of Section 6 are designed to ensure the responsible and prudent use of antimicrobial agents in aquatic animals.
- 9) The standards in the chapters of Section 7 are designed for the implementation of welfare measures for farmed fish. The standards cover the general principles for welfare of farmed fish, including during transport, stunning and killing for human consumption, and when killing for disease control purposes.

- 10) The standards in each of the chapters of Sections 8 to 11 are designed to prevent the pathogenic agents of OIE listed diseases from being introduced into an importing country. Each disease chapter includes a list of currently known susceptible species. The standards take into account the nature of the traded commodity, the aquatic animal health status of the exporting country, zone or compartment, and the risk reduction measures applicable to each commodity.

These standards assume that the agent is either not present in the importing country or is the subject of a control or eradication programme. Sections 8 to 11 each relate to amphibian, crustacean, fish and molluscan hosts, respectively.

C. Specific issues

- 1) Notification

Chapter 1.1. describes Member Countries' obligations under OIE Organic Statutes. Listed diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to the OIE on other aquatic animal health events of epidemiological significance, including occurrence of emerging diseases.

Chapter 1.2. describes the criteria for the inclusion of a disease listed by the OIE.

Chapter 1.3. specifies the diseases that are listed by the OIE. Diseases are divided into four sections corresponding to amphibian, crustacean, fish and molluscan hosts, respectively.

- 2) Pathogen differentiation

Some pathogens have one or more variants. Existence of highly pathogenic variants and the need to differentiate them from more benign variants are recognised in the *Aquatic Code*. When pathogenic agents have strains that are stable, possess characteristics that can be used for diagnostic purposes, and display different levels of pathogenicity, different standards providing protection proportionate to the risk posed by the different strains should be applied. Infection with infectious salmon anaemia virus is the first listed disease for which risk management options based on strain differentiation are provided.

- 3) Determining the susceptibility of species

The *Aquatic Code* proposes the use of criteria to assess the susceptibility of host species to the pathogenic agents of diseases listed in the *Aquatic Code*. This is important in the aquaculture context, given the large number of existing and new aquaculture species.

- 4) Trade requirements

Aquatic animal health measures related to international trade should be based on OIE standards. A Member Country may authorise the importation of aquatic animals or aquatic animal products into its territory under conditions different from those recommended by the *Aquatic Code*. To scientifically justify more stringent measures, the importing country should conduct a risk analysis in accordance with OIE standards, as described in Chapter 2.1. Members of the WTO should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapters 5.1. to 5.3. describe the obligations and ethical responsibilities of importing and exporting countries in international trade. Competent Authorities and all veterinarians and certifying officials directly involved in international trade should be familiar with these chapters. Chapter 5.3. also describes the OIE informal procedure for dispute mediation.

Disease-specific chapters in the *Aquatic Code* include articles listing the commodities that are considered safe for trade without the imposition of disease-specific sanitary measures, regardless of the status of the exporting country or zone for the pathogenic agent in question. Where such a list is present, importing countries should not require any conditions related to the agent in question with respect to the listed commodities.

- 5) Trade in aquatic animal commodities

Chapter 5.4. describes the criteria used to assess the safety of aquatic animal commodities.

Based on assessments using criteria in Article 5.4.1., in all disease-specific chapters, point 1 of Article X.X.3. lists aquatic animal commodities that may be imported for any purpose from a country, zone or compartment not declared free from the disease in question. The criteria for inclusion of aquatic animal commodities in point 1 of Article X.X.3. are based on the absence of the pathogenic agent or inactivation of the pathogenic agent by treatment or processing.

Based on assessments using criteria in Article 5.4.2, in all disease-specific chapters, point 1 of Article X.X.12. (for Chapter 10.4. the relevant Article is 10.4.15.) lists aquatic animal commodities for retail trade for human consumption from a country, zone or compartment not declared free from the disease in question. The criteria for inclusion of aquatic animal commodities in point 1 of Article X.X.12. include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely presence of viable pathogenic agent in the waste.

6) International health certificates

An international aquatic animal health certificate is an official document that the Competent Authority of the exporting country issues in accordance with Chapter 5.1. and Chapter 5.2. It lists aquatic animal health requirements for the exported commodity. The quality of the exporting country's Aquatic Animal Health Services is essential in providing assurances to trading partners regarding the safety of exported aquatic animal commodities. This includes the Aquatic Animal Health Services' ethical approach to the provision of international health certificates and their history in meeting their notification obligations.

International health certificates underpin international trade and provide assurances to the importing country regarding the health status of the aquatic animal commodities imported. The measures prescribed should take into account the health status of both exporting and importing countries and be based upon the standards in the *Aquatic Code*.

The following steps should be taken when drafting international aquatic animal health certificates:

- a) identify the diseases, from which the importing country is justified in seeking protection because of its own aquatic animal health status. Importing countries should not impose measures in regards to diseases that occur in their own territory but are not subject to official control programmes;
- b) for commodities capable of transmitting these diseases through international trade, the importing country should apply the relevant articles in the disease-specific chapters. The application of the articles should be adapted to the disease status of the exporting country, zone or compartment. Such a status should be established in accordance with Article 1.4.6. except when articles of the relevant disease chapter specify otherwise;
- c) when preparing international aquatic animal health certificates, the importing country should endeavour to use terms and expressions in accordance with the definitions given in the Glossary. As stated in Article 5.2.3., international aquatic animal health certificates should be kept as simple as possible and should be clearly worded, to avoid misunderstanding of the importing country's requirements;
- d) Chapter 5.10. provides, as further guidance to Member Countries, model health certificates that should be used as a baseline.

7) Guidance notes for importers and exporters

It is recommended that Competent Authorities prepare 'guidance notes' to assist importers and exporters to understand trade requirements. These notes should identify and explain the trade conditions, including the measures to be applied before and after export and during transport and unloading, and the relevant legal obligations and operational procedures. The guidance notes should advise on all details to be included in the health certification accompanying the consignment to its destination. Exporters should also be reminded of the International Air Transport Association rules governing air transport of aquatic animals and aquatic animal products.

GLOSSARY

For the purpose of the *Aquatic Code*:

ANTIMICROBIAL AGENT

means a naturally occurring, semi-synthetic or synthetic substance that at *in vivo* concentrations exhibits antimicrobial activity (kill or inhibit the growth of microorganisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

AQUACULTURE

means the farming of *aquatic animals* with some sort of intervention in the rearing process to enhance production, such as regular stocking, feeding, protection from predators, etc.

AQUACULTURE ESTABLISHMENT

means an establishment in which amphibians, fish, molluscs or crustaceans for breeding, stocking or sale are raised or kept.

AQUATIC ANIMAL HEALTH PROFESSIONAL

means a person who, for the purposes of the *Aquatic Code*, is authorised by the *Competent Authority* to carry out certain designated tasks in a *territory* and has the appropriate qualifications and training to perform the designated tasks.

AQUATIC ANIMAL HEALTH SERVICES

means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Aquatic Code* in the territory. The Aquatic Animal Health Services are under the overall control and direction of the *Competent Authority*. Private sector organisations, *veterinarians* or *aquatic animal health professionals* are normally accredited or approved by the *Competent Authority* to deliver the delegated functions.

AQUATIC ANIMAL HEALTH STATUS

means the status of a country, *zone* or *compartment* with respect to an *aquatic animal disease* in accordance with the criteria listed in the relevant chapter of the *Aquatic Code* dealing with the *disease*.

AQUATIC ANIMAL PRODUCTS

means non-viable *aquatic animals* and products from *aquatic animals*.

AQUATIC ANIMALS

means all life stages (including *eggs* and *gametes*) of fish, molluscs, crustaceans and amphibians originating from *aquaculture establishments* or removed from the wild, for farming purposes, for release into the environment, for human consumption or for ornamental purposes.

AQUATIC CODE

means the OIE *Aquatic Animal Health Code*.

AQUATIC MANUAL

means the OIE *Manual of Diagnostic Tests for Aquatic Animals*.

BASIC BIOSECURITY CONDITIONS

means a set of conditions applying to a particular *disease*, and a particular *zone* or country, required to ensure adequate disease security, such as:

- a) the *disease*, including suspicion of the *disease*, is compulsorily notifiable to the *Competent Authority*; and
- b) an *early detection system* is in place within the *zone* or country; and
- c) import requirements to prevent the introduction of *disease* into the country or *zone*, as outlined in the *Aquatic Code*, are in place.

BIAS

means a tendency of an estimate to differ in a non-random fashion from the true value of a population parameter.

BIOLOGICAL PRODUCTS

means:

- a) biological reagents for use in the *diagnosis* of certain *diseases*;
- b) sera for use in the prevention and treatment of certain *diseases*;
- c) inactivated or modified vaccines for use in preventive vaccination against certain *diseases*;
- d) genetic material of infectious agents;
- e) endocrine tissues from fish or used in fish.

BIOSECURITY

means a set of management and physical measures designed to reduce the *risk* of introduction, establishment and spread of *pathogenic agents* to, from and within an *aquatic animal* population.

BIOSECURITY PLAN

means a plan that identifies significant potential pathways for the introduction and spread of *disease* in a *zone* or *compartment*, and describes the measures which are being, or will be, applied to mitigate the *risks* to introduce and spread *disease*, taking into consideration the recommendations in the *Aquatic Code*. The plan should also describe how these measures are audited, with respect to both their implementation and their targeting, to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

CASE

means an individual *aquatic animal* infected by a *pathogenic agent*, with or without clinical signs.

CASE DEFINITION

is a set of criteria used to distinguish a *case* animal or an *epidemiological unit* from a non-case.

CERTIFYING OFFICIAL

means a person authorised by the *Competent Authority* to sign health certificates for *aquatic animals*.

COMMODITY

means *aquatic animals*, *aquatic animal products*, *biological products* and *pathological material*.

COMPARTMENT

means one or more *aquaculture establishments* under a common *biosecurity* management system containing an *aquatic animal* population with a distinct health status with respect to a specific *disease* or *diseases* for which required *surveillance* and control measures are applied and *basic biosecurity conditions* are met for the purpose of *international trade*. Such *compartments* must be clearly documented by the *Competent Authority(ies)*.

COMPETENT AUTHORITY

means the *Veterinary Authority* or other Governmental Authority of a Member Country having the responsibility and competence for ensuring or supervising the implementation of *aquatic animal* health and welfare measures, international health certification and other standards and recommendations in the *Aquatic Code* in the whole territory.

CONTAINER

means a transport appliance:

- a) of a permanent type and sufficiently strong to enable repeated use;
- b) specially constructed to facilitate transport of *aquatic animals* or *aquatic animal products* by one or several means of transport;
- c) provided with fittings that make it easy to manipulate, particularly for trans-shipment from one kind of transport *vehicle* to another;
- d) constructed in a watertight way, easy to load and unload and capable of being cleansed and disinfected;
- e) ensuring safe and optimal transport of *aquatic animals*.

CONTINGENCY PLAN

means a documented work plan designed to ensure that all needed actions, requirements and resources are provided in order to eradicate or bring under control *outbreaks* of specified *diseases* of *aquatic animals*.

DIAGNOSIS

means determination of the nature of a *disease*.

DISEASE

means clinical or non-clinical *infection* with one or more aetiological agents.

DISINFECTANTS

means chemical compounds or physical processes capable of destroying *pathogenic agents* or inhibiting their growth in the course of *disinfection*.

DISINFECTION

means the process of cleaning and applying *disinfectants* to inactivate *pathogenic agents* on potentially contaminated items.

EARLY DETECTION SYSTEM

means an efficient system for ensuring the rapid recognition of signs that are suspicious of a *listed disease*, or an *emerging disease* situation, or unexplained mortality, in *aquatic animals* in an *aquaculture establishment* or in the wild, and the rapid communication of the event to the *Competent Authority*, with the aim of activating diagnostic investigation by the *Aquatic Animal Health Services* with minimal delay. Such a system will include the following characteristics:

- a) broad awareness, e.g. among the personnel employed at *aquaculture establishments* or involved in processing, of the characteristic signs of the *listed diseases* and *emerging diseases*;
- b) *veterinarians* or *aquatic animal health professionals* trained in recognising and reporting suspicions of *disease* occurrence;
- c) ability of the *Aquatic Animal Health Services* to undertake rapid and effective *disease* investigation based on a national chain of command;
- d) access by the *Aquatic Animal Health Services* to laboratories with the facilities for diagnosing and differentiating *listed diseases* and *emerging diseases*;
- e) the legal obligation of private *veterinarians* or *aquatic animal health professionals* to report suspicions of *disease* occurrence to the *Competent Authority*.

EGG

means a viable fertilised *ovum* of an *aquatic animal*. 'Green eggs' means newly fertilised ova of fish. 'Eyed eggs' means *eggs* of fish where the eyes of the embryo are visible and that the *eggs* may be transported.

EMERGING DISEASE

means a *disease*, other than *listed diseases*, which has a significant impact on *aquatic animal* or public health resulting from:

- a) a change of known *pathogenic agent* or its spread to a new geographic area or species; or
- b) a newly recognised or suspected *pathogenic agent*.

EPIDEMIOLOGICAL UNIT

means a group of animals that share approximately the same *risk* of exposure to a *pathogenic agent* with a defined location. This may be because they share a common aquatic environment (e.g. fish in a pond, caged fish in a lake), or because management practices make it likely that a *pathogenic agent* in one group of animals would quickly spread to other animals (e.g. all the ponds on a farm, all the ponds in a village system).

EVISCERATED FISH

means fish from which internal organs, excluding the brain and gills, have been removed.

EXPORTING COUNTRY

means a country from which *aquatic animals* or *aquatic animal products*, *biological products* or *pathological material* are sent to a destination in another country.

FOLLOWING

means, for *disease* management purposes, an operation where an *aquaculture establishment* is emptied of *aquatic animals* susceptible to a *disease* of concern or known to be capable of transferring the *pathogenic agent*, and, where feasible, of the carrying water. For *aquatic animals* of unknown susceptibility and those agreed not to be capable of acting as carriers of a *disease* of concern, decisions on *following* should be based on a *risk assessment*.

FEED

means any material (single or multiple), whether processed, semi-processed or raw, as well as live organisms, which is intended to be fed directly to *aquatic animals*.

FEED INGREDIENT

means a component, part or constituent of any combination or mixture making up a *feed*, including feed additives, whether or not it has a nutritional value in the animal's diet. Ingredients may be of terrestrial or aquatic, plant or animal origin and may be organic or inorganic substances.

FREE COMPARTMENT

means a *compartment* that fulfils the requirements for *self-declaration of freedom from disease* with respect to the *disease(s)* under consideration in accordance with the relevant chapter(s) in the *Aquatic Code*.

FREE COUNTRY

means a country that fulfils the requirements for *self-declaration of freedom from disease* with respect to the *disease(s)* under consideration in accordance with the relevant chapter(s) in the *Aquatic Code*.

FREE ZONE

means a *zone* that fulfils the requirements for *self-declaration of freedom from disease* with respect to the *disease(s)* under consideration in accordance with the relevant chapter(s) in the *Aquatic Code*.

FRONTIER POST

means any international airport or any port, railway station or road post open to *international trade*.

GAMETES

means the sperm or unfertilised *eggs* of *aquatic animals* that are held or transported separately prior to fertilisation.

HAZARD

means a biological, chemical or physical agent in, or a condition of, an *aquatic animal* or *aquatic animal product* with the potential to cause an adverse effect on *aquatic animal* health or public health.

HEADQUARTERS

means the Permanent Secretariat of the World Organisation for Animal Health (OIE), located at:

12, rue de Prony, 75017 Paris, FRANCE

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IMPORTING COUNTRY

means a country that is the final destination to which *aquatic animals*, *aquatic animal products*, *biological products* or *pathological material* are sent.

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 *zone* in which a *disease* has been diagnosed.

INFECTION

means the presence of a multiplying or otherwise developing or latent *pathogenic agent* in a host. This term is understood to include infestation where the *pathogenic agent* is a parasite in or on a host.

INTERNATIONAL AQUATIC ANIMAL HEALTH CERTIFICATE

means a certificate, issued in conformity with the provisions of Chapter 5.11., describing the *aquatic animal* health and/or public health requirements that should be fulfilled prior to export of *commodity*.

INTERNATIONAL TRADE

means import, export or transit of *aquatic animals*, *aquatic animal products*, *biological products* and *pathological material*.

LISTED DISEASES

means *diseases* that are referred to in Chapter 1.3.

MEAL

means a product derived from an *aquatic animal* that has been ground and heat processed to reduce the moisture content to less than 10%.

NOTIFICATION

means the procedure by which:

- a) the *Competent Authority* informs the *Headquarters*,
 - b) the *Headquarters* inform *Competent Authorities* of Member Countries
- of the occurrence of a *disease* in accordance with the provisions of Chapter 1.1.

OUTBREAK

means an occurrence of one or more *cases* in an *epidemiological unit*.

PATHOGENIC AGENT

means an organism that causes or contributes to the development of a *disease*.

PATHOLOGICAL MATERIAL

means samples obtained from live or dead *aquatic animals*, containing or suspected of containing *pathogenic agents*, to be sent to a laboratory.

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.

PROBABILITY SAMPLING

means a sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

PROTECTION ZONE

means a *zone* established to protect the health status of *aquatic animals* in a *free country* or *free zone*, from those in a country or *zone* of a different *aquatic animal health status*, using measures based on the epidemiology of the *disease* under consideration to prevent spread of the *pathogenic agent* into a *free country* or *free zone*. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of *surveillance*.

QUARANTINE

means maintaining a group of *aquatic animals* in isolation with no direct or indirect contact with other *aquatic animals*, in order to undergo observation for a specified length of time and, if appropriate, testing and treatment, including proper treatment of the effluent waters.

RISK

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

RISK ANALYSIS

means the process composed of *hazard* identification, *risk assessment*, *risk management* and *risk communication*.

RISK ASSESSMENT

means the scientific evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a *hazard*.

RISK COMMUNICATION

is the interactive exchange of information and opinions throughout the *risk analysis* process concerning *risk*, *risk*-related factors and *risk* perceptions among *risk* assessors, *risk* managers, *risk* communicators, the general public and other interested parties.

RISK MANAGEMENT

means the process of identifying, selecting and implementing measures that can be applied to reduce the level of *risk*.

SANITARY MEASURE

means a measure, such as those described in various chapters of the *Aquatic Code*, destined to protect *aquatic animal* or human health or life within the *territory* of the Member Country from *risks* arising from the entry, establishment and/or spread of a *hazard*.

SELF-DECLARATION OF FREEDOM FROM DISEASE

means declaration by the *Competent Authority* of the Member Country concerned that the country, *zone* or *compartment* is free from a *listed disease* based on implementation of the provisions of the *Aquatic Code* and the *Aquatic Manual*. [NOTE: The Member Country is encouraged to inform the OIE of its claimed status and the OIE may publish the claim but publication does not imply OIE endorsement of the claim.]

SENSITIVITY

means the proportion of true positive tests given in a diagnostic test, i.e. the number of true positive results divided by the number of true positive and false negative results.

SPECIFICITY

means the probability that absence of *infection* will be correctly identified by a diagnostic test, i.e. the number of true negative results divided by the number of true negative and false positive results.

STAMPING-OUT POLICY

means the carrying out under the authority of the *Competent Authority*, on confirmation of a *disease*, of preventive *aquatic animal* health measures, consisting of killing the *aquatic animals* that are affected, those suspected of being affected in the population and those in other populations that have been exposed to *infection* by direct or indirect contact of a kind likely to cause the transmission of the *pathogenic agent*. All these *aquatic animals*, vaccinated or unvaccinated, on an infected site should be killed and the carcasses destroyed by burning or burial, or by any other method that will eliminate the spread of *infection* through the carcasses or products of the *aquatic animals* destroyed.

This policy should be accompanied by cleansing and *disinfection* procedures as defined in the *Aquatic Code*. *Fallowing* should be for an appropriate period determined by *risk assessment*.

STUDY POPULATION

means the population from which *surveillance* data are derived. This may be the same as the *target population* or a subset of it.

SUBPOPULATION

means a distinct part of a population identifiable in accordance with specific common *aquatic animal* health characteristics.

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.

SUSCEPTIBLE SPECIES

means a species of *aquatic animal* in which *infection* has been demonstrated by the occurrence of natural cases or by experimental exposure to the *pathogenic agent* that mimics natural transmission pathways.

TARGET POPULATION

means, for the purposes of demonstrating freedom from *infection*, the population of interest, usually made up of all *aquatic animals* of species susceptible to a specified *pathogenic agent* in a defined country, *zone* or *aquaculture establishment*.

TARGETED SURVEILLANCE

means *surveillance* targeted at a specific *disease* or *infection*.

TERRITORY

means land and water under jurisdiction of a country.

TRANSIT COUNTRY

means a country through which *aquatic animals, aquatic animal products, biological products or pathological material* destined for an *importing country*, are transported or in which a stopover is made at a *frontier post*.

UNIT

means individually identifiable elements. This is a generic concept used to describe, for example, the members of a population, or the elements selected when sampling. In these contexts, examples of *units* include individual animals, ponds, nets, cages, farms, villages, districts, etc.

VEHICLE

means any method of transport by land, air or water.

VETERINARIAN

means a person with appropriate education, registered or licensed by the relevant *veterinary statutory body* of a country to practise veterinary medicine/science in that country.

VETERINARY AUTHORITY

means the Governmental Authority of a Member Country, comprising *veterinarians*, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of *aquatic animal* health and welfare measures, international *aquatic animal* health certification and other standards and recommendations in the *Aquatic Code* in the whole *territory*.

VETERINARY STATUTORY BODY

means an autonomous authority regulating *veterinarians* and veterinary para-professionals.

WATER CATCHMENT

means an area or basin of land bounded by natural features such as hills or mountains, into which all run-off water flows.

ZONE

means a portion of one or more countries comprising:

- a) an entire *water catchment* from the source of a waterway to the estuary or lake, or
- b) more than one *water catchment*, or
- c) part of a *water catchment* from the source of a waterway to a barrier that prevents the introduction of a specific *disease* or *diseases*, or
- d) part of a coastal area with a precise geographical delimitation, or
- e) an estuary with a precise geographical delimitation,

that consists of a contiguous hydrological system with a distinct health status with respect to a specific *disease* or *diseases*. The *zones* must be clearly documented (e.g. by a map or other precise locators such as GPS co-ordinates) by the *Competent Authority(ies)*.

SECTION 1.

NOTIFICATION, DISEASES LISTED BY THE OIE AND SURVEILLANCE FOR AQUATIC ANIMALS

CHAPTER 1.1.

NOTIFICATION OF DISEASES, AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

Article 1.1.1.

For the purposes of the *Aquatic Code* and in terms of Articles 5, 9 and 10 of the OIE Organic Statutes, every Member Country of the OIE shall recognise the right of the *Headquarters* to communicate directly with the *Competent Authority* of its *territory or territories*.

All *notifications* and all information sent by the OIE to the *Competent Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Competent Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

- 1) Member Countries shall make available to other Member Countries, through the OIE, whatever information is necessary to minimise the spread of important *diseases of aquatic animals* and their *pathogenic agents* and to assist in achieving better world-wide control of these *diseases*.
- 2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.
- 3) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the current OIE *disease* reporting format.
- 4) The detection of the *pathogenic agent* of a *listed disease* in an *aquatic animal* should be reported, even in the absence of clinical signs. Recognising that scientific knowledge concerning the relationship between *pathogenic agents* and clinical *disease* is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of clinical *disease*, Member Countries shall ensure through their reports that they comply with the spirit and intention of point 1 above.
- 5) In addition to notifying findings in accordance with Article 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of *diseases*. Information shall include possible *quarantine* measures and restrictions on the movement of *aquatic animals*, *aquatic animal products*, *biological products* and other miscellaneous objects which could by their nature be responsible for transmission of *disease*. In the case of *diseases* transmitted by vectors, the measures taken against such vectors shall also be specified.

Article 1.1.3.

The *Competent Authority* shall, under the responsibility of the Delegate, send to the *Headquarters* of the OIE:

- 1) in accordance with relevant provisions in the *disease-specific chapters*, *notification*, through the World Animal Health Information System (WAHIS) or by fax or e-mail within 24 hours of any of the following events:
 - a) first occurrence of a *listed disease* in a country, a *zone* or a *compartment*;
 - b) re-occurrence of a *listed disease* in a country, a *zone* or a *compartment* following the final report that declared the *outbreak* ended;
 - c) first occurrence of a new strain of a *pathogenic agent* of a *listed disease* in a country, a *zone* or a *compartment*;
 - d) a sudden and unexpected change in the distribution or increase in incidence or virulence of, or morbidity or mortality caused by the *pathogenic agent* of a *listed disease*, present within a country, a *zone* or a *compartment*;
 - e) occurrence of a *listed disease* in a new host species.

In deciding whether findings justify immediate *notification* (within 24 hours), Member Countries must ensure that they comply with the obligations of Chapters 5.1. and 5.2. (especially Article 5.1.1.), to report developments that may have implications for *international trade*;

- 2) weekly reports subsequent to a *notification* under point 1 above, to provide further information on the evolution of the event which justified the *notification*. These reports should continue until the *disease* has been eradicated or the situation has become sufficiently stable so that six-monthly reporting under point 3 will satisfy the obligation of the Member Country to the OIE; for each event notified, a final report on the event should be submitted;
- 3) six-monthly reports on the absence or presence and evolution of *listed diseases* and information of epidemiological significance to other Member Countries;
- 4) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

Competent Authorities shall, under the responsibility of the Delegate, send to the *Headquarters*:

- 1) a *notification* through WAHIS or by fax or e-mail, when an *emerging disease* has been detected in a country, a *zone* or a *compartment*;
- 2) periodic reports subsequent to a *notification* of an *emerging disease*, as described under point 1. These should continue until:
 - a) the *disease* has been eradicated; or
 - b) the situation becomes sufficiently stable; or
 - c) sufficient scientific information is available to determine whether it meets the criteria for listing.

Article 1.1.5.

- 1) The *Competent Authority* of a country in which an *infected zone* or *compartment* was located shall inform the *Headquarters* when this *zone* or *compartment* is free from the *disease*.
- 2) An *infected zone* or *compartment* for a particular *disease* shall be considered as such until a period exceeding the infective period specified in the *Aquatic Code* has elapsed after the last reported *case* and when full prophylactic and appropriate *aquatic animal* health measures have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in various *disease-specific chapters* of the *Aquatic Code*.
- 3) A Member Country may be considered to regain freedom from a specific *disease* when all relevant conditions given in the *Aquatic Code* have been fulfilled.
- 4) The *Competent Authority* of a Member Country which sets up one or several *free zones* or *free compartments* shall inform the *Headquarters*, giving necessary details, including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the *zones* or *compartments* on a map of the territory of the Member Country.

Article 1.1.6.

- 1) Although Member Countries are only required to notify *listed diseases*, and *emerging diseases*, they are encouraged to inform the OIE of other important *aquatic animal* health events.
 - 2) The *Headquarters* shall communicate by e-mail or World Animal Health Information Database (WAHID) to *Competent Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.5. and other relevant information.
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CHAPTER 1.2.

CRITERIA FOR LISTING AQUATIC ANIMAL DISEASES

Article 1.2.1.

Introduction

This chapter describes the criteria for listing *diseases* in Chapter 1.3. The objective of listing is to support Member Countries' efforts to prevent the transboundary spread of important *diseases* of *aquatic animals* through transparent and consistent reporting.

For the *diseases* listed in accordance with Article 1.2.2., the corresponding *disease*-specific chapters in the *Aquatic Code* provide standards for safe *international trade* in *aquatic animals* and their products.

The requirements for *notification of listed diseases* are detailed in Chapter 1.1.

Article 1.2.2.

Criteria for listing an aquatic animal disease

Diseases proposed for listing should meet the relevant criteria as set out in A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a *disease* should have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8. Such proposals should be accompanied by a *case definition* for the *disease* under consideration.

No.	Criteria for listing	Explanatory notes
A. Consequences		
1.	The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in susceptible species, and that morbidity or mortality are related primarily to the infectious agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.
2.	Or	The disease has been shown to or scientific evidence indicates that it is likely to cause significant morbidity or mortality in wild aquatic animal populations.
3.	Or	The agent is of public health concern.
And B. Spread		
4.	Infectious aetiology of the disease is proven.	
5.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.
		Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.

No.		Criteria for listing	Explanatory notes
And B. Spread			
6.	And	Likelihood of international spread, including via live aquatic animals, their products or fomites.	International trade in aquatic animal species susceptible to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is likely.
7.	And	Several countries or countries with zones may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.4.	Free countries/zones could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible. However, individual countries that run a control programme on such a disease can propose its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of broodstock from widespread diseases, or the protection of the last remaining free zones from a widespread disease.
And C. Diagnosis			
8.		A repeatable and robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (See <i>Aquatic Manual</i> .) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

CHAPTER 1.3.

DISEASES LISTED BY THE OIE

Preamble: The following *diseases* are listed by the OIE in accordance with the criteria for listing an *aquatic animal disease* (see Article 1.2.2.).

In case of modifications of this list of *aquatic animal diseases* adopted by the World Assembly of Delegates, the new list comes into force on 1 January of the following year.

Article 1.3.1.

The following *diseases* of fish are listed by the OIE:

- Epizootic haematopoietic necrosis disease
- Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)
- Infection with *Gyrodactylus salaris*
- Infection with HPR-deleted or HPR0 infectious salmon anaemia virus
- Infection with salmonid alphavirus
- Infectious haematopoietic necrosis
- Koi herpesvirus disease
- Red sea bream iridoviral disease
- Spring viraemia of carp
- Viral haemorrhagic septicaemia.

Article 1.3.2.

The following *diseases* of molluscs are listed by the OIE:

- Infection with abalone herpesvirus
- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*.

Article 1.3.3.

The following *diseases* of crustaceans are listed by the OIE:

- Acute hepatopancreatic necrosis disease
- Crayfish plague (*Aphanomyces astaci*)
- Infection with yellow head virus
- Infectious hypodermal and haematopoietic necrosis
- Infectious myonecrosis
- Necrotising hepatopancreatitis
- Taura syndrome
- White spot disease
- White tail disease.

Article 1.3.4.

The following *diseases* of amphibians are listed by the OIE:

- Infection with *Batrachochytrium dendrobatidis*
 - Infection with ranavirus.
-

CHAPTER 1.4.

AQUATIC ANIMAL HEALTH SURVEILLANCE

Article 1.4.1.

Introduction and objectives

- 1) *Surveillance* activities may be performed to achieve any of the following objectives:
 - a) demonstrating the absence of *disease*;
 - b) identifying events requiring *notification* as listed in Article 1.1.3.;
 - c) determining the occurrence or distribution of endemic disease, including changes to their *incidence* or *prevalence* (or its contributing factors), in order to:
 - i) provide information for domestic *disease* control programmes,
 - ii) provide relevant *disease* occurrence information to be used by trading partners for qualitative and quantitative *risk assessment*.

The type of *surveillance* applied depends on the desired outputs needed to support decision-making. *Surveillance* data determine the quality of disease status reports and should satisfy information requirements for accurate *risk analysis* both for *international trade* as well as for national decision-making. *Surveillance* of endemic diseases provides valuable information for day-to-day health management and can act as the foundation for detecting *outbreaks* of exotic disease and demonstrating specific *disease* freedom.

Surveillance systems described in this chapter should also be used to generate information for decisions on prescribed *disease* prevention and control programmes. However, the actual strategies for prevention and control are beyond the scope of this chapter on *surveillance* recommendations.

Having a suitable management strategy to respond to *surveillance* data is of utmost importance for the successful implementation of *surveillance* systems.

- 2) Essential prerequisites to enable a Member Country to provide information for the evaluation of its animal health status are:
 - a) that the particular Member Country complies with the provisions of Chapter 3.1. on the quality of the *Aquatic Animal Health Services*;
 - b) that, where possible, *surveillance* data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);
 - c) that transparency in the planning and execution of *surveillance* activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.1.
- 3) The following recommendations may be applied to all *diseases*, their agents, and *susceptible species* as listed in the *Aquatic Manual*, and are designed to assist with the development of *surveillance* methodologies. Where possible, the development of *surveillance* systems using these recommendations should be based on the relevant information in the individual *disease* chapters in the *Aquatic Manual*. These recommendations are also applicable to non-listed *diseases* that may be of importance to a country or region, such as new or *emerging diseases*. There is sometimes a perception that *surveillance* can only be conducted using sophisticated methodologies. However, an effective *surveillance* system can also be developed by making use of gross observations and already available resources.
- 4) It would be impractical to try to develop a *surveillance* system for all the known *aquatic animal diseases* for which a country has *susceptible species*. Therefore prioritising the *diseases* to be included in a *surveillance* system should be conducted considering:
 - a) the needs to provide assurance of disease status for trade purposes;
 - b) the resources of the country;
 - c) the financial impact or threat posed by the different *diseases*;
 - d) the importance of an industry-wide *disease* control programme within a country or region.
- 5) More detailed information in each *disease* chapter (where it exists) of the *Aquatic Manual* may be used to further refine the general approaches described in this chapter. Where detailed *disease*-specific information is not available, *surveillance* can also be conducted following the recommendations in this chapter. Access to epidemiological expertise would be invaluable for the design, implementation of the system and interpretation of results derived from a *surveillance* system.

Article 1.4.2.

Principles of surveillance

- 1) *Surveillance* may be based on many different data sources and can be classified in a number of ways, including:
 - a) the means by which data are collected (targeted versus non-targeted);
 - b) the *disease* focus (pathogen-specific versus general *surveillance*); and
 - c) the way in which units for observation are selected (surveys versus non-random data sources).
- 2) *Surveillance* activities include:
 - a) population-based surveys, such as:
 - i) systematic sampling at slaughter;
 - ii) random surveys;
 - b) non-random *surveillance* activities, such as:
 - i) *disease* reporting or *notifications*;
 - ii) control programmes/health schemes;
 - iii) targeted testing/screening;
 - iv) post-mortem inspections;
 - v) laboratory investigation records;
 - vi) biological specimen banks;
 - vii) sentinel units;
 - viii) field observations;
 - ix) farm production records.
- 3) In addition, *surveillance* data should be supported by related information, such as:
 - a) data on the epidemiology of the *disease*, including environmental, and host and wild reservoir population distributions;
 - b) data on farmed and wild animal movements and trading patterns for *aquatic animals* and *aquatic animal products*, including potential for exposure to populations of wild *aquatic animals*, water sources or other contacts;
 - c) national animal health regulations, including information on compliance with them and their effectiveness;
 - d) history of imports of potentially infected material; and
 - e) *biosecurity* measures in place.
- 4) The sources of evidence should be fully described. A survey should include a description of the sampling strategy used for the selection of units for testing. For non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any *biases* that may be inherent in the system.

Article 1.4.3.

Critical elements of surveillance

In assessing the quality of a *surveillance* system, the following critical elements need to be addressed.

1. Populations

Ideally, *surveillance* should be carried out in such a way as to take into account all animal species susceptible to the *disease* in a country, *zone* or *compartment*. The *surveillance* activity may cover all individuals in the population or part of them. Estimates of total population at risk for each species are required. When *surveillance* is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

For *listed diseases*, definitions of appropriate populations should be based on the specific recommendations of the *disease* chapters of the *Aquatic Manual*.

2. Epidemiological unit

The relevant *epidemiological unit* for the *surveillance* system should be defined and documented to ensure that it is representative of the population or targeted *subpopulations* that would generate the most useful inferences about *disease* patterns. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

3. Clustering

Disease in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering of *disease* may occur in space (e.g. tank, pond, farm, or *compartment*), time (e.g. season), or animal subgroups (e.g. age, physiological condition). Clustering should be taken into account in the design of *surveillance* activities and interpretation of *surveillance* data.

4. Case and outbreak definitions

Clear and unambiguous *case definitions* and outbreak definitions should be developed and documented for each *disease* under *surveillance*, using, where they exist, the standards in this chapter and the *Aquatic Manual*.

5. Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision-making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of *surveillance* data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and *surveillance* systems, and types, quality, and amounts of data/information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this chapter and fully documented, and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision-making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

6. Testing

Surveillance involves the detection of *disease* by the use of appropriate *case definitions* based on the results of one or more tests for evidence of *disease* status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its *sensitivity* and *specificity* and predictive values. Imperfect *sensitivity* and/or *specificity* will have an impact on the conclusions from *surveillance*. Therefore, these parameters should be taken into account in the design of *surveillance* systems and analysis of *surveillance* data as described in this chapter.

Although not determined for many *aquatic animal diseases*, *sensitivity* and *specificity* should be estimated as best as possible for a specific testing situation. Alternatively, where values for *sensitivity* and/or *specificity* for a particular test and testing situation are estimated in the *disease* chapter in the *Aquatic Manual*, these values may be used as a guide.

Samples from a number of *aquatic animals* or units may be pooled and subjected to a testing protocol. The results should be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pool size and testing procedure.

7. Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

8. Validation

Results from animal health *surveillance* systems are subject to one or more potential *biases*. When assessing the results, care should be taken to identify potential *biases* that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

9. Data collection and management

The success of a *surveillance* system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during *disease* control interventions, inspections for movement control or during *disease* eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

- a) the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;

- b) motivation of the people involved in the *surveillance* system;
- c) the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;
- d) maintenance of disaggregated data rather than the compilation of summary data;
- e) minimisation of transcription errors during data processing and communication.

Article 1.4.4.

Population-based surveys

In addition to the principles for *surveillance* discussed in Article 1.4.6., the following recommendations should be used when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire *target population* (i.e. a census) or on a sample. Periodic or repeated surveys conducted in order to document *disease* freedom should be done using probability based sampling methods (simple random selection, cluster sampling, stratified sampling, systematic sampling) so that data from the *study population* can be extrapolated to the *target population* in a statistically valid manner. Non-probability based sampling methods (convenience, expert choice, quota) can also be used. Recognising the inherent impracticalities in sampling from some *aquatic animal* populations, non-probability based sampling could be used when *biases* are recognised and used to optimise detection.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any *biases* that may be inherent in the survey design.

2. Survey design

The population of *epidemiological units* should first be clearly defined; hereafter sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the *disease* and the resources available.

3. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study such as the presence or absence of *disease*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of a *disease* in a population of unknown disease status, sampling methods that optimise the detection of *disease* can be used. In such cases, care should be taken regarding the inferences made from the results.

4. Sampling methods

When selecting *epidemiological units* from within a population the objectives of the *surveillance* system should be considered. In general, *probability sampling* (e.g. simple random selection) is preferable. When this is not possible, sampling should provide the best practical chance of generating optimal inferences about *disease* patterns in the *target population*.

In any case, the sampling method used at all stages should be fully documented and justified.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *disease*) or to estimate a parameter (e.g. the *prevalence* of *disease*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected *prevalence* (also referred to as the threshold prevalence), the level of confidence desired of the survey results and the performance (e.g. *sensitivity* and *specificity* estimates) of the tests used.

Article 1.4.5.

Non-random data sources used in surveillance

Surveillance systems routinely use non-random data, either alone or in combination with surveys.

1. Common non-random surveillance data sources

A wide variety of non-random *surveillance* data sources may be available. These vary in their primary purpose and the type of *surveillance* information they are able to provide. Some *surveillance* systems are primarily established as *early detection systems*, but may also provide valuable information to demonstrate freedom from *disease*. Other systems provide cross-sectional information suitable for *prevalence* estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of *incidence* data (e.g. *disease* reporting systems, sentinel sites, testing schemes).

a) Disease reporting or notification system

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for *risk analysis*, or for early detection. The first step of a *disease* reporting or *notification* system is often based on the observation of abnormalities (e.g. clinical signs, reduced growth, elevated mortality rates, behavioural changes, etc.), which can provide important information about the occurrence of endemic, exotic or new *diseases*. Effective laboratory support is, however, an important component of most reporting systems. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high *specificity*. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimised.

b) Control programmes/health schemes

Animal *disease* control programmes or health schemes, while focusing on the control or eradication of specific *diseases*, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to *surveillance*.

c) Targeted sampling

This may involve sampling targeted to selected sections of the population (*subpopulations*), in which *disease* is more likely to be introduced or found. Examples include selecting culled and dead animals for testing, animals exhibiting clinical signs, animals located in a defined geographical area and specific age or *commodity* group.

d) Post-harvest inspections

Inspections of *aquatic animal* slaughter premises or processing plants may provide valuable *surveillance* data provided diseased *aquatic animals* survive to slaughter. Post-harvest inspections are likely to provide good coverage only for particular age groups and geographical areas. Post-harvest *surveillance* data are subject to obvious *biases* in relation to *target population* and *study population* (e.g. only animals of a particular class and age may be slaughtered for human consumption in significant numbers). Such *biases* need to be recognised when analysing *surveillance* data.

Both for traceback in the event of detection of *disease* and for analysis of spatial and population-level coverage, there should be, if possible, an effective identification system that relates each animal in the slaughter premises/processing plant to its locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful *surveillance* information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. If available, the method listed in the *Aquatic Manual* in relation to the purpose of testing should be used. As with post-harvest inspections, there needs to be a mechanism to relate specimens to the farm of origin. It should be recognised that laboratory submissions may not accurately reflect the *disease* situation on the farm.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *disease*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/exposure status in a specified geographical location to detect the occurrence of *disease*. They are particularly useful for *surveillance* of *diseases* with a strong spatial component, such as vector-borne *diseases*. Sentinel units provide the opportunity to target *surveillance* depending on the likelihood of *disease*

(related to vector habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *disease*, or provide data on *prevalence* and *incidence* as well as the distribution of *disease*. Cohabitation of sentinel units (preferably of the most *susceptible species* and life stage) with a susceptible population should be considered for testing *disease* in populations of valuable animals, the lethal sampling of which may be unacceptable (e.g. ornamental fish) or in animal *subpopulations* where sampling techniques are incapable of detecting the presence of *disease* or *infection* (e.g. where vaccination means that serological tests are inapplicable).

h) Field observations

Clinical observations of *epidemiological units* in the field are an important source of *surveillance* data. The sensitivity and/or specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised *case definition* is applied. Education of potential field observers in application of the *case definition* and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the population level. If production records are accurate and consistently maintained, the sensitivity of this approach may be quite high (depending on the *disease*), but the specificity is often quite low.

2. Critical elements for non-random data used in surveillance

There are a number of critical factors that should be taken into account when using non-random *surveillance* data such as coverage of the population, duplication of data, and *sensitivity* and *specificity* of tests that may give rise to difficulties in the interpretation of data. *Surveillance* data from non-random data sources may increase the level of confidence or be able to detect a lower level of *prevalence* with the same level of confidence compared to surveys.

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random *surveillance* data. This most often requires information on parameters of importance to the *surveillance* system, such as sensitivity and specificity and prior probabilities of *infection*, i.e. apparent *prevalences* (e.g. for predictive value calculations). Where no such data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple or recurrent (e.g. time series) data sources should be scientifically valid, and fully documented including references to published material.

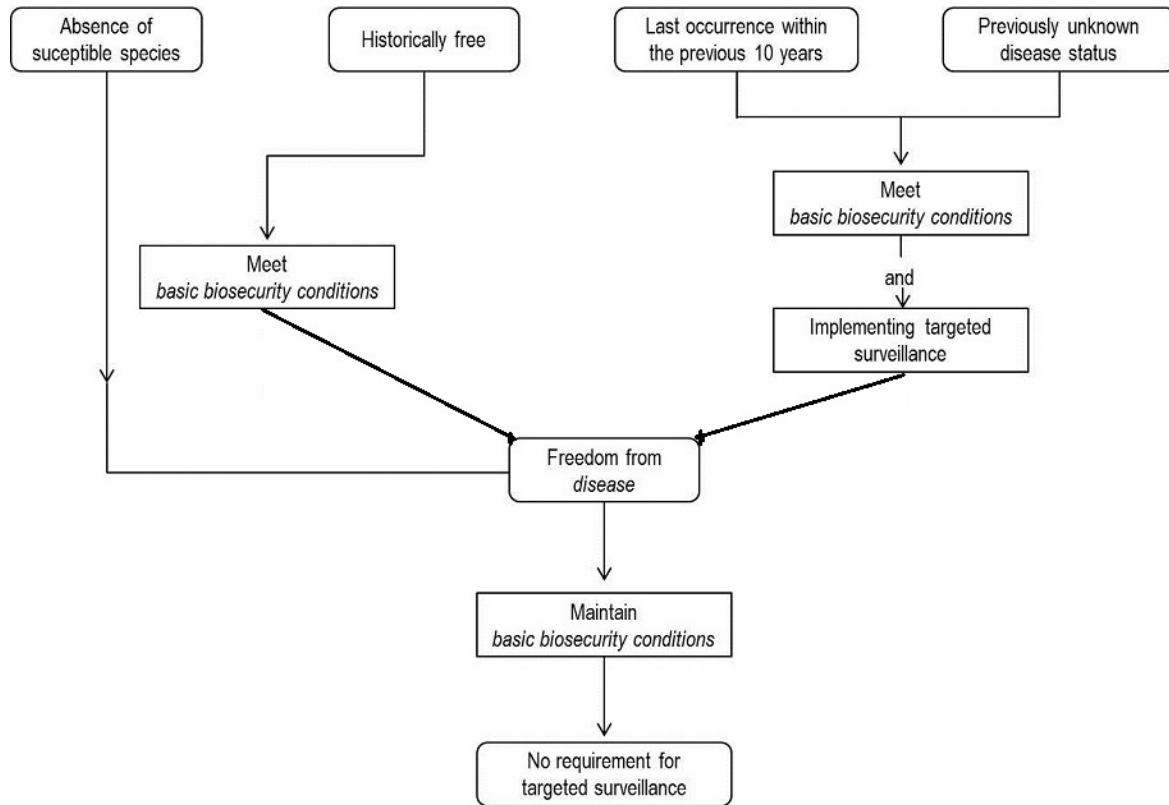
Surveillance information gathered from the same country, *zone* or *compartment* at different times (e.g. repeated annual surveys) may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take into account the decreased value of older information. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

Article 1.4.6.

Pathways to demonstrate freedom from disease

The different paths to declaration of freedom from *disease* are summarised in the diagram below.



1. Absence of susceptible species

Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised as being free from *disease* without applying *targeted surveillance* if there are no *susceptible species* (as listed in the relevant chapter of this *Aquatic Manual*, or in the scientific literature) present in that country, *zone* or *compartment*.

2. Historically free

Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be declared free from *disease* without formally applying a pathogen-specific *surveillance* programme when:

- a) there has never been a substantiated occurrence of *disease* reported officially or in the scientific literature (peer reviewed), or
- b) *disease* has not occurred for at least ten years, provided that the *pathogenic agents* are likely to produce identifiable clinical signs in observable susceptible animals,

and for at least the past ten years:

- c) the *basic biosecurity conditions* are in place and effectively enforced;
- d) no vaccination against the *disease* has been carried out unless otherwise allowed for in the *Aquatic Code*;
- e) *disease* is not known to be established in wild *aquatic animals* within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for historical freedom if there is any evidence of *disease* in wild *aquatic animals*. However, specific *surveillance* in wild *aquatic animals* is not necessary.)

A country, *zone* or *compartment* that was self-declared free on the basis of the absence of *susceptible species*, but subsequently introduces any of the *susceptible species* as listed in the *Aquatic Manual*, may be considered historically free from the *disease* provided that:

- f) the country, *zone* or *compartment* of origin was declared free of the *disease* at the time of introduction;
- g) *basic biosecurity conditions* were introduced prior to the introduction;
- h) no vaccination against the *disease* has been carried out unless otherwise allowed for in the *disease*-specific chapter of this *Aquatic Code*.

3. Last occurrence within the previous ten years/previously unknown status

Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease* has ceased to occur) within the previous ten years or where the disease status is unknown, should follow the pathogen-specific

surveillance requirements in the *Aquatic Manual* if they exist. In the absence of *disease*-specific information to aid the development of a *surveillance* system, declaration of *disease* freedom should follow at least two surveys per year (for at least two consecutive years) to be conducted three or more months apart, on the appropriate species, at the appropriate life stage and at times of the year when temperature and season offer the best opportunity to detect the pathogen. Surveys should be designed to provide an overall 95% confidence or greater and with a design *prevalence* at the animal and higher levels of aggregation (i.e. pond, farm, village, etc.) of 2% or lower (this value may be different for different *diseases* and may be provided in the *disease*-specific chapter in the *Aquatic Manual*). Such surveys should not be based on voluntary submission and should be developed following the recommendations provided in the *Aquatic Manual*. Survey results will provide sufficient evidence of *disease* freedom provided that for at least the past ten years these additional criteria are met:

- a) the *basic biosecurity conditions* are in place and effectively enforced;
- b) no vaccination against the *disease* has been carried out unless otherwise provided in the *Aquatic Code*;
- c) *disease* is not known to be established in wild *aquatic animals* within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for freedom if there is any evidence of *disease* in wild *aquatic animals*. Specific *surveillance* in wild *aquatic animals* of *susceptible species* is necessary to confirm absence.)

Article 1.4.7.

Maintenance of disease free status

A country or *zone* that has been declared free from *disease* following the provisions of the *Aquatic Code* may discontinue pathogen-specific *surveillance* while maintaining the disease free status provided that:

- 1) if present, the pathogen is likely to produce identifiable clinical signs in observable *susceptible species*;
- 2) the *basic biosecurity conditions* are in place and effectively enforced;
- 3) no vaccination against the *disease* has been carried out unless otherwise provided in the *Aquatic Code*;
- 4) where applicable, *surveillance* has previously demonstrated that *disease* is not present in populations of wild *aquatic animal* of *susceptible species*.

A special case can be made for a *disease free compartment* in a country or *zone* not declared *disease* free, *surveillance* should be maintained at a level commensurate with the degree of *risk* and exposure to potential sources of *disease* is prevented.

Article 1.4.8.

Design of surveillance programmes to demonstrate freedom from disease

A *surveillance* programme to demonstrate freedom from *disease* should meet the following requirements in addition to the general requirements for *surveillance* outlined in this chapter.

Freedom from *disease* implies the absence of the *pathogenic agent* in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *disease*. Demonstrating freedom from *disease* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Member Countries) that *disease* with a specified pathogen is not present in a population. In practice, it is not possible to prove (i.e. be 100% confident) that a population is free from *disease*. Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *disease*, if present, is present in less than a specified proportion of the population (i.e. threshold prevalence).

However, apparent *disease* at any level in the *target population* automatically invalidates any freedom from *disease* claim unless the positive test results are accepted as false positives based on specificity values described in the relevant *disease* chapter.

The provisions of this Article are based on the principles described above and the following premises:

- in the absence of *disease* and vaccination, the farmed and wild animal populations would become susceptible over a period of time;
- the *pathogenic agents* to which these provisions apply are likely to produce identifiable clinical signs in observable susceptible animals;
- to increase the probability of detecting the specific *pathogenic agent*, the susceptibility of the *aquatic animal* and the timing of sampling should be under appropriate conditions;
- the *Aquatic Animal Health Services* will be able to investigate, diagnose and report *disease*, if present;

- the appropriate diagnostic method as described in the *Aquatic Manual* be used;
- any claim for the absence of *disease* over a long period of time in a susceptible population can be substantiated by effective *disease* investigation and reporting by a Member Country.

1. Objectives

The objective of this kind of *surveillance* system is to contribute on an on-going basis evidence to demonstrate freedom from *disease* in a particular country, *zone* or *compartment* with a known confidence and reference to a predetermined design *prevalence* and diagnostic test characteristics. The level of confidence and the design *prevalence* will depend on the testing situation, *disease* and host population characteristics and on the resources available.

A single such survey can contribute evidence adding to an on-going collection of health data. However, single surveys in isolation rarely, if ever, provide sufficient evidence that an *aquatic animal disease* is absent and should be augmented with on-going targeted evidence collection (e.g. ongoing *disease* sampling or passive detection capabilities) to substantiate claims of freedom from *disease*.

2. Population

The population of *epidemiological units* should be clearly defined. The *target population* consists of all individuals of all *susceptible species* to the *disease* in a country, *zone* or *compartment* to which the *surveillance* results apply. Sometimes components of the *target population* are at higher risk of being the point of introduction for an exotic disease. In these cases, it is advisable to focus *surveillance* efforts on this part of the population, such as farms on a geographical border.

The design of the survey will depend on the size and structure of the population being studied. If the population is relatively small and can be considered to be homogenous with regards to *risk of infection*, a single-stage survey can be used. If different of the same *aquaculture establishment* do not share water, they may be considered as epidemiologically separate populations.

In larger populations where a sampling frame is not available, or when there is a likelihood of clustering of *disease*, multi-stage sampling is required. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. ponds, farms or villages) are selected. At the second stage, animals are selected for testing from each of the selected groups.

In the case of a complex (e.g. multi-level) population structure, multi-level sampling may be used and the data analysed accordingly.

3. Sources of evidence

Surveillance data may originate from a number of different sources, including:

- a) population-based surveys using one or more tests to detect the aetiological agent or evidence of *infection*;
- b) other non-random sources of data, such as:
 - i) sentinel sites;
 - ii) *disease notifications* and laboratory investigation records;
 - iii) academic and other scientific studies;
- c) a knowledge of the biology of the agent, including environmental, host population distribution, known geographical distribution, vector distribution and climatic information;
- d) history of imports of potentially infected material;
- e) *biosecurity* measures in place;
- f) any other sources of information that provide contributory evidence regarding *disease* in the country, *zone* or *compartment*.

The sources of evidence should be fully described. A survey should include a description of the sampling strategy used for the selection of units for testing. For complex *surveillance* systems, a full description of the system is required including consideration of any *biases* that may be inherent in the system. Evidence to support claims of freedom from *disease* can use non-random sources of information provided that, overall, any *biases* introduced subsequently favour the detection.

4. Statistical methodology

Analysis of test results from a survey shall be in accordance with the provisions of this chapter and consider the following factors:

- a) the survey design;
- b) the *sensitivity* and *specificity* of the test, or test system;
- c) the design *prevalence* (or *prevalences* where a multi-stage design is used);
- d) the results of the survey.

Analysis of data for evidence of freedom from *infection* involves estimating the probability (alpha) that the evidence observed (the results of *surveillance*) could have been produced under the null hypothesis that *infection* is present in the population at a specified *prevalence(s)* (the design *prevalences*). The confidence in (or, equivalently, the *sensitivity* of) the *surveillance* system that produced the evidence is equal to 1-alpha. If the confidence level exceeds a pre-set threshold, the evidence is deemed adequate to demonstrate freedom from *infection*.

The required level of confidence in the *surveillance* system (probability that the system would detect *infection* if *infection* were present at the specified level) should be greater than or equal to 95%.

The power (probability that the system would report that no *infection* is present if *infection* is truly not present) may be set to any value. By convention, this is often set to 80%, but may be adjusted in accordance with the country's or *zone's* requirements.

Different statistical methodologies for the calculation of the probability alpha, including both quantitative and qualitative approaches, are acceptable as long as they are based on accepted scientific principles.

The methodology used to calculate the confidence in the *surveillance* system should be scientifically based and clearly documented, including references to published work describing the methodology.

Statistical analysis of *surveillance* data often requires assumptions about population parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or different populations, expected biology of the agent, and so on. The uncertainty around these assumptions should be quantified and considered in the analysis (e.g. in the form of prior probability distributions in a Bayesian setting).

For *surveillance* systems used to demonstrate freedom from specific *diseases*, calculation of the confidence of a *surveillance* system is based on the null hypothesis that *infection* is present in the population. The level of *infection* is specified by the design *prevalence*. In the simplest case, this is the *prevalence of infection* in a homogenous population. More commonly, in the presence of a complex (e.g. multi-level) population structure more than one design *prevalence* value is required, for instance, the animal-level *prevalence* (proportion of infected animals in an infected farm) and the group-level *prevalence* (proportion of infected farms in the country, *zone* or *compartment*). Further levels of clustering may be considered, requiring further design *prevalence* values.

The values for design *prevalence* used in calculations should be those specified in the relevant *disease* chapter (if present) of the *Aquatic Manual*. If not specified for the particular *disease*, justification for the selection of design *prevalence* values should be provided, and should be based on the following recommendations:

- At the individual animal level, the design *prevalence* is based on the biology of the *infection* in the population. It is equal to the minimum expected *prevalence of infection* in the *study population*, if the *infection* had become established in that population. It is dependent on the dynamics of *infection* in the population and the definition of the *study population* (which may be defined to maximise the expected *prevalence* in the presence of *infection*).
- A suitable design *prevalence* value at the animal level (e.g. *prevalence* of infected animals in a cage) may be:
 - between 1% and 5% for *infections* that are present in a small part of the population e.g. are transmitted slowly or are at the early stages of an *outbreak of disease*, etc.;
 - over 5% for highly transmissible *infections*.

If reliable information, including expert opinion, on the expected *prevalence* in an infected population is not available, a value of 2% should be used for the design *prevalence*.

- At higher levels (e.g. cage, pond, farm, village, etc.) the design *prevalence* usually reflects the *prevalence of infection* that is practically and reasonably able to be detected by a *surveillance* system. Detection of *infection* at the lowest limit (a single infected unit in the population) is rarely feasible in large populations. The expected

behaviour of the *infection* may also play a role. *Infections* that have the ability to spread rapidly between farms may have a higher farm-level design *prevalence* than slow-moving *infections*.

A suitable design *prevalence* value for the first level of clustering (e.g. proportion of infected farms in a *zone*) is normally not greater than 2%. If a higher design *prevalence* is selected, it should be justified.

When *surveillance* data are used to estimate *incidence* and *prevalence* measures for the purpose of describing *disease* occurrence in terms of animal unit, time and place, these measures can be calculated for an entire population and specific time period, or for subsets defined by host characteristics (e.g. age-specific *incidence*). *Incidence* estimation requires on-going *surveillance* to detect new *cases* while *prevalence* is the estimated proportion of infected individuals in a population at a given time point. The estimation process should consider test *sensitivity* and *specificity*.

5. Clustering of infection

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a *zone*). Except when dealing with demonstrably homogenous populations, *surveillance* should take this clustering into account in the design and the statistical analysis of the data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

6. Test characteristics

All *surveillance* involves performing one or more tests for evidence of the presence of current or past *infection*, ranging from detailed laboratory examinations to farmer observations. The performance level of a test at the population level is described in terms of its *sensitivity* and *specificity*. Imperfect *sensitivity* and/or *specificity* impact on the interpretation of *surveillance* results and should be taken into account in the analysis of *surveillance* data. For example, in the case of a test with imperfect *specificity*, if the population is free of *disease* or has a very low *prevalence* of *infection*, all or a large proportion of positive tests will be false. Subsequently, samples that test positive can be confirmed or refuted using a highly specific test. Where more than one test is used in a *surveillance* system (sometimes called using tests in series or parallel), the *sensitivity* and *specificity* of the test combination should be calculated.

All calculations should take the performance level (*sensitivity* and *specificity*) of any tests used into account. The values of *sensitivity* and *specificity* used for calculations should be specified, and the method used to determine or estimate these values should be documented. Test *sensitivity* and *specificity* can be different when applied to different populations and testing scenarios. For example, test *sensitivity* may be lower when testing carrier animals with low level *infections* compared to moribund animals with clinical disease. Alternatively, *specificity* depends on the presence of cross-reacting agents, the distribution of which may be different under different conditions or regions. Ideally, test performance should be assessed under the conditions of use otherwise increased uncertainty exists regarding their performance. In the absence of local assessment of tests, values for *sensitivity* and/or *specificity* for a particular test that are specified in the *Aquatic Manual* may be used but the increased uncertainty associated with these estimates should be incorporated into the analysis of results.

Pooled testing involves the pooling of specimens from multiple individuals and performing a single test on the pool. Pooled testing is an acceptable approach in many situations. Where pooled testing is used, the results of testing should be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pooled testing procedure and for the applicable pool sizes being used. Analysis of the results of pooled testing should, where possible, be performed using accepted, statistically based methodologies, which should be fully documented, including published references.

When applied to a *surveillance* system, the probabilities of correct assessment of the health status of the *epidemiological unit* is affected by the entire sampling process, including sample selection, collection, handling and processing, as well as the actual laboratory test performance.

7. Multiple sources of information

Where multiple different data sources providing evidence of freedom from *infection* exist, each of these data sources may be analysed accordingly. The resulting estimates of the confidence in each data source may be combined to provide an overall level of confidence for the combined data sources.

The methodology used to combine the estimates from multiple data sources:

- a) should be scientifically valid, and fully documented, including references to published material; and
- b) should, where possible, take into account any lack of statistical independence between different data sources.

Surveillance information gathered from the same country, *zone* or *compartment* at different times (e.g. repeated annual surveys) may provide cumulative evidence of animal health status. Such evidence gathered over time may

be combined to provide an overall level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of *surveillance* information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take into account the decreased value of older information. The sensitivity, specificity and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

8. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the characteristic of interest (in this case, the presence or absence of *infection*). The survey design may involve sampling at several levels. For sampling at the level of the *epidemiological units* or higher units, a formal *probability sampling* (e.g. simple random sampling) method should be used. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems.

When sampling below the level of the *epidemiological unit* (e.g. individual animal), the sampling method used should provide the best practical chance of generating a sample that is representative of the population of the chosen *epidemiological unit*. Collecting a truly representative sample of individual animals (whether from a pond, cage or fishery) is often very difficult. To maximise the chance of finding *infection*, the aim should be to bias the sampling towards infected animals, e.g. selecting moribund animals, life stages with a greater chance of active *infection*, etc.

Biased sampling in this context involves sampling from a defined *study population* that has a different probability of *infection* than the *target population* of which it is a *subpopulation*. Once the *study population* has been identified, the objective is still to select a representative sample from this *subpopulation*.

The sampling method used at all levels should be fully documented and justified.

9. Sample size

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* (or *prevalences* where a multi-stage design is used);
- the level of confidence that is desired of the survey results.

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

- the size of the population (but it is acceptable to assume that the population is infinitely large);
- the desired power of the survey;
- uncertainty about *sensitivity* and *specificity*.

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 *pathogenic agent* in host populations.

FreeCalc¹ is a suitable software for the calculation of sample sizes at varying parameter values. The table below provides examples of sample sizes generated by the software for a type I and type II error of 5% (i.e. 95% confidence and 95% statistical power). However, this does not mean that a type 1 and type 2 error of 0.05 should always be used. For example, using a test with *sensitivity* and *specificity* of 99%, 528 units should be sampled. If nine or less of those units test positive, the population can still be considered free of the *disease* at a design *prevalence* of 2% provided that all efforts are made to ensure that all presumed false positives are indeed false. This means that there is a 95% confidence that the *prevalence* is 2% or lower.

In the case in which the values of Se and Sp are not known (e.g. no information is available in the *disease-specific* chapter in the *Aquatic Manual*), they should not automatically be assumed to be 100%. All positive results should be included and discussed in any report regarding that particular survey and all efforts should be made to ensure that all presumed false positives are indeed false.

10. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

Design prevalence	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false positive if the population is free
2	100	100	149	0
2	100	99	524	9
2	100	95	1,671	98
2	99	100	150	0
2	99	99	528	9
2	99	95	1,707	100
2	95	100	157	0
2	95	99	542	9
2	95	95	1,854	108
2	90	100	165	0
2	90	99	607	10
2	90	95	2,059	119
2	80	100	186	0
2	80	99	750	12
2	80	95	2,599	148
5	100	100	59	0
5	100	99	128	3
5	100	95	330	23
5	99	100	59	0
5	99	99	129	3
5	99	95	331	23
5	95	100	62	0
5	95	99	134	3
5	95	95	351	24
5	90	100	66	0
5	90	99	166	4
5	90	95	398	27
5	80	100	74	0
5	80	99	183	4
5	80	95	486	32
10	100	100	29	0
10	100	99	56	2
10	100	95	105	9
10	99	100	29	0
10	99	99	57	2

Design prevalence	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false positive if the population is free
10	99	95	106	9
10	95	100	30	0
10	95	99	59	2
10	95	95	109	9
10	90	100	32	0
10	90	99	62	2
10	90	95	123	10
10	80	100	36	0
10	80	99	69	2
10	80	95	152	12

Article 1.4.9.

Specific requirements for complex non-survey data sources for freedom from disease

Data sources that provide evidence of freedom from *infection*, but are not based on structured population-based surveys may also be used to demonstrate freedom, either alone or in combination with other data sources. Different methodologies may be used for the analysis of such data sources, but the methodology should comply with the provisions of this chapter. The approach used should, where possible, also take into account any lack of statistical independence between observations.

Analytical methodologies based on the use of step-wise probability estimates to describe the *surveillance* system may determine the probability of each step either by:

- 1) the analysis of available data, using a scientifically valid methodology; or where no data are available,
- 2) the use of estimates based on expert opinion, gathered and combined using a formal, documented and scientifically valid methodology.

Where there is significant uncertainty and/or variability in estimates used in the analysis, stochastic modelling or other equivalent techniques should be used to assess the impact of this uncertainty and/or variability on the final estimate of confidence.

Article 1.4.10.

Surveillance for distribution and occurrence of disease

Surveillance to determine distribution and occurrence of *disease* or of other relevant health related events is widely used to assess the *prevalence* and *incidence* of selected *disease* as an aid to decision-making, for example implementation of control and eradication programmes. It also has relevance for the international movement of animals and products when movement occurs among infected countries.

In contrast to *surveillance* to demonstrate freedom from *disease*, *surveillance* for the distribution and occurrence of *disease* is usually designed to collect data about a number of variables of animal health relevance, for example:

- *prevalence* or *incidence* of *disease* in wild or cultured animals;
- morbidity and mortality rates;
- frequency of *disease* risk factors and their quantification;
- frequency distribution of variables in *epidemiological units*;
- frequency distribution of the number of days elapsing between suspicion of *disease* and laboratory confirmation of the *diagnostic* and/or to the adoption of control measures;
- farm production records, etc.

This article describes *surveillance* to estimate parameters of *disease* occurrence.

1. Objectives

The objective of this kind of *surveillance* system is to contribute on an on-going basis evidence to assess the occurrence and distribution of *disease* or *infection* in a particular country, *zone* or *compartment*. This will provide information for domestic *disease* control programmes and relevant *disease* occurrence information to be used by trading partners for qualitative and quantitative *risk assessment*.

A single such survey can contribute evidence adding to an on-going collection of health data.

2. Population

The population of *epidemiological units* should be clearly defined. The *target population* consists of all individuals of all species susceptible to the *disease* in a country, *zone* or *compartment* to which the *surveillance* results apply. Some local areas within a region may be known to be free of the *disease* of concern, allowing resources to be concentrated on known positive areas for greater precision of prevalence estimates and only verification of expected 0 prevalence areas.

The design of the survey will depend on the size and structure of the population being studied. If the population is relatively small and can be considered to be homogenous with regards to *risk* of *infection*, a single-stage survey can be used.

In larger populations where a sampling frame is not available, or when there is a likelihood of clustering of *disease*, multi-stage sampling is required. For example, a multi-stage sampling process may involve sampling of farms or villages followed by sampling of fish from selected ponds within the sampled farms/villages.

In the case of a complex (e.g. multi-level) population structure, multi-level sampling may be used and the data analysed accordingly.

3. Sources of evidence

Surveillance data may originate from a number of different sources, including:

- a) population-based surveys using one or more tests to detect the agent;
- b) other non-random sources of data, such as:
 - i) sentinel sites;
 - ii) *disease notifications* and laboratory investigation records;
 - iii) academic and other scientific studies;
- c) a knowledge of the biology of the agent, including environmental, host population distribution, known geographical distribution, vector distribution and climatic information;
- d) history of imports of potentially infected material;
- e) *biosecurity* measures in place;
- f) any other sources of information that provide contributory evidence regarding *disease* or *infection* in the country, *zone* or *compartment*.

The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For complex *surveillance* systems, a full description of the system is required including consideration of any *biases* that may be inherent in the system. Evidence to support changes in *prevalence/incidence* of endemic disease should be based on valid, reliable methods to generate precise estimates with known error.

4. Statistical methodology

Analysis of survey data should be in accordance with the provisions of this chapter and should consider the following factors:

- a) the survey design;
- b) the *sensitivity* and *specificity* of the test, or test system;
- c) the results of the survey.

For *surveillance* systems used to describe disease patterns, the purpose is to estimate *prevalence* or *incidence* with confidence intervals or probability intervals. The magnitude of these intervals expresses the precision of the estimates and is related to sample size. Narrow intervals are desirable but will require larger sample sizes and more dedication of resources. The precision of the estimates and the power to detect differences in *prevalence* between populations or between time points depends not only on sample size, but also on the actual value of the *prevalence* in the population or the actual difference. For this reason, when designing the *surveillance* system, a prior estimate/assumption of expected *prevalence* or expected difference in *prevalence* should be made.

For the purpose of describing *disease* occurrence, measures of animal unit, time and place can be calculated for an entire population and specific time period, or for subsets defined by host characteristics (e.g. age-specific

incidence). *Incidence* estimation requires on-going *surveillance* to detect new *cases* in a specified time period while *prevalence* is the estimated proportion of infected individuals in a population at a given time point. The estimation process should consider test *sensitivity* and *specificity*.

Statistical analysis of *surveillance* data often requires assumptions about population parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or different populations, expected biology of the agent, information contained in the *disease-specific* chapter of the *Aquatic Manual*, and so on. The uncertainty around these assumptions should be quantified and considered in the analysis (e.g. in the form of prior probability distributions in a Bayesian setting).

When *surveillance* objectives are to estimate *prevalence/incidence* or changes in *disease* patterns, statistical analysis should account for sampling error. Analytic methods should be thoroughly considered and consultation with biostatistician/quantitative epidemiologist consulted beginning in the planning stages and continued throughout the programme.

5. Clustering of infection

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a *zone*). Except when dealing with demonstrably homogenous populations, *surveillance* should take this clustering into account in the design and the statistical analysis of the data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*. For endemic diseases, it is important to identify characteristics of the population which contribute to clustering and thus provide efficiency in *disease* investigation and control.

6. Test characteristics

All *surveillance* involves performing one or more tests for evidence of the presence of current or past *infection*, ranging from detailed laboratory examinations to farmer observations. The performance level of a test at the population level is described in terms of its *sensitivity* and *specificity*. Imperfect *sensitivity* and/or *specificity* impact on the interpretation of *surveillance* results and should be taken into account in the analysis of *surveillance* data. For example, in populations with low *prevalence* of *infection*, a large proportion of positive tests may be false unless the tests used have perfect *specificity*. To ensure detection in such instances, a highly sensitive test is frequently used for initial screening and then confirmed with highly specific tests.

All calculations should take the performance level (*sensitivity* and *specificity*) of any tests used into account. The values of *sensitivity* and *specificity* used for calculations should be specified, and the method used to determine or estimate these values should be documented. Test *sensitivity* and *specificity* can be different when applied to different populations and testing scenarios. For example, test *sensitivity* may be lower when testing carrier animals with low level *infections* compared to moribund animals with clinical *disease*. Alternatively, *specificity* depends on the presence of cross-reacting agents, the distribution of which may be different under different conditions or regions. Ideally, test performance should be assessed under the conditions of use otherwise increased uncertainty exists regarding their performance. In the absence of local assessment of tests, values for *sensitivity* and/or *specificity* for a particular test that are specified in the *Aquatic Manual* may be used but the increased uncertainty associated with these estimates should be incorporated into the analysis of results.

Pooled testing involves the pooling of specimens from multiple individuals and performing a single test on the pool. Pooled testing is an acceptable approach in many situations. Where pooled testing is used, the results of testing should be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pooled testing procedure and for the applicable pool sizes being used. Analysis of the results of pooled testing should, where possible, be performed using accepted, statistically based methodologies, which should be fully documented, including published references.

Test results from *surveillance* for endemic disease will provide estimates of apparent *prevalence* (AP). Using diagnostic sensitivity (DSe) and diagnostic specificity (DSp), true *prevalence* (TP) should be calculated with the following formula:

$$TP = (AP + DSp - 1)/(DSe + DSp - 1)$$

In addition, it should be remembered that different laboratories may obtain conflicting results for various tests, host, or procedure-related reasons. Therefore, sensitivity and specificity parameters should be validated for the particular laboratory and process.

7. Multiple sources of information

Where multiple different data sources providing information on *infection* or *disease* are generated, each of these data sources may be analysed and presented separately.

Surveillance information gathered from the same country, *zone* or *compartment* at different times and similar methodology (e.g. repeated annual surveys) may provide cumulative evidence of animal health status and changes. Such evidence gathered over time may be combined (e.g. using Bayesian methodology) to provide more precise estimates and details of *disease* distribution within a population.

Apparent changes in *disease* occurrence of endemic diseases may be real or due to other factors influencing detection proficiency.

8. Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the characteristic of interest (in this case, the presence or absence of *infection*). The survey design may involve sampling at several levels. For sampling at the level of the *epidemiological units* or higher units, a formal *probability sampling* (e.g. simple random sampling) method should be used. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems.

When sampling below the level of the *epidemiological unit* (e.g. individual animal), the method used should be probability-based sampling. Collecting a true probability-based sample is often very difficult and care should therefore be taken in the analysis and interpretation of results obtained using any other method, the danger being that inferences could not be made about the sampled population.

The sampling method used at all levels should be fully documented and justified.

9. Sample size

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 (single or in combination);
- expected *prevalence* or *incidence* in the population (or *prevalences/incidences* where a multi-stage design is used);
- the level of confidence that is desired of the survey results;
- the precision desired (i.e. the width of the confidence or probability intervals).

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

- the size of the population (but it is acceptable to assume that the population is infinitely large);
- uncertainty about *sensitivity* and *specificity*.

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 *pathogenic agent* in host populations.

A number of software packages, e.g. Survey Tool Box (www.aciar.gov.au; www.ausvet.com.au), WinPEPI (www.sagebrushpress.com/pepibook.html) can be used for the calculation of sample sizes.

In the case in which the values of *Se* and *Sp* are not known (e.g. no information is available in the *disease*-specific chapter in the *Aquatic Manual*), they should not automatically be assumed to be 100%. Assumed values should be produced in consultation with subject-matter experts.

10. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

Article 1.4.11.

Examples of surveillance programmes

The following examples describe *surveillance* systems and approaches to the analysis of evidence for demonstrating freedom from *disease*. The purpose of these examples is:

- to illustrate the range of approaches that may be acceptable;
- to provide practical guidance and models that may be used for the design of specific *surveillance* systems; and
- to provide references to available resources that are useful in the development and analysis of *surveillance* systems.

While these examples demonstrate ways in which freedom from *disease* may be successfully demonstrated, they are not intended to be prescriptive. Countries are free to use different approaches, as long as they meet the requirements of this chapter.

The examples deal with the use of surveys and are designed to illustrate different survey designs, sampling schemes, the calculation of sample size, and analysis of results. It is important to note that alternative approaches to demonstrating freedom using complex non-survey-based data sources are also currently being developed and may soon be published².

1. Example 1. – One-stage structured survey (farm certification)

a) Context

A freshwater *aquaculture* industry raising fish in tanks has established a farm certification scheme. This involves demonstrating farm-level freedom from a particular (hypothetical) disease (Disease X). The *disease* does not spread very quickly, and is most common during the winter months, with adult fish at the end of the production cycle being most severely affected. Farms consist of a number of grow-out tanks, ranging from 2 to 20, and each tank holds between 1,000 and 5,000 fish.

b) Objective

The objective is to implement *surveillance* that is capable of providing evidence that an individual farm is free from Disease X. (The issue of national or *zone* freedom, as opposed to farm freedom, is considered in the next example.)

c) Approach

The accreditation scheme establishes a set of standard operating procedures and requirements for declaration of freedom, based on the recommendations given in this chapter. These require farms to undertake a survey capable of producing 95% confidence that the *disease* would be detected if it were present. Once farms have been surveyed without detecting *disease*, they are recognised as free, as long as they maintain a set of minimum *biosecurity* standards. These standards are designed to prevent the introduction of Disease X into the farm (through the implementation of controls specific to the method of spread of that *disease*) and to ensure that the *disease* would be detected rapidly if it were to enter the farm (based on evidence of adequate health record keeping and the prompt investigation of unusual *disease* events). The effective implementation of these *biosecurity* measures is evaluated with annual on-farm audits conducted by independent auditors.

d) Survey standards

Based on the recommendations given in this chapter, a set of standards are established for the conduct of surveys to demonstrate freedom from *infection* with causative agent of Disease X. These standards include:

- i) The level of confidence required of the survey is 95% (i.e. Type I error = 5%).
- ii) The power of the survey is arbitrarily set at 95% (i.e. Type II error = 5%, which means that there is a 5% chance of concluding that a non-diseased farm is infected).

- iii) The *target population* is all the fish on the farm. Due to the patterns of *disease* in this production system, in which only fish in the final stages of grow-out, and only in winter are affected, the *study population* is defined as grow-out fish during the winter months.
 - iv) The issue of clustering is considered. As fish are grouped into tanks, this is the logical level at which to consider clustering. However, when a farm is infected, the *disease* often occurs in multiple tanks, so there is little evidence of strong clustering. Also, the small number of tanks on a single farm means that it is difficult to define a design *prevalence* at the tank level (i.e. the proportion of infected tanks that the survey should be able to detect on the farm). For these reasons, it is decided to treat the entire grow-out population of each farm as a single homogenous population.
 - v) Stratification is also considered. In order to ensure full representation, it is decided to stratify the sample size by tank, proportional to the population of each tank.
 - vi) The design *prevalence* at the animal level is determined based on the epidemiology of the *disease*. The *disease* does not spread quickly; however, in the defined *target population*, it has been reported to affect at least 10% of fish if the population is infected. In order to take the most conservative approach, an arbitrarily low design *prevalence* of 2% is used. A *prevalence* of 10% may have been used (and would result in a much smaller sample size), but the authorities were not convinced by the thought that the population could still be infected at a level of say 5%, and *disease* still not be detected.
 - vii) The test used involves destructive sampling of the fish, and is based on an antigen-detection enzyme-linked immunosorbent assay (ELISA). Disease X is present in some parts of the country (hence the need for a farm-level accreditation programme). This has provided the opportunity for the *sensitivity* and the *specificity* of the ELISA to be evaluated in similar populations to those on farms. A recent study (using a combination of histology and culture as a gold standard) estimated the *sensitivity* of the ELISA to be 98% (95% confidence interval 96.7–99.2%), and the *specificity* to be 99.4% (99.2–99.6%). Due to the relatively narrow confidence intervals, it was decided to use the point estimates of the *sensitivity* and *specificity* rather than complicate calculations by taking the uncertainty in those estimates into account.
- e) Sample size

The sample size required to meet the objectives of the survey is calculated to take the population size, the test performance, the confidence required and the design *prevalence* into account. As the population of each farm is relatively large, differences in the total population of each farm have little effect on the calculated sample size. The other parameters for sample size calculation are fixed across all farms. Therefore, a standard sample size (based on the use of this particular ELISA, in this population) is calculated. The sample size calculations are performed using the FreeCalc software. Based on the parameters listed above, the sample size required is calculated to be 410 fish per farm. In addition, the programme calculates that, given the imperfect *specificity*, it is still possible for the test to produce up to five false-positive reactors from an uninfected population using this sample size. The authorities are not comfortable with dealing with false-positive reactors, so it is decided to change the test system to include a confirmatory test for any positive reactors. Culture is selected as the most appropriate test, as it has a *specificity* that is considered to be 100%. However, its *sensitivity* is only 90% due to the difficulty of growing the organism.

As two tests are now being used, the performance of the test system should be calculated, and the sample size recalculated based on the test system performance.

Using this combination of tests (in which a sample is considered positive only if it tests positive to both tests), the *specificity* of the combined two tests can be calculated by the formula:

$$Sp_{combined} = Sp_1 \times Sp_2 - (Sp_1 \times Sp_2)$$

which produces a combined specificity of $1 + 0.994 - (1 \times 0.994) = 100\%$.

The *sensitivity* may be calculated by the formula:

$$Se_{combined} = Se_1 \times Se_2$$

which produces a combined sensitivity of $0.9 \times 0.98 = 88.2\%$.

These new values are used to calculate the survey sample size yielding a result of 169 fish. It is worth noting that attempts to improve the performance of a test (in this case increase *specificity*) generally result in a decrease in the performance of the other aspect of the test performance (*sensitivity* in this example).

However, in this case, the loss of *sensitivity* is more than compensated for by the decreased sample size due to the improved *specificity*.

It is also worth noting that, when using a test system with 100% *specificity*, the effective power of the survey will always be 100%, regardless of the figure used in the design. This is because it is not possible to make a Type II error, and conclude that the farm is infected when it is not.

A check of the impact of population size on the calculated sample size is worthwhile. The calculated sample size is based on an infinitely large population. If the population size is smaller, the impact on sample size is shown in the following table:

Population size	Sample size
1,000	157
2,000	163
5,000	166
10,000	169

Based on these calculations, it is clear that, for the population sizes under consideration, there is little effect on the sample size. For the sake of simplicity, a standard sample size of 169 is used, regardless of the number of grow-out fish on the farm.

f) Sampling

The selection of individual fish to include in the sample should be done in such a manner as to give the best chance of the sample being representative of the *study population*. A fuller description of how this may be achieved under different circumstances is provided in Survey Toolbox³. An example of a single farm will be used to illustrate some of the issues.

One farm has a total of eight tanks, four of which are used for grow-out. At the time of the survey (during winter), the four grow-out tanks have 1,850, 4,250, 4,270 and 4,880 fish, respectively, giving a total population of 15,250 grow-out fish.

Simple random sampling from this entire population is likely to produce sample sizes from each tank roughly in proportion to the number of fish in each tank. However, proportional stratified sampling will guarantee that each tank is represented in proportion. This simply involves dividing the sample size between tanks in proportion to their population. The first tank has 1,850 fish out of a total of 15,250, representing 12.13%. Therefore 12.13% of the sample (21 fish) should be taken from the first tank. Using a similar approach the sample size for the other three tanks is 47, 47 and 54 fish, respectively.

Once the sample for each tank is determined, the problem remains as to how to select 21 fish from a tank of 1,850 so that they are representative of the population. Several options exist.

- i) If the fish can be handled individually, random systematic sampling may be used. For example, samples can be collected at harvest or during routine management activities involving handling the fish (such as grading or vaccination).

If fish are handled, systematic sampling simply involves selecting a fish at regular intervals. For instance, to select 21 from 1,850, the sampling interval should be $1,850/21 = 88$. This means that every 88th fish from the tank should be sampled. To ensure randomness, it is good practice to use a random number between 1 and 88 (in this case) to select the first fish (e.g. using a random number table), and then select every 88th fish after that.

- ii) If fish cannot be handled individually (by far the most common, and more difficult, circumstance) then the fish to be sampled should be captured from the tanks. Fish should be captured in the most efficient and practical way possible; however, every effort should be made to try to ensure that the sample is representative. In this example, a dip net is the normal method used for capturing fish. Using a dip net, convenience sampling would involve capturing 21 fish by repeatedly dipping at one spot and capturing the easiest fish (perhaps the smaller ones). This approach is strongly discouraged. One method of

increasing the representativeness is to sample at different locations in the tank – some at one end, some at either side, some at the other end, some in the middle, some close to the edge. Additionally, if there are differences among the fish, an attempt should be made to capture fish in such a way as to give different groups of fish a chance of being caught (i.e. do not just try to catch the small ones, but include big ones as well).

This method of collecting a sample is far from the ideal of random sampling, but due to the practical difficulties of implementing random sampling of individual fish, this approach is acceptable, as long as the efforts made to increase the representativeness of the sample are both genuine and fully documented.

g) Testing

Specimens are collected, processed and tested in accordance with standardised procedures developed under the certification programme and designed to meet the requirements of the *Aquatic Manual*. The testing protocol dictates that any specimens that test positive to ELISA be submitted for culture, and that any positive culture results indicate a true positive specimen (i.e. that the farm is not free from *disease*). It is important that this protocol be adhered to exactly. If a positive culture is found, then it is not acceptable to retest it, unless further testing is specified in the original testing protocol, and the impact of such testing accounted for in the test system *sensitivity* and *specificity* estimates (and therefore the sample size).

h) Analysis

If the calculated sample size of 169 is used, and no positive reactors are found, then the survey will have a confidence of 95%. This can be confirmed by analysing the results using the FreeCalc software mentioned above (which reports a confidence level of 95.06%).

It may happen in some cases that the survey is not conducted exactly as planned, and the actual sample size is less than the target sample size. However, the size of the farm may also be smaller. In these cases, it is advisable to analyse the farm data on a farm-by-farm basis. For example, if only 165 specimens were collected from a farm with only 2,520 fish, the resulting confidence would still be 95%. If only 160 fish were collected, the confidence is only 94.5%. If a rigid target of 95% confidence is used, then this survey would fail to meet that target and more evidence would be required.

2. Example 2 – Two-stages structured survey (national freedom)

a) Context

A country aims to declare freedom from Disease Y of crustaceans. The industry in this country is based largely on small-holder ponds, grouped closely together in and around villages. The *disease* is reasonably highly contagious, and causes mass mortality mid to late in the production cycle, with affected animals becoming moribund and dying in a matter of days. Affected animals show few characteristic signs, but an infected pond will almost invariably break down with mass mortality unless harvested beforehand. It is more common in late summer, but can occur at any time of year. It also occurs occasionally early in the production cycle. In this country, there are some limitations to the availability of laboratory facilities and the transport infrastructure. However, there is a relatively large government structure, and a comprehensive network of fisheries officers.

b) Objective

The objective is to establish national freedom from Disease Y. The *surveillance* system should meet the requirements of this chapter, but should also be able to be practically implemented in this small-holder production system.

c) Approach

The *aquaculture* authorities decide to use a survey to gather evidence of freedom, using a two-stage survey design (sampling villages at the first level, and ponds at the second). Laboratory testing of specimens from a

large number of farms is not considered feasible, so a combined test system is developed to minimise the need for expensive laboratory tests.

The unit of observation and analysis is, in this case, the pond, rather than the individual animal. This means that the *diagnostic* is being made at the pond level (an infected pond or a non-infected pond) rather than at the animal level.

The survey is therefore a survey to demonstrate that no villages are infected (using a random sample of villages and making a village-level *diagnostic*). The test used to make a village-level *diagnostic* is, in fact, another survey, this time to demonstrate that no ponds in the village are affected. A test is then performed at the pond level (farmer observation followed, if necessary, by further laboratory testing).

d) Survey standards

- i) The confidence to be achieved by the survey is 95%. The power is set at 95% (but is likely to be virtually 100% if the test system used achieves nearly 100% *specificity*, as demonstrated in the previous example).
- ii) The *target population* is all ponds stocked with shrimp in the country during the study period. The *study population* is the same, except that those remote areas to which access is not possible are excluded. As *outbreaks* can occur at any time of year, and at any stage of the production cycle, it is decided not to further refine the definition of the population to target a particular time or age.
- iii) Three tests are used. The first is farmer observation, to determine if mass mortality is occurring in a particular pond. If a pond is positive to the first test (i.e. mass mortality is detected), a second test is applied. The second test used is polymerase chain reaction (PCR). Cases positive to PCR are further tested using transmission experiments.
- iv) Farmer observation can be treated as a test just like any other. In this case, the observation of mass mortality is being used as a test for the presence of Disease Y. As there are a variety of other *diseases* that are capable of causing mass mortality, the test is not very specific. On the other hand, it is quite unusual for Disease Y to be present, and not result in mass mortality, so the test is quite sensitive. A standard *case definition* is established for mass mortality' (for instance, greater than 20% of the pond's population of shrimp observed dead in the space of less than one week). Based on this definition, farmers are able to 'diagnose' each pond as having mass mortality. Some farmers may be over-sensitive and decide that mass mortality is occurring when only a small proportion of shrimp are found dead (false positives, leading to a decrease in specificity) while a small number of others fail to recognise the mortalities, decreasing sensitivity.

In order to quantify the sensitivity and specificity of farmer observation of mass mortalities, as a test for Disease Y, a separate study is carried out. This involves both a retrospective study of the number of mass mortality events in a population that is thought to be free from *disease*, as well as a study of farmers presented with a series of mortality scenarios, to assess their ability to accurately identify a pond with mass mortality. By combining these results, it is estimated that the *sensitivity* of farmer-reported mass mortalities as a test for Disease Y is 87% while the *specificity* is 68%.

- v) When a farmer detects a pond with mass mortality, specimens are collected from moribund shrimp following a prescribed protocol. Tissue samples from 20 shrimp are collected, and pooled for PCR testing. In the laboratory, the ability of pooled PCR to identify a single infected animal in a pool of 20 has been studied, and the sensitivity of the procedure is 98.6%. A similar study of negative specimens has shown that positive results have occasionally occurred, probably due to laboratory contamination, but maybe also because of the presence of non-viable genetic material from another source (shrimp-based feed stuffs are suspected). The *specificity* is therefore estimated at 99%.
- vi) Published studies in other countries have shown that the *sensitivity* of transmission tests, the third type of test to be used, is 95%, partly due to variability in the load of the agent in inoculated material. The *specificity* is agreed to be 100%.
- vii) Based on these figures, the combined test system *sensitivity* and *specificity* are calculated using the formulae presented in Example 1, first with the first two tests, and then with the combined effect of the first two tests and the third test. The result is a *sensitivity* of 81.5% and a *specificity* of 100%.

- viii) The design *prevalence* should be calculated at two levels. First, the pond-level design *prevalence* (the proportion of ponds in a village that would be infected if *disease* were present) is determined. In neighbouring infected countries, experience has shown that ponds in close contact with each other are quickly infected. It is unusual to observe an infected village with fewer than 20% of ponds infected. Conservatively, a design *prevalence* of 5% is used. The second value for design *prevalence* applies at the village level, or the proportion of infected villages that could be identified by the survey. As it is conceivable that the *infection* may persist in a local area without rapid spread to other parts of the country, a value of 1% is used. This is considered to be the lowest design *prevalence* value for which a survey can be practically designed.
 - ix) The population of villages in the country is 65,302, in accordance with official government records. Those with shrimp ponds number 12,890, based on records maintained by the *aquaculture* authorities. These are generated through a five-yearly agricultural census, and updated annually based on reports of fisheries officers. There are no records available of the number of ponds in each of these villages.
- e) Sample size

Sample size is calculated for the two levels of sampling, first the number of villages to be sampled and then the number of ponds to be sampled. The number of villages to be sampled depends on the *sensitivity* and the *specificity* of the test used to classify villages as infected or not infected. As the 'test' used in each village is really just another survey, the *sensitivity* is equal to the confidence and the *specificity* is equal to the power of the village-level survey. It is possible to adjust both confidence and power by changing the sample size in the village survey (number of ponds examined), which means that we can determine, within certain limits, what *sensitivity* and *specificity* we achieve.

This allows a flexible approach to sample size calculation. If a smaller first-stage sample size is desired (a small number of villages), a high *sensitivity* and *specificity* are needed, which means that the number of ponds in each village that need to be examined is larger. A smaller number of ponds will result in lower *sensitivity* and *specificity*, requiring a larger number of villages. The approach to determining the optimal (least cost) combination of first- and second-stage sample sizes is described in Survey Toolbox.

A further complication is presented by the fact that each village has a different number of ponds. In order to achieve the same (or similar) confidence and power (*sensitivity* and *specificity*) for each village, a different sample size may be required. The authorities choose to produce a table of sample sizes for the number of ponds to sample in each village, based on the total ponds in each village.

An example of one possible approach to determining the sample size follows:

The target sensitivity (confidence) achieved by each village-level survey is 95%. The target specificity is 100%. Using the FreeCalc software, with a design *prevalence* of 1% (the survey is able to detect *disease* if 1% or more villages are infected), the first-stage sample size is calculated as 314 villages. Within each village, the test used is the combined test system described above with a *sensitivity* of 81.5% and a *specificity* of 100%. Based on these figures the following table is developed, listing the number of ponds that need to be sampled in order to achieve 95% sensitivity.

- f) Sampling

First-stage sampling (selection of villages) is done using random numbers and a sampling frame based on the fisheries authorities list of villages with shrimp ponds. The villages are listed on a spreadsheet with each village numbered from 1 to 12,890. A random number table (such as that included in Survey Toolbox) or software designed for the generation of random numbers (such as EpiCalc⁴) is used.

Population	Sample size
30	29
40	39
60	47
80	52
100	55
120	57
140	59
160	61
180	62
200	63
220	64
240	64
260	65
280	65
300	66
320	66
340	67
360	67
380	67
400	67
420	68
440	68
460	68
480	68
500	68
1,000	70

The second stage of sampling involves random selection of ponds within each village. This requires a sampling frame, or list of each pond in the village. The fisheries authorities use trained local fisheries officers to coordinate the survey. For each selected village, the officer visits the village and convenes a meeting of all shrimp farmers. At the meeting, they are asked how many ponds they have and a list of farmers' names and the number of ponds is compiled. A simple random sample of the appropriate number of ponds (between 29 and 70, from the table above, depending on the number of ponds in the village) is selected from this list. This is done either using software (such as Survey Toolbox's Random Animal Programme), or manually with a random number table or decimal dice for random number selection. Details of this process are described in Survey Toolbox. This selection process identifies a particular pond in terms of the name of the owner, and the sequence number amongst the ponds owned (e.g. Mr Smith's 3rd pond). Identification of the actual pond is based on the owners own numbering system for the ponds.

g) Testing

Once ponds have been identified, the actual survey consists of 'testing those ponds'. In practice, this involves the farmers observing the ponds during one complete production cycle. The local fisheries officer makes weekly visits to each farmer to check if any of the selected ponds have suffered mass mortality. If any are

observed (i.e. the first test is positive), 20 moribund shrimp are collected for laboratory examination (first PCR, and then, if positive, transmission experiments).

h) Analysis

Analysis is performed in two stages. First, the results from each village are analysed to ensure that they meet the required level of confidence. If the target sample size is achieved (and only negative results obtained), the confidence should be 95% or greater in each village. At the second stage, the results from each village are analysed to provide a country level of confidence. Again, if the target sample size (number of villages) is achieved, this should exceed 95%.

3. Example 3. – Spatial sampling and the use of tests with imperfect specificity

a) Context

A country has an oyster culture industry, based primarily on rack culture of oysters in 23 estuaries distributed along the coastline. In similar regions in other countries, Disease Z causes mortalities in late summer/early autumn. During an *outbreak* a high proportion of oysters are affected; however, it is suspected that the agent may be present at relatively low *prevalence* in the absence of *disease outbreaks*.

b) Objective

The national authorities wish to demonstrate national freedom from Disease Z. If the *disease* should be detected, a secondary objective of the survey is to collect adequate evidence to support zoning at the estuary level.

c) Approach

The authorities conclude that clinical *surveillance* for *disease outbreaks* is inadequate because of the possibility of low level subclinical *infections*. It is therefore decided to base *surveillance* on a two-stage survey, in which sampled oysters are subjected to laboratory testing. The first stage of the survey is the selection of estuaries. However, due to the objective of providing evidence for zoning (should disease be found in any of the estuaries), it is decided to use a census approach and sample every estuary. In essence this means that there will be 23 separate surveys, one for each estuary. A range of options for sampling oysters are considered, including sampling at harvest or marketing, or using farms (oyster leases) as a level of sampling or stratification. However, the peak time of activity of the agent does not correspond to the harvest period, and the use of farms would exclude the significant numbers of wild oysters present in the estuaries. It is therefore decided to attempt to simulate simple random sampling from the entire oyster population in the estuary, using a spatial sampling approach.

d) Survey standards

i) The *target population* is all of the oysters in each of the estuaries. The *study population* is the oysters present during the peak disease-risk period in late summer early autumn. Wild and cultured oysters are both susceptible to *disease*, and may have associated with them different (but unknown) *risks* of *infection*. They are therefore both included in the *study population*. As will be described below, sampling is based on mapping. Therefore the *study population* can more accurately be described as that population falling within those mapped areas identified as oyster habitats.

ii) A design *prevalence* value is only required at the oyster level (as a census is being used at the estuary level). While the *disease* is often recognised with a very high *prevalence* during *outbreaks*, a low value is used to account for the possibility of persistence of the agent in the absence of clinical signs. A value of 2% is selected.

iii) The test used is histopathology with immuno-staining techniques. This test is known to produce occasional false-positive results due to nonspecific staining, but is very sensitive. Published studies indicate values of 99.1% for sensitivity and 98.2% for specificity. No other practical tests are available. This means that it is not possible to definitively differentiate false positives from true positives, and that in a survey of any size, a few false positives are expected (i.e. 1.8%).

iv) The confidence is set at 95% and the power at 80%. In the previous examples, due to the assumed 100% *specificity* achieved by use of multiple tests, the effective power was 100%. In this case, with imperfect specificity, there will be a risk of falsely concluding that a healthy estuary is infected, so the power is not 100%. The choice of a relatively low figure (80%) means that there is a one in five chance of falsely calling an estuary infected when it is not infected, but it also dramatically decreases the survey costs, through a lower sample size.

e) Sample size

Based on the assumption that the sampling procedure will mimic simple random sampling, the sample size (number of oysters to sample per estuary) can be calculated with FreeCalc. The population size (number of oysters per estuary) is assumed to be very large. The calculated sample size, using the sensitivity, specificity and design *prevalence* figures given above, is 450. FreeCalc also reports that, based on this sample size and the *specificity* of the test, it is possible to get ten or fewer false-positive test results, and still conclude that the population is free from *disease*. This is because, if the population were infected at 2% or greater, the anticipated number of positive reactors from a sample of 450 would be greater than 10. In fact, we would expect 9 true positives ($450 \times 2\% \times 99.1\%$) and 8 false positives ($450 \times 98\% \times 1.8\%$) or a total of 17 positives if the population were infected at a *prevalence* of 2%.

This illustrates how probability theory and adequate sample size can help differentiate between true- and false-positive results when there is no alternative but to use a test with imperfect *specificity*.

f) Sampling

The aim is to collect a sample of 450 oysters that represent an entire estuary. Simple random sampling depends on creating a sampling frame listing every oyster (not possible) and systematic sampling depends on being able to (at least conceptually) line up all the oysters (again, not possible). The authorities decide to use spatial sampling to approximate simple random sampling. Spatial sampling involves selecting random points (defined by coordinates), and then selecting oysters near the selected points. In order to avoid selecting many points with no oysters nearby, the estuary is first mapped (the fisheries authorities already have digital maps defining oyster leases available). To these maps areas with significant concentrations of wild oysters are also added, based on local expertise. Pairs of random numbers are generated such that the defined point falls within the defined oyster areas. Other schemes are considered (including using a rope marked at regular intervals, laid out on a lease to define a transect, and collecting an oyster adjacent to each mark on the rope) but the random coordinate approach is adopted.

Survey then visit each point by boat (using a GPS Global Positioning System unit to pinpoint the location). A range of approaches is available for selecting which oyster to select from a densely populated area, but it should involve some effort at randomness. Survey staff opt for a simple approach: when the GPS receiver indicates that the site has been reached, a pebble is tossed in the air and the oyster closest to the point where it lands is selected. Where oysters are arranged vertically (e.g. wild oysters growing up a post), a systematic approach is used to determine the depth of the oyster to select. First, an oyster at the surface, next, an oyster halfway down, and thirdly, an oyster as deep as can be reached from the boat.

This approach runs the risk of *bias* towards lightly populated areas, so an estimate of the relative density of oysters at each sampling point is used to weight the results (see Survey Toolbox for more details).

g) Testing

Specimens are collected, processed, and analysed following a standardised procedure. The results are classified as definitively positive (showing strong staining in a highly characteristic pattern, possibly with associated signs of tissue damage), probably positive (on the balance of probabilities, but less characteristic staining), and negative.

h) Analysis

The interpretation of the results when using a test with imperfect *specificity* is based on the assumption that, in order to conclude that the population is free from *infection*, any positive result identified is really a false positive. With a sample size of 450, up to 10 false positives may be expected while still concluding that the population is free from *disease*. However, if there is reasonable evidence that there is even a single true positive, then the population cannot be considered free. This is the reason for the classification of positive results into definitive and probable positives. If there are any definitive positives at all, the population in that estuary should be considered infected. The probable positives are consistent with false positives, and therefore up to ten may be accepted. Using FreeCalc the actual confidence achieved based on the number of (presumed) false positives detected can be calculated. For instance, if 8 'probably positive' results were detected from an estuary, the confidence level for the survey would be 98.76%. On the other hand, if 15 'probably positive' results were detected, the confidence is only 61.9%, indicating that the estuary is likely to be infected.

i) Discussion

Normally, it may be safely assumed that a *surveillance* system aimed at demonstrating freedom from *disease* is 100% specific. This is because any suspected occurrence of *disease* is investigated until a definitive decision can be made. If the conclusion is that the *case* is truly a *case* of *disease*, then there is no issue of declaring freedom – the *disease* is known to be present. This example presents a different situation where, due to lack of suitable tests, it is not possible for the *surveillance* system to be 100% specific. This may represent an unusual situation in practice, but illustrates that methods exist for dealing with this sort of problem. In practice, a conclusion that a country (or estuary) is free from *infection*, in the face of a small (but statistically acceptable) number of positive results, will usually be backed up by further evidence (such as the absence of clinical *disease*).

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- 1 FreeCalc – Cameron, AR. 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>
 - 2 International EpiLab, Denmark, Research Theme 1: Freedom from disease. http://www.vetinst.dk/high_uk.asp?page_id=196
 - 3 Survey Toolbox for Aquatic Animal Diseases – A Practical Manual and Software Package. Cameron A.R. (2002). Australian Centre for International Agricultural Research (ACIAR), Monograph No. 94, 375 pp. ISBN 1 86320 350 8. Printed version available from ACIAR (<http://www.aciar.gov.au>). Electronic version available for free download from <http://www.ausvet.com.au>
 - 4 <http://www.myatt.demon.co.uk/epicalc.htm>

CHAPTER 1.5.

CRITERIA FOR LISTING SPECIES AS SUSCEPTIBLE TO INFECTION WITH A SPECIFIC PATHOGEN

Article 1.5.1.

The purpose of this chapter is to provide criteria for determining which species are listed as susceptible in Article 1.5.2. of each *disease-specific* chapter in the *Aquatic Code*.

Article 1.5.2.

Scope

Susceptibility may include clinical or non-clinical *infection* but does not include mechanical vectors (i.e. species that may carry the *pathogenic agent* without replication).

The decision to list a species as susceptible should be based on a finding that the evidence is definite. However, possible susceptibility of a species is also important information and this should also be included in Section 2.2.1. entitled «Susceptible host species» of the relevant *disease-specific* chapter of the *Aquatic Manual*.

Article 1.5.3.

Approach

A three-stage approach is outlined in this chapter to assess susceptibility of a species to *infection* with a specified *pathogenic agent* and is based on:

- 1) criteria to determine whether the route of transmission is consistent with natural pathways for the *infection* (as described in Article 1.5.4.);
- 2) criteria to determine whether the *pathogenic agent* has been adequately identified (as described in Article 1.5.5.);
- 3) criteria to determine whether the evidence indicates that presence of the *pathogenic agent* constitutes an *infection* (as described in Article 1.5.6.).

Article 1.5.4.

Stage 1: criteria to determine whether the route of transmission is consistent with natural pathways for the infection

The evidence should be classified as transmission through:

- 1) natural occurrence; includes situations where *infection* has occurred without experimental intervention e.g. *infection* in wild or farmed populations; or
- 2) non-invasive experimental procedures; includes cohabitation with infected hosts, *infection* by immersion or ingestion; or
- 3) invasive experimental procedure; includes injection, exposure to unnaturally high loads of pathogen, or exposure to stressors (e.g. temperature) not encountered in the host's natural or culture environment.

Consideration needs to be given to whether experimental procedures (e.g. inoculation, infectivity load) mimic natural pathways for *disease* transmission. Consideration should also be given to environmental factors as these may affect host resistance or transmission of the pathogen.

Article 1.5.5.

Stage 2: criteria to determine whether the pathogenic agent has been adequately identified

The *pathogenic agent* should be identified and confirmed in accordance with the methods described in Section 7 (corroborative diagnostic criteria) of the relevant disease chapter in the *Aquatic Manual*, or other methods that have been demonstrated to be equivalent.

Article 1.5.6.

Stage 3: criteria to determine whether the evidence indicates that presence of the pathogenic agent constitutes an infection

A combination of the following criteria should be used to determine *infection* (see Article 1.5.7.):

- A. the *pathogenic agent* is multiplying in the host, or developing stages of the *pathogenic agent* are present in or on the host;
- B. viable *pathogenic agent* is isolated from the proposed *susceptible species*, or infectivity is demonstrated by way of transmission to naive individuals;
- C. clinical or pathological changes are associated with the *infection*;
- D. the specific location of the pathogen corresponds with the expected target tissues.

The type of evidence to demonstrate *infection* will depend on the *pathogenic agent* and potential host species under consideration.

Article 1.5.7.

Outcomes of the assessment

The decision to list a species as susceptible should be based on a finding of definite evidence. Evidence should be provided for the following:

- 1) Transmission has been obtained naturally or by experimental procedures that mimic natural pathways for the *infection* in accordance with Article 1.5.4.;

AND

- 2) the identity of the *pathogenic agent* has been confirmed in accordance with Article 1.5.5.;

AND

- 3) there is evidence of *infection* with the *pathogenic agent* in the suspect host species in accordance with criteria A to D in Article 1.5.6.. Evidence to support criterion A alone is sufficient to determine *infection*. In the absence of evidence to meet criterion A, satisfying at least two of criteria B, C or D would be required to determine *infection*.

Article 1.5.8.

Species for which there is incomplete evidence for susceptibility

The decision to list a species as susceptible in Article 1.5.2. of each *disease-specific* chapter should be based on a finding that the evidence is definite.

However, where there is insufficient evidence to demonstrate susceptibility through the approach described in Article 1.5.3. because transmission does not mimic natural pathways of *infection*, or the identity of the *pathogenic agent* has not been confirmed, or *infection* is only partially supported, information will be included in the relevant *disease-specific* chapter in the *Aquatic Manual*.

If there is insufficient evidence to demonstrate susceptibility of a species, the *Competent Authority* should assess the risk of spread of the pathogen under consideration, in accordance with the recommendations in Chapter 2.1., prior to the implementation of import health measures.

SECTION 2.

RISK ANALYSIS

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

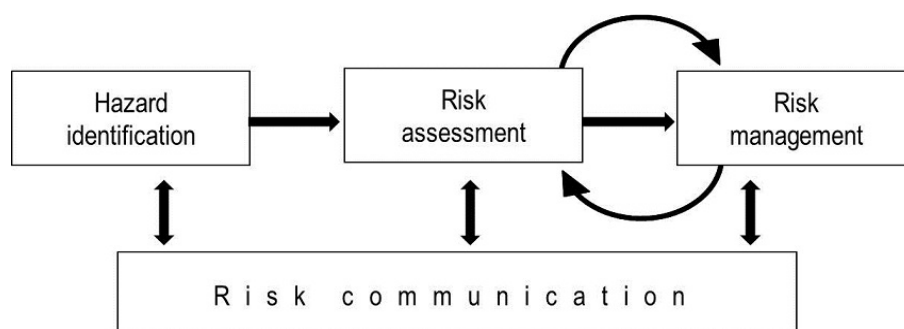
The importation of *aquatic animals* and *aquatic animal products* involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of *aquatic animals*, *aquatic animal products*, *aquatic animal genetic material*, *feedstuffs*, *biological products* and *pathological material*. The principles and methods are the same whether the *commodities* are derived from aquatic and/or terrestrial animal sources. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. However, it cannot provide details on the means by which a *risk analysis* is carried out as the purpose of the *Aquatic Code* is simply to outline the necessary basic steps. The components of *risk analysis* are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. The four components of risk analysis



The *risk assessment* is the component of the analysis that estimates the *risks* associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly for those *diseases* listed in the *Aquatic Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*. In such cases it is more likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision-making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

The process of import *risk analysis* on *aquatic animals* and *aquatic animal products* usually needs to take into consideration the results of an evaluation of the *Aquatic Animal Health Services*, zoning and compartmentalisation, and *surveillance* systems that are in place for monitoring *aquatic animal* health in the *exporting country*. These are described in separate chapters in the *Aquatic Code*.

Article 2.1.2.

Hazard identification

Hazard identification involves identifying the *pathogenic agents* that could potentially produce adverse consequences associated with the importation of a *commodity*.

The *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each *hazard* is already present in the *importing country*, and whether it is a *listed disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as *hazards* or not *hazards*. The *risk assessment* should be concluded if *hazard* identification fails to identify *hazards* associated with the importation.

The evaluation of the *Aquatic Animal Health Services*, *surveillance* and control programmes, and zoning and compartmentalisation systems are important inputs for assessing the likelihood of *hazards* being present in the *aquatic animal* population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Aquatic Code*, thus eliminating the need for a *risk assessment*.

Article 2.1.3.

Principles of risk assessment

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

Article 2.1.4.

Risk assessment steps

1. Entry assessment

Entry assessment consists of describing the biological pathway(s) necessary for an importation activity to introduce a *pathogenic agent* into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the entry of each of the *hazards* (the *pathogenic agents*) or under each specified set of conditions

with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the entry assessment are:

- a) Biological factors
 - Species, strain or genotype, and age of *aquatic animal*
 - Strain of agent
 - Tissue sites of *infection* and/or contamination
 - Vaccination, testing, treatment and *quarantine*.
- b) Country factors
 - *Incidence* or *prevalence*
 - Evaluation of *Aquatic Animal Health Services*, *surveillance* and control programmes, and zoning and compartmentalisation systems of the *exporting country*.
- c) Commodity factors
 - Whether the *commodity* is alive or dead
 - Quantity of *commodity* to be imported
 - Ease of contamination
 - Effect of the various processing methods on the *pathogenic agent* in the *commodity*
 - Effect of storage and transport on the *pathogenic agent* in the *commodity*.

If the entry assessment demonstrates no significant *risk*, the *risk assessment* does not need to continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of animals and humans in the *importing country* to the *hazards* (in this case the *pathogenic agents*) from a given *risk* source, and estimating the probability of these exposure(s) occurring, either qualitatively (in words) or quantitatively (as a numerical estimate).

The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, and the number, species and other characteristics of the animal and human populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

- a) Biological factors
 - Properties of the agent (e.g. virulence, pathogenicity and survival parameters)
 - Genotype of host.
- b) Country factors
 - Presence of potential vectors or intermediate hosts
 - *Aquatic animal* demographics (e.g. presence of known susceptible and carrier species, distribution)
 - Human and terrestrial animal demographics (e.g. possibility of scavengers, presence of piscivorous birds)
 - Customs and cultural practices
 - Geographical and environmental characteristics (e.g. hydrographic data, temperature ranges, water courses).
- c) Commodity factors
 - Whether the *commodity* is alive or dead
 - Quantity of *commodity* to be imported
 - Intended use of the imported *aquatic animals* or *products* (e.g. domestic consumption, restocking, incorporation in or use as *aquaculture feed* or bait)
 - Waste disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* may conclude at this step.

3. Consequence assessment

Consequence assessment consists of describing the relationship between specified exposures to a biological agent and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability

of them occurring. This estimate may be either qualitative (in words) or quantitative (a numerical estimate). Examples of consequences include:

- a) Direct consequences
 - *Aquatic animal infection, disease*, production losses and facility closures
 - Public health consequences.
- b) Indirect consequences
 - *Surveillance* and control costs
 - Compensation costs
 - Potential trade losses
 - Adverse, and possibly irreversible, consequences to the environment.

4. Risk estimation

Risk estimation consists of integrating the results of the entry assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus *risk* estimation takes into account the whole of the *risk* pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- The various populations of *aquatic animals* and/or estimated numbers of *aquaculture establishments* or people likely to experience health impacts of various degrees of severity over time
- Probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates
- Portrayal of the variance of all model inputs
- A sensitivity analysis to rank the inputs as to their contribution to the variance of the *risk* estimation output
- Analysis of the dependence and correlation between model inputs.

Article 2.1.5.

Principles of risk management

- 1) *Risk management* is the process of deciding upon and implementing measures to address the *risks* identified in the *risk assessment*, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under international trade agreements.
- 2) The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions of the standards.

Article 2.1.6.

Risk management components

- 1) *Risk evaluation* - the process of comparing the *risk* estimated in the *risk assessment* with the reduction in *risk* expected from the proposed *risk management* measures.
- 2) Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of *risk* with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the *risk management* options.
- 3) Implementation - the process of following through with the *risk management* decision and ensuring that the *risk management* measures are in place.
- 4) Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 2.1.7.

Principles of risk communication

- 1) *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis*, and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision-makers and interested parties in the *importing* and *exporting countries*. It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.
 - 2) A *risk communication* strategy should be put in place at the start of each *risk analysis*.
 - 3) The *communication of risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.
 - 4) The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic aquaculturists, recreational and commercial fishermen, conservation and wildlife groups, consumer groups, and domestic and foreign industry groups.
 - 5) The assumptions and uncertainty in the model, model inputs and the *risk* estimates of the *risk assessment* should be communicated.
 - 6) Peer review of *risk analyses* is an essential component of *risk communication* in order to obtain a scientific critique and to ensure that the data, information, methods and assumptions are the best available.
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SECTION 3.

QUALITY OF AQUATIC ANIMAL HEALTH SERVICES

CHAPTER 3.1.

QUALITY OF AQUATIC ANIMAL HEALTH SERVICES

Article 3.1.1.

The quality of *Aquatic Animal Health Services* depends on a set of factors, which include fundamental principles of an ethical, organisational, legislative, regulatory and technical nature. The *Aquatic Animal Health Services* shall conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by a Member Country's *Aquatic Animal Health Service* is important in the establishment and maintenance of confidence in its *aquatic animal health status* and *international aquatic animal health certificates* provided by the *Aquatic Animal Health Service* of other Member Countries.

These fundamental principles are presented in Article 3.1.2. Other factors to consider when evaluating *Aquatic Animal Health Services* are described in the *Aquatic Code* (*notification*, principles of certification, etc.).

The ability of *Aquatic Animal Health Services* to deliver appropriate services, monitor and control *aquatic animal diseases* based on Member Countries' *aquatic animal health* legislation and regulations, can be measured through an evaluation or audit whose general principles are described in Articles 3.1.3. and 3.1.4.

A procedure for evaluating *Aquatic Animal Health Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

Article 3.1.2.

Fundamental principles of quality

Aquatic Animal Health Services should comply with the following principles to ensure the quality of their activities:

1. Professional judgement

Aquatic Animal Health Services should ensure that personnel have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

Care should be taken to ensure that the *Aquatic Animal Health Service* personnel are free from any commercial, financial, hierarchical, political or other pressures which may inappropriately influence their judgement or decisions.

3. Impartiality

Aquatic Animal Health Services should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

Aquatic Animal Health Services are responsible for ensuring that the work of each of their personnel is of a consistently high level of integrity. Any fraud, corruption or falsification should be identified, documented and corrected.

5. Objectivity

Aquatic Animal Health Services should conduct themselves, in an objective, transparent and non-discriminatory manner.

6. Aquatic animal health legislation and regulations

Aquatic animal health legislation and regulations are a fundamental element that supports good governance and provides the legal framework for all key activities of the *Aquatic Animal Health Service*.

Legislation and regulations should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, they should define and document the responsibilities and structure of the organisations in charge of traceability and control of *aquatic animal* movements, *aquatic animal disease* control and reporting systems, epidemiological *surveillance* and communication of epidemiological information.

7. General organisation

Aquatic Animal Health Services should be able to demonstrate that they are able to anticipate the requirements for, and have control of, the establishment and application of *aquatic animal* health measures, and of international *aquatic animal* health certification activities. This should be demonstrated by means of appropriate legislation and regulations, sufficient financial resources and effective organisation.

Aquatic Animal Health Services should have at their disposal effective systems for *aquatic animal disease surveillance, diagnosis* and *notification* of *disease* problems that may occur in the national *territory*, in accordance with the provisions of the *Aquatic Code*. They should at all times endeavour to improve their performance in terms of *aquatic animal* health information systems and *aquatic animal disease* control.

Aquatic Animal Health Services should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international aquatic animal health certificates*.

Each position within the *Aquatic Animal Health Services* that has an impact on their quality should be described.

These job descriptions should include the requirements for education, training, technical knowledge and experience.

8. Quality policy

Aquatic Animal Health Services should define and document their policy and objectives for, and commitment to, quality, and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The recommendations provided in this chapter describe a suitable reference system, which should be used if a Member Country chooses to adopt a quality system.

9. Procedures and standards

Aquatic Animal Health Services should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

- a) programming and management of activities, including international *aquatic animal* health certification activities;
- b) prevention, control and *notification* of *disease outbreaks*;
- c) *risk analysis*, epidemiological *surveillance* and zoning;
- d) emergency preparedness for disasters which could have an impact on *aquatic animal* health and welfare of farmed fish;
- e) inspection and sampling techniques;
- f) diagnostic tests for *aquatic animal diseases*;
- g) preparation, production, registration and control of *biological products* for use in the *diagnostic* or prevention of *diseases*;
- h) border controls and import regulations;
- i) *disinfection*;

j) treatments intended to inactivate pathogens in *aquatic animal* products.

Where there are standards in the *Aquatic Code* or in the *Aquatic Manual*, *Aquatic Animal Health Services* should comply with these standards when applying *aquatic animal* health measures and when issuing *international aquatic animal health certificates*.

10. Information, complaints and appeals

Aquatic Animal Health Services should undertake to reply to requests from *Aquatic Animal Health Services* of other Member Countries or any other authority, in particular ensuring that any requests for information, complaints or appeals that are presented are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by *Aquatic Animal Health Services*.

11. Documentation

Aquatic Animal Health Services should have at their disposal a reliable and up-to-date documentation system suited to their activities.

12. Self-evaluation

Aquatic Animal Health Services should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the effectiveness of their organisational components and resource adequacy.

A procedure for evaluating *Aquatic Animal Health Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

13. Communication

Aquatic Animal Health Services should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.

14. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 3.1.3.

For the purposes of the *Aquatic Code*, every Member Country should recognise the right of another Member Country to undertake, or request it to undertake, an evaluation of its *Aquatic Animal Health Services* where the initiating Member Country is an actual or a prospective importer of *aquatic animal commodities* and/or where the evaluation is to be a component of a *risk analysis* process that is to be used to determine or review *sanitary measures* which apply to such trade.

A Member Country has the right to expect that the evaluation of its *Aquatic Animal Health Services* will be conducted in an objective and transparent manner. A Member Country undertaking an evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 3.1.4.

A Member Country which intends to conduct an evaluation of another Member Country's *Aquatic Animal Health Services* should provide notice in writing, and allow sufficient time for the other Member Country to comply with the request. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Aquatic Animal Health Services* by another Member Country, and following bilateral agreement of the evaluation process and criteria, a Member Country should expeditiously provide the Member Country requesting the evaluation with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 3.1.1. and in Article 3.1.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 3.1.1., prevailing in the countries concerned.

The outcome of an evaluation conducted by a Member Country should be provided in writing as soon as possible, and in any case within four months of receipt of the relevant information, to the Member Country which has undergone the evaluation. The evaluation report should detail any findings that affect trade prospects. The Member Country which conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Member Countries over the conduct or the conclusions of the evaluation of *Aquatic Animal Health Services*, the matter should be dealt with having regard to the procedures set out in Article 3.1.3.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of *Aquatic Animal Health Services* of Member Countries. Member Countries can make a request to the OIE for an evaluation of their *Aquatic Animal Health Services*.

The World Assembly of OIE Delegates may endorse a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE recommends an expert(s) from that list.

The expert(s) facilitate(s) the evaluation of the *Aquatic Animal Health Services* of the Member Country using the OIE *Performance of Veterinary Services and/or Aquatic Animal Health Services (OIE PVS Tool: Aquatic)*.

The expert(s) produce(s) a report in consultation with the Veterinary Services of the Member Country.

The report is submitted to the Director General of the OIE and, with the consent of the Member Country, published by the OIE.

CHAPTER 3.2.

COMMUNICATION

Article 3.2.1.

General considerations

In general, communication entails the exchange of information between various individual, institutional and public groups for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages in accordance with situations, objectives and target audiences.

The recognition of communication as a discipline of the *Aquatic Animal Health Services* and its incorporation within it is critical for their operations. The integration of *aquatic animal* health and communication expertises is essential for effective communication. Communication between the *Aquatic Animal Health Services* and Veterinary Services (particularly where *Aquatic Animal Health Services* are separate from, and independent of Veterinary Services) is especially important.

Communication should be an integral part of all the activities of the *Aquatic Animal Health Services* including animal health (*surveillance*, early detection and rapid response, prevention and control), *aquatic animal* welfare and veterinary public health (food safety, zoonoses) and veterinary medicine.

Objectives of this chapter on communication for the *Aquatic Animal Health Services* are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.2.2.

Principles of communication

- 1) *Aquatic Animal Health Services* should have the authority and capability to communicate on matters within their mandate.
- 2) *Aquatic animal* health and communication expertises should be combined.
- 3) Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of *Aquatic Animal Health Services* (Article 3.1.2.)
- 4) Communication should be a continuous process.
- 5) *Aquatic Animal Health Services* should have oversight of planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.2.3.

Definitions

Communication: means the discipline of informing, guiding and motivating individual, institutional and public groups, ideally on the basis of interactive exchanges, about any issue under the competence of the *Aquatic Animal Health Services*.

Crisis: means a situation of great threat, difficulty or uncertainty when issues under the competence of the *Aquatic Animal Health Services* require immediate action.

Crisis communication: means the process of communicating information as accurately as possible, albeit potentially incomplete, within time constraints in the event of a crisis.

Outbreak communication: means the process of communicating in the event of an *outbreak*. Outbreak communication includes notification.

Article 3.2.4.

Communication system

In addition to the Principles of Communication the following elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system:

1. Organisational chart indicating a direct link between the communication personnel and the Competent Authority, through the chain of command such as dedicated communication unit and communication officer

2. Human resources
 - a) Identified and accessible official communication focal point
 - b) Job descriptions of communication personnel identifying roles and responsibilities
 - c) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication
 - d) Continuous training and education on communication provided to communication personnel.

3. Financial and physical resources
 - a) Clearly identified budget for communication that provides adequate funding
 - b) Provision or access to appropriate material resources in order to carry out roles and responsibilities: suitable premises or accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet.

4. Management of the communication system
 - a) Roles and responsibilities of the communication personnel
 - i) Report to the *Competent Authority*
 - ii) Engage in decision-making process by providing guidance and expertise on communication issues to the *Competent Authority*
 - iii) Be responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures
 - iv) Function as contact point on communication issues for the *Aquatic Animal Health Services*
 - v) Provide and coordinate continuous education on communication for the *Aquatic Animal Health Services*.
 - b) Strategic plan for communication

A well-designed strategic plan for communication should support the *Aquatic Animal Health Services* strategic plan and have management support and commitment. The strategic plan for communication should address all high level organization-wide long-term communication objectives.

A strategic plan for communication should be monitored and periodically reviewed, and should identify measurable performance objectives and techniques to assess the effectiveness of communication.

The strategic plan for communication should consider the different types of communication: routine communication, risk communication, outbreak communication and crisis communication, to allow individuals, affected or interested parties, an entire community or the general public to make the best possible decisions and be informed of policy decisions and their rationale.

The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the *Aquatic Animal Health Services*, higher visibility of and improved trust and credibility in the *Aquatic Animal Health Services*. These will enhance understanding and/or acceptance of policy decisions and subsequent change of perception, attitude and/or behaviour.

c) Operational plans for communication

Operational plans for communication should be based on the assessment of specific issues and should identify specific objectives and target audiences such as staff, partners, stakeholders, media and the general public.

Each operational plan for communication should consist of a well-planned series of activities using different techniques, tools, messages and channels to achieve intended objectives and utilising available resources within a specific timeframe.

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.1.

ZONING AND COMPARTMENTALISATION

Article 4.1.1.

Introduction

Given the difficulty of establishing and maintaining freedom from a particular *disease* for an entire country especially for *diseases* whose entry is difficult to control, there may be benefits to one or more Member Countries in establishing and maintaining a *subpopulation* with a distinct aquatic animal health status. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this chapter to define *subpopulations* of distinct aquatic animal health status for the purpose of *disease* control or *international trade*. Compartmentalisation applies to a *subpopulation* when management practices related to *biosecurity* are the defining factors, while zoning applies when a *subpopulation* is defined on a geographical basis. In practice, spatial considerations and good management play important roles in the application of both concepts.

This chapter is to assist Member Countries wishing to establish and maintain different *subpopulations*, using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.

Before trade in *aquatic animals* or *aquatic animal products* may occur, an *importing country* needs to be satisfied that its *aquatic animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its *territory*.

In addition to contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within Member Countries. Zoning may encourage the more efficient use of resources, and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild *aquatic animals* through *biosecurity* measures, which a *zone* (through geographical separation) would not achieve. Following an *outbreak* of *disease*, compartmentalisation may allow a Member Country be able to take advantage of epidemiological links among *subpopulations* or common practices relating to *biosecurity*, despite diverse geographical locations, to facilitate *disease* control and/or the resumption of trade.

Zoning and compartmentalisation may not be applicable to all *diseases*, but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain the status of a *free zone* or *free compartment* following an *outbreak* of *disease*, Member Countries should follow the recommendations in the relevant *disease* chapter in the *Aquatic Code*.

Article 4.1.2.

General considerations

The *Competent Authority* of an *exporting country* that is establishing a *zone* or *compartment* for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Aquatic Code*, including those on *surveillance*, and the identification and traceability of *aquatic animals*. The *Competent Authority* of an *exporting country* should be able to explain to the *Competent Authority* of an *importing country* the basis for its claim of a distinct *aquatic animal health status* for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, *risk* of introduction and establishment of *disease*, and applicable *biosecurity* measures. The *exporting country* should be able to demonstrate, through detailed documentation supplied to the *importing country*, published through official channels, that it has implemented the recommendations in the *Aquatic Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Aquatic Code* are applied, and the *Competent Authority* of the *exporting country* certifies that this is the case. Note that an *importing country* may adopt a higher level of protection where it is scientifically justified and the obligations referred to in Article 5.3.1. are met.

Where countries share a *zone* or *compartment*, the *Competent Authority* of each country should collaborate to define and fulfil their respective responsibilities.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources and the technical capability of the *Aquatic Animal Health Service* (and of the relevant industry, in the case of a *compartment*) including *disease surveillance* and *diagnosis*.

Article 4.1.3.

Principles for defining a zone or compartment, including protection zones

In conjunction with the above considerations and the definitions of *zone* and *compartment*, the following principles should apply when Member Countries define a *zone* or *compartment*.

- 1) The extent of a *zone* should be established by the *Aquatic Animal Health Service* on the basis of the definition of *zone* and made public through official channels.
- 2) A *protection zone* may be established to preserve the health status of *aquatic animals* in a *free country* or *free zone*, from adjacent countries or zones of different *aquatic animal health status*. Measures should be implemented based on the epidemiology of the *disease* under consideration to prevent introduction of the *pathogenic agent*. These measures should include intensified movement control and *surveillance* and may include vaccination, raised awareness or other measures.
The application of these measures can be in the entire *free zone* or in a defined area within and/or outside the *free zone*.
- 3) The factors defining a *compartment* should be established by the *Aquatic Animal Health Service* on the basis of relevant criteria such as management and husbandry practices related to *biosecurity*, and made public through official channels.
- 4) *Aquatic animals* belonging to such *subpopulations* need to be recognisable as such through a clear epidemiological separation from other *aquatic animals* and all things presenting a *disease risk*.
- 5) For a *zone* or *compartment*, the *Aquatic Animal Health Service* should document in detail the measures taken to ensure the identification of the *subpopulation*, for example by means of registration of all the *aquaculture establishments* located in such a *zone* or *compartment* and the establishment and maintenance of its *aquatic animal health status* through a *biosecurity plan*. The measures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, the *aquatic animal health status* in adjacent areas, applicable *biosecurity* measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *aquatic animals*, and commercial management and husbandry practices), and *surveillance*.
- 6) For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant enterprise/industry and the *Aquatic Animal Health Service*, and their respective responsibilities, including the procedures for oversight of the operation of the *compartment* by the *Aquatic Animal Health Service*.

- 7) For a *compartment*, the *biosecurity plan* should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted and the management practices are adequate to meet the definition of the *compartment*. In addition to information on *aquatic animal* movements, the *biosecurity plan* should include production and stock records, *feed* sources, traceability, *surveillance* results, visitor logbook, morbidity and mortality history, medications, vaccinations, water supply and effluent treatments, documentation of training and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary in accordance with the *aquatic animal* species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.
 - 8) Thus defined, the *zones* and *compartments* constitute the relevant *subpopulations* for the application of the recommendations in Sections 8 to 11.
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CHAPTER 4.2.

APPLICATION OF COMPARTMENTALISATION

Article 4.2.1.

Introduction and objectives

The recommendations in this chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.1. with the objective to facilitate trade in *aquatic animals* and products of aquatic animal origin and as a tool for *disease* management.

Establishing and maintaining a *disease-free* status throughout the country should be the ultimate goal for Member Countries. However, establishing and maintaining a *disease-free* status for an entire country may be difficult, especially in the case of *diseases* that exist in wild *aquatic animal* species or can easily cross international boundaries. For many *diseases*, Member Countries have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based on management and *biosecurity* practices. However, spatial considerations and good management practices play a role in the application of both concepts.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and *biosecurity* measures to create a functional separation of *subpopulations*.

For example, an *aquaculture establishment* in an infected country or *infected zone* might have *biosecurity* measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease-specific* separation between *subpopulations*.

In *disease free countries* or *free zones*, it is preferable that *compartments* are defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *infected zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* should be under the responsibility of the *Competent Authority* in the country. For the purposes of this chapter, compliance by the Member Countries with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.2.2.

Principles for defining a compartment

A *compartment* may be established with respect to a specific *disease* or *diseases*. A *compartment* should be clearly defined. This should indicate, *inter alia*, the location of all its components including *establishments*, as well as related functional units (such as brood stock facilities, hatcheries, nurseries, grow-out facilities, slaughterhouses, processing plants, etc.). It should also describe their interrelationships and their contribution to an epidemiological separation between the *aquatic animals* in a *compartment* and *subpopulations* elsewhere with a different health status. The definition of *compartment* should encompass *disease-specific* epidemiological factors, the *aquatic animal* species in the *compartment*, production systems, *biosecurity* practices, infrastructural factors and *surveillance*.

Article 4.2.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* should provide to the *Aquatic Animal Health Service* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and *biosecurity* measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with *biosecurity* measures and, in some instances, may alter the degree of confidence achieved by general *biosecurity* and *surveillance* measures:

- a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;
- b) location, disease status and *biosecurity* of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:
 - i) *aquatic animal* populations with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;
 - ii) slaughterhouses or processing plants;
 - iii) exhibitions, 'put and take' fisheries, fish markets, restaurants with live fish and other points of *aquatic animal* concentration.

2. Infrastructural factors

Structural aspects of an *establishment* or *establishments* within a *compartment* contribute to the effectiveness of its *biosecurity*. Consideration should be given to:

- a) water supply;
- b) effective means of physical separation;
- c) facilities for people entry including access control;
- d) *vehicle* and vessel access including washing and *disinfection* procedures;
- e) unloading and loading facilities;
- f) isolation facilities for introduced *aquatic animals*;
- g) facilities for the introduction of material and equipment;
- h) infrastructure to store *feed* and veterinary products;
- i) disposal of *aquatic animal* waste;
- j) measures to prevent exposure to fomites, mechanical or biological vectors;
- k) *feed* supply/source.

3. Biosecurity plan

The integrity of the *compartment* relies on effective *biosecurity*. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

- a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including *aquatic animal* movements, wild *aquatic animals*, potential vectors, *vehicles*, people, *biological products*, equipment, fomites, *feed*, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;
- b) the critical control points for each pathway;
- c) measures to mitigate exposure for each critical control point;
- d) standard operating procedures including:
 - i) implementation, maintenance, monitoring of compliance with the *risk* mitigation measures;
 - ii) application of corrective actions;
 - iii) verification of the process;
 - iv) record keeping;
- e) *contingency plan* in the event of a change in the level of exposure;
- f) reporting procedures to the *Competent Authority*;
- g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on *biosecurity* principles and practices;
- h) the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity plan* in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The *biosecurity* risk of all operations of the *compartment* should be re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment,

concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the *pathogenic agent* into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid traceability system. Although individual identification of *aquatic animals* may not be feasible, the *Competent Authority* should provide sufficient assurance of traceability in such a way that their history and movements can be documented and audited.

All *aquatic animal* movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, approved by the *Competent Authority*. Movements within the *compartment* need not be certified but should be recorded and documented at the *compartment* level.

Article 4.2.4.

Documentation

Documentation should provide clear evidence that the *biosecurity*, *surveillance*, traceability and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include production unit records (e.g. cage, pond), *feed* sources, laboratory tests, mortality records, visitor logbook, morbidity history, water supply and effluent treatments, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant chapter of the *Aquatic Code*.

In addition, a *compartment* seeking recognition should submit to the *Competent Authority* a baseline aquatic animal health report indicating the presence or absence of *listed diseases*. This report should be regularly updated to reflect the current aquatic animal health status of the *compartment*.

Vaccination records including the *aquatic animal* groups vaccinated, type of vaccine and frequency of administration should be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary in accordance with the species and *disease(s)* for which the *compartment* was defined.

All relevant information should be recorded in a transparent manner and be easily accessible so as to be auditable by the *Competent Authority*.

Article 4.2.5.

Surveillance for the pathogenic agent or disease

The *surveillance* system should comply with Chapter 1.4. on *surveillance* and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased risk of exposure to the agent for which the *compartment* has been defined, the sensitivity of the internal and external *surveillance* system should be reviewed, documented and, where necessary, increased. At the same time, *biosecurity* measures in place should be reassessed and increased if necessary.

1. Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data so that the *Competent Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

The *biosecurity* measures applied in a *compartment* should be appropriate to the level of exposure of the *compartment*. *External surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of targeted and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., *targeted surveillance* based on an assessment of risk factors may be the most efficient *surveillance* approach. *Targeted surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.2.6.

Diagnostic capabilities and procedures

Officially-designated laboratory facilities should be available for sample testing. All laboratory tests and procedures should comply with the recommendations of the *Aquatic Manual* for the specific *disease*. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Competent Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.2.7.

Emergency response and notification

Early detection, *diagnosis*, *notification* of *disease* and rapid response are critical to minimise the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, the free status of the *compartment* should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.

In case of the detection of any *disease* not present in accordance with the baseline animal health report of the *compartment* referred to in Article 4.2.4., the management of the *compartment* should notify the *Competent Authority*, and initiate a review to determine whether there has been a breach in the *biosecurity* measures and notify the *Competent Authority*. If a significant breach in *biosecurity*, even in the absence of *outbreak*, is detected, export certification as a *free compartment* should be suspended. *Disease-free* status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original *biosecurity* level and the *Competent Authority* re-approves the status of the *compartment*.

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Competent Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional *biosecurity* measures are needed to ensure that the integrity of the *compartment* is maintained.

Article 4.2.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Aquatic Animal Health Services*, including laboratories, should be clearly documented in accordance with Chapter 3.1., to provide confidence in the integrity of the *compartment*.

The *Competent Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Competent Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

CHAPTER 4.3.

GENERAL RECOMMENDATIONS ON DISINFECTION

Article 4.3.1.

Disinfection is employed as a common *disease* management tool in *aquaculture*. *Disinfection* procedures should be part of a *disinfection* programme designed for a specific purpose. *Disinfection* may be used in *biosecurity* programmes to eradicate or exclude specific *diseases* from *aquaculture establishments*, as well as a routine *sanitary measure* to reduce *disease incidence* within *aquaculture establishments*.

Disinfection of installations and equipment and transport units should be carried out using procedures that prevent the contamination of other water and other *aquatic animal* populations with infectious material. There is a great variety of products and procedures for washing and disinfecting installations or equipment used in *aquaculture establishments* or for treating effluents, and wastes from *quarantine* and processing plants. The decision on which product to use should take into account their microbiocidal efficacy, their safety for *aquatic animals* and the environment.

Article 4.3.2.

The manufacturer's instructions for effective use of a *disinfectant* under *aquaculture* conditions should be followed. *Disinfectants* to be used in *aquaculture* should be evaluated/tested against relevant aquatic pathogens under relevant conditions. Approved procedures for the use of *disinfectants* in *aquaculture* should be established.

The efficacy of *disinfection* is affected by various factors, including temperature, pH, and the presence of organic matter. At high temperatures, the disinfecting action is faster as long as the decomposition of the *disinfectant* does not occur. At low temperatures, the biocidal efficacy of most *disinfectants* decreases. Many *disinfectants* have an optimum pH range/level, and product choice should depend on the pH of the diluent (water). For example, quaternary ammonia is more efficient at alkaline pH while iodine and iodophores are more efficient at neutral or acid pH. The presence of organic material and greasy substances may significantly reduce the efficacy of a *disinfectant*. Therefore, surfaces should be cleaned thoroughly before applying *disinfectants*.

The use of *disinfectants* may require measures to protect personnel, *aquatic animals* and the environment. The manufacturer's instructions for safe use and disposal should be followed.

Article 4.3.3.

Specific *disinfection* procedures are provided in Chapter 1.1.3. of the *Aquatic Manual*.

CHAPTER 4.4.

RECOMMENDATIONS FOR SURFACE DISINFECTION OF SALMONID EGGS

Article 4.4.1.

Introduction

The practice of disinfecting salmonid *eggs* at hatcheries is an essential part of ensuring that endemic *diseases* are not transferred between incubators and between facilities and forms a part of routine hatchery hygiene protocols. The *disinfection* process is also important when trading salmonid *eggs* between *compartments*, *zones* or countries to prevent the transfer of some *pathogenic agents*. Although generally effective for *disinfection* of the *egg* surface and reproductive fluids, the use of *disinfectants* will not prevent vertical transmission.

Salmonid *eggs* may be disinfected with a number of chemical agents. However, the most common method used is *disinfection* with the iodine-based product, povidone-iodine.

Iodophores, commonly povidone-iodine solutions, have the advantage of providing a neutral pH, being non-irritant and are relatively non-toxic. The neutral pH is important for minimising toxicity and ensuring efficacy. It is recommended to follow manufacturer's instructions to identify circumstances where pH may be a concern. If other iodine based agents are used for *disinfection* it is essential that they be adequately buffered.

Article 4.4.2.

Disinfection protocol for salmonid eggs

This *disinfection* protocol may be applied to newly fertilised or eyed salmonid *eggs*. However newly fertilised *eggs* should be allowed to commence hardening prior to undergoing the *disinfection* protocol. Although there is a considerable margin of safety for hardened *eggs*, the *disinfection* protocol is not recommended for unfertilised ova or during fertilisation. It is essential that the pH of the iodophore solution is maintained between 6 and 8.

To disinfect salmonid *eggs* the following protocol should be applied:

- 1) rinsed in 0.9% pathogen free saline (30-60 seconds) to remove organic matter; then
- 2) immersed in a iodophore solution containing 100 ppm available iodine for a minimum of 10 minutes. The iodophore solution should be used only once. The ratio of *eggs* to iodophore solution should be a minimum of 1:4; then
- 3) rinsed again in 0.9% pathogen free saline for 30-60 seconds; then
- 4) held in pathogen free water.

All rinsing and *disinfection* solutions should be prepared using pathogen free water. Iodophore solutions may be buffered using sodium bicarbonate (NaHCO₃) if the pH is low.

CHAPTER 4.5.

CONTINGENCY PLANNING

Article 4.5.1.

A number of *diseases* are regarded as posing a potential threat to *aquaculture* as well as to wild stocks of *aquatic animals* world-wide. The introduction of such *diseases* into countries recognised to be free from these *diseases* or into countries with an established control system and eradication programme for such *diseases*, may result in significant losses. In order to diminish such losses, the *Competent Authority* responsible for *aquatic animal* health may need to act quickly and should develop a *contingency plan(s)* before such events occur.

Article 4.5.2.

Legal powers

Countries must establish the necessary legal provisions that are needed for the implementation of a *contingency plan(s)*. Such legal powers must include provisions for establishing a list of *diseases* for which action is needed, definitions of how such *diseases* should be managed if detected, provisions for access to infected/suspected sites, and other legal provisions, as needed.

Article 4.5.3.

Crises centre(s)

Countries must establish specified crises centre(s) (*disease control centre[s]*) that shall have the responsibility for the co-ordination of all control measures to be carried out. Such centres could either be located centrally or locally, depending on the infrastructure in a given country. A list of the crises centre(s) that has(have) the necessary facilities to carry out *disease control* measures should be made widely available.

The *contingency plan(s)* should also state that the crises centre(s) has(have) the authority to act rapidly to bring a given *disease* situation under control by contacting the personnel, organisations, *aquaculture establishments*, etc., that are involved directly or indirectly in managing an *outbreak* of a *disease*.

Article 4.5.4.

Personnel

The *contingency plan(s)* should provide information on the staff required to undertake the control measures, their responsibilities, and instructions on the chain of command.

Article 4.5.5.

Instructions

Countries establishing a *contingency plan(s)* should provide a detailed set of instructions on actions to be taken when a specified *aquatic animal disease* is suspected or confirmed. These could include:

- 1) diagnostic procedures in national reference laboratories;
- 2) confirmation of *diagnosis*, if necessary, at an OIE Reference Laboratory;
- 3) standing instructions to *aquatic animal* health personnel in the field;
- 4) instructions for handling/disposal of dead *aquatic animals* at an *aquaculture establishment*;
- 5) instructions for sanitary slaughtering;

- 6) instructions for *disease* control at the local level;
- 7) instructions for the establishment of *quarantine* areas and observation (*surveillance*) zones;
- 8) provisions for controlling movements of *aquatic animals* in established zones;
- 9) *disinfection* procedures;
- 10) *fallowing* procedures;
- 11) *surveillance* methods for establishing successful eradication;
- 12) re-stocking procedures;
- 13) compensation issues;
- 14) reporting procedures;
- 15) provisions for raising public awareness of *aquatic animal disease*.

Article 4.5.6.

Diagnostic laboratories

Countries establishing a *contingency plan(s)* should establish national reference laboratories having the necessary facilities for diagnostic work on *aquatic animal diseases* that can be carried out rapidly. The national laboratory(ies) must also have established a set of instructions as regards rapid transportation of samples, and established protocols for quality assurance and diagnostic procedures to be used.

Article 4.5.7.

Training programmes

Countries establishing a *contingency plan(s)* must establish necessary training programmes to ensure that skills in field, administrative and diagnostic procedures are maintained. Announced and unannounced field exercises for administrators and *aquatic animal* personnel should be carried out to maintain the state of readiness.

CHAPTER 4.6.

FALLOWING IN AQUACULTURE

Article 4.6.1.

Introduction

Gaps in *aquaculture* production at the same location are commonly recognised to be of value in resting or restoring the local environment. As part of this strategy, *fallowing* can break re-infection cycles by removing loci of a *disease* from a farm. Consequently, *fallowing* is often carried out as a regular *disease* management measure in *aquaculture*, especially prior to the introduction of new populations of *aquatic animals* into a previously used site. In order to promote improved health in *aquaculture*, the *Aquatic Animal Health Service* in a country may encourage the use of *fallowing* as a routine management strategy for many *diseases*. Account should be taken of the likely beneficial effects of *fallowing* in proportion to the economic costs involved. The *Aquatic Animal Health Service* should also consider such factors as the level of *risk* to the local and national *aquaculture* operations, previous knowledge of the severity of a *disease(s)*, the infective period and distribution of the *pathogenic agent(s)*, the socioeconomic conditions, and benefits pertaining to the general aquatic resources. When the infective period is not known, the farm may be fallowed for a period, the length of which should be based on a *risk assessment*.

However, where an official *stamping-out policy* is being carried out for a *disease* of concern, the *Aquatic Animal Health Service* should require that an infected *aquaculture establishment*, and all other *aquaculture establishments* in an officially established *infected zone*, be subjected to a required period of *fallowing*, if necessary synchronised.

Article 4.6.2.

Legal powers

In cases where *fallowing* may be a compulsory measure, for instance in the establishment or restoration of a *disease free zone*, countries should establish a legal framework for the implementation of *fallowing* procedures in *aquaculture establishments*. Legal provisions could include:

- 1) defining the *disease* circumstances when *fallowing* or synchronised *fallowing* is required;
- 2) defining mechanisms based on *risk assessment* where individual *disease*-specific measures may be determined, including *disinfection* and the length of the *fallowing* period prior to the re-introduction of *susceptible species*;
- 3) following permission by the *Competent Authority* to restock with *susceptible species*, defining a period of *surveillance* and *diagnostic* to verify freedom from the specified *disease*.

Article 4.6.3.

Technical parameters for the implementation of a statutory fallowing plan

Fallowing of a farm should start immediately after:

- 1) removal of all *susceptible species* of *aquatic animals* for the *disease* of concern; and
- 2) removal of all species capable of acting as carriers of the *disease* of concern; and
- 3) if appropriate, removal of other species; and
- 4) removal of water in which infected stocks have been held, where feasible; and
- 5) equipment and other materials contaminated or otherwise capable of harbouring *infection* have either been removed or subjected to *disinfection* to standards approved by the *Aquatic Animal Health Service*.

The length of the statutory *fallowing* period should be based on scientific evidence of the likelihood of a *pathogenic agent* remaining infective outside its *aquaculture* host(s) in the local environment, at a level likely to cause an unacceptable risk of re-infection of the *aquaculture establishment*. Account should be taken of the extent of the *disease outbreak*, local availability of alternative hosts, the survival and infectivity characteristics of the *pathogenic agent* and the local climatological, geographical and hydrographical factors. In addition, the level of *risk* to the local *aquaculture* industry and

wider aquatic resources may be included. A scientifically based *risk assessment* approach should be used to determine the length of the *fallowing* period.

Article 4.6.4.

Instructions

Countries establishing *fallowing* procedures should develop a detailed set of instructions for *disinfection of aquaculture establishments* prior to *fallowing*. For this purpose, the instructions set out in Chapter 4.3. of the *Aquatic Code* and in Chapter 1.1.3. of the *Aquatic Manual* should be used as guidelines, taking into account current scientific knowledge on the efficacy of the treatments for the *pathogenic agent* of concern.

Article 4.6.5.

Restocking

No *aquaculture establishment* that has been under compulsory *fallowing* should be restocked until the *fallowing* period has been completed and permission from the *Competent Authority* has been received. When restocking, care should be taken not to use stocks of *aquatic animals* that would compromise the objectives of the *fallowing* procedure.

To increase confidence in the effectiveness of the *fallowing* procedures, all farms subjected to compulsory *fallowing* should have a period of high level official *surveillance* after *susceptible species* have been restocked. The duration and intensity of the *surveillance* should be appropriate for the *disease* of concern and local conditions.

CHAPTER 4.7.

HANDLING, DISPOSAL AND TREATMENT OF AQUATIC ANIMAL WASTE

Article 4.7.1.

Introduction

The objective of this chapter is to provide guidance on storage, transport, disposal and treatment of *aquatic animal* wastes so as to manage *risks* to *aquatic animal* health. The recommendations in this chapter are general in nature. The choice of one or more of the recommended methods should comply with relevant local and national legislation.

Disposal methods should take into consideration a range of factors, including the cause of mortality. It may be appropriate to carry out a *risk assessment* on the disposal options.

In the case of killing of animals for disease control purposes or unusually large mortalities, this may require approval from, or supervision by, the *Competent Authority*.

In the event of *aquatic animal* mortalities of a significant nature in *aquaculture* or in the wild, the *Competent Authority* should be notified so that necessary steps can be taken to dispose of the dead *aquatic animals*, in order to minimise the *risk* for possible spread of *aquatic animal disease*.

Article 4.7.2.

Scope

The scope of this chapter covers *aquatic animal* waste derived from: i) routine *aquaculture* operations; ii) on shore processing, irrespective of origin; iii) mass killing for disease control purposes and iv) mass mortality (including in the wild).

Article 4.7.3.

Definitions

Aquatic animal waste means the entire body or parts of *aquatic animals* that have died or been killed for disease control purposes as well as slaughtered *aquatic animals*, and their parts, that are not intended for human consumption.

High risk waste means *aquatic animal* waste that constitutes, or is suspected of constituting, a serious health *risk* to *aquatic animals* or humans.

Low risk waste means *aquatic animal* waste that is not high risk waste.

Article 4.7.4.

Governance

The *Competent Authority* should oversee the efficient and effective disposal of *aquatic animal* waste. Cooperation among all relevant agencies and stakeholders involved in *aquatic animal* health is necessary to ensure safe handling and disposal. In this context the following aspects should be addressed:

- 1) physical, logistical and data access by relevant personnel, in cooperation with stakeholders, including access of the *Competent Authority* to the *aquatic animal* waste;
- 2) movement controls and the authority to make exemptions under certain *biosecurity* conditions, for example for transport of *aquatic animal* waste to another location for disposal;

- 3) the determination of the method and location of disposal, and the necessary equipment and facilities, by the *Competent Authority*, in consultation with other authorities including government organisations responsible for the protection of human health and the environment.

Article 4.7.5.

Storage, transport and labelling

Following collection, *aquatic animal* waste should be stored for the minimum time practical; however, where storage is necessary there should be sufficient capacity for the expected waste and the *Competent Authority* may require additional measures.

The storage area should be separated from *aquaculture* sites and bodies of water to minimise the *risk* of spread of *pathogenic agents*. The containers of stored *aquatic animal* waste should be leak-proof and secured to prevent contact with *aquatic animals*, other animals or birds and unauthorised personnel.

Aquatic animal waste infected by an agent causing a *disease* referred to in the *Aquatic Code* or suspected of being so, may not be transported without permission from the *Competent Authority*. The *Competent Authority* may assess the requirement for this condition based on the disease situation in the Member Country (e.g. where a *disease* referred to in the *Aquatic Code* is enzootic in the Member Country).

If low risk waste becomes contaminated with high risk waste, such waste should then be considered high risk waste.

Containers used for transport of *aquatic animal* waste should be leak-proof and labelled regarding content. Transport should be accompanied by appropriate documentation detailing origin, content and destination to allow tracing if required.

Equipment used for transportation should be cleaned and disinfected before being returned, as described in Chapter 4.3.

Article 4.7.6.

Approval and operational requirements of disposal plants

1. Requirement for approval

All disposal plants dealing with *aquatic animal* waste should be approved by the *Competent Authority*. However, disposal plants using only low risk waste for production of products not intended to be used in animals may be exempted from approval but should be registered by the *Competent Authority*.

2. Conditions for approval

For a disposal plant to be approved to deal with *aquatic animal* waste, it should:

- a) be adequately separated from thoroughfares through which contamination may be spread, other premises (such *aquaculture* facilities, slaughterhouses, processing plants) and bodies of water, so as to minimise the *risk* of spread of *pathogenic agents*;
- b) be designed and equipped to the satisfaction of the *Competent Authority*;
- c) have access to approved or accredited laboratories;
- d) fulfil requirements for handling the *aquatic animal* waste and products specified by the *Competent Authority*.

Any substantial proposed changes to the disposal plant should be approved by the *Competent Authority*.

Approval should be withdrawn or suspended, as appropriate, if a disposal plant no longer fulfils the criteria given by the *Competent Authority*.

3. Operating requirements

The disposal plant should operate using procedures that minimise the *risk* of spread of *pathogenic agents*, including:

- a) separation of clean and unclean areas, including consideration of workflow, and good hygienic procedures for personnel;
- b) equipment and surfaces should be easy to clean and disinfect;
- c) handling and treatment of *aquatic animal* waste should take place as soon as possible after being received;
- d) effluent waste water should be collected and disinfected before leaving the premises;

- e) incorporating measures to prevent access of birds, insects, rodents or other animals to the disposal plant;
- f) a system for registration and labelling of material for tracing purposes.

A system for internal control, identifying critical points and means of control for such points, should be in place at the disposal plants. A general documentation system for internal control including sampling for control of critical points should be established.

Spot checks of batches should be carried out to check the microbiological standards following processing. Products from incineration plants may be exempted from such checks. The *Competent Authority* may grant exemptions on specified conditions.

If testing of the product from processed high risk waste shows that the product is not satisfactorily produced and thus poses a *risk* for the spread of *pathogenic agents*, disposal plants should report immediately to the *Competent Authority* who may then require additional measures. These products should not be transported from disposal plants without permission from the *Competent Authority*.

Results from the different samples and checks should be kept for a given period decided upon by the *Competent Authority*. Analyses and sampling should be carried out in accordance with international standards.

Disposal plants applying treatments based on time and pressure should be able to measure and record these parameters.

Disposal plants should maintain records related to quantity and type of raw material received, supplier, quantity and type of finished product, receivers, critical check points, and deviations from provisions stipulated in relevant regulations. These should be made available to the *Competent Authority* on request.

Article 4.7.7.

Methods for disposal of high risk waste

Recommended methods for disposal of high risk waste from *aquatic animals* are as follows:

1. Rendering

Rendering will inactivate all of the known *aquatic animal pathogenic agents*.

Rendering is generally carried out in a closed system using a combination of mechanical treatments and time/temperature combinations leading to stable, sterilised products, such as fish *meal* and fish oil.

The process typically involves pre-heating to 50–60°C, followed by cooking of the raw waste at 95–100°C for 15 to 20 minutes. The oil and proteins are separated by pressing and centrifuging involving temperatures of 90°C. The production of *meal* involves further high temperature treatments.

2. Incineration

Incineration is a controlled burning process carried out in fixed incinerators or mobile air curtain incinerators. Mobile air curtain incinerators enable the process to be carried out on site thus removing the need to transport the *aquatic animal waste*.

Incinerators may only be capable of handling limited volumes of *aquatic animal waste*.

3. Sterilisation

The minimum requirement for sterilisation is a core temperature of at least 90°C for at least 60 minutes, but other time/temperature combinations are also available and effective.

4. Composting

Composting does not inactivate all *pathogenic agents*; therefore, high risk waste should be heated (85°C for 25 minutes or an equivalent temperature/time combination) prior to the composting process.

Effective composting depends upon a combination of pH, temperature, moisture and time factors. Depending on the type of composting (e.g. windrows, closed vessel) and the raw material used, as well as the climatic conditions, the temperature parameters of the process and the heat distribution in the material may be different.

When held in windrows, the entire material needs an exposure time of at least two weeks at 55°C, while in closed vessels exposure to 65°C for one week is required.

5. Biogas production

Biogas production does not inactivate all *pathogenic agents*; therefore, high risk waste should be treated to ensure inactivation of *pathogenic agents* prior to the biogas production process. The method chosen should be shown to inactivate the *pathogenic agents* of concern.

Biogas production is a process whereby organic matter in biological waste products is fermented under anaerobic conditions.

The two main types of biogas production are mesophilic anaerobe digestion and thermophilic anaerobe digestion. Both processes are normally continuous, and a portion of the end material is removed every 2–12 hours. There is a risk that new material which has been in the reactor for only 2–12 hours may be removed with the finished products.

6. Ensiling

Ensiling does not inactivate all *pathogenic agents*; therefore, high risk waste should be heated (85°C for 25 minutes or an equivalent temperature/time combination) prior to the ensiling process.

Ensiling of *aquatic animal* waste in an organic acid such as formic acid is an effective method of inactivating most *pathogenic agents* within 48 hours. The pH in the ensiling process should be maintained at, or below, 4.0 throughout the process.

7. Burial

Burial may take place either in a landfill site or other locations approved by the *Competent Authority* based on *risk assessments* as regards *aquatic animal* health, public health and possible environmental impacts.

Whenever possible, the *aquatic animal* waste should be subjected to a treatment that ensures inactivation of the *pathogenic agents* prior to burial.

In selecting an acceptable burial site, consideration should be given to the following:

- a) Location – the possible effects of the fire's heat, smoke and odour on nearby structures, underground and aerial utilities, roads and residential areas. The site should be surrounded by an adequate firebreak.
- b) Access – easy access for equipment and delivery of *aquatic animal* waste. Fencing and restricted admittance may be necessary.
- c) Pit construction – rocky areas should be avoided. Soils with good stability, capable of withstanding the weight of equipment used to dig and fill the pits, should be selected. If required, diversion banks can be constructed to prevent surface runoff entering the pit or to prevent any liquids escaping from the burial site. Pit dimensions depend on the volume of the *aquatic animal* waste to be buried and should be easy to fill.
- d) Pit closure – contents should be covered with unslaked lime (CaO) at a rate of 85 kg per 1,000 kg of *aquatic animal* waste to hasten decomposition and prevent scavenging.

8. Pyre-burning

Pyre-burning may not be suitable for large amounts of *aquatic animal* waste.

In selecting an acceptable pyre-burning site, the following considerations are important:

- a) Location – the possible effects of the fire's heat, smoke and odour on nearby structures, underground and aerial utilities, roads and residential areas. The site should be surrounded by an adequate firebreak.
- b) Access – for equipment to construct the pyre and maintain the fire, for the delivery of fuel and *aquatic animal* waste.

Pyre-burning needs considerable amounts of fuel and all required fuel should be on site before the burning is started. If the pyre-burning is carried out correctly, *aquatic animal* wastes will be destroyed within 48 hours.

When leaving the pyre-burning site, *vehicles* and containers should be disinfected.

Alternatively, high risk waste may be disposed of by any methods, approved by the *Competent Authority*, which ensure an equivalent reduction of *risk*.

Article 4.7.8.

Methods of disposal for low risk waste

Low risk waste can be disposed of using all methods described in Article 4.7.7. In the case of composting or biogas production it is not necessary to heat treat the low risk waste prior to disposal.

Alternatively, the following methods may be used:

1. Ensiling

Ensiling of *aquatic animal* waste in an organic acid such as formic acid is an effective method of inactivating most *pathogenic agents* within 48 hours. The pH in the ensiling process should be maintained at, or below, 4.0 throughout the process.

The *Competent Authority* may require ensiling as a treatment prior to one of the disposal methods described in Article 4.7.7.

2. Pasteurisation

Pasteurisation does not inactivate all *pathogenic agents*. Heat treatment at temperatures below 100°C can be considered as pasteurisation. Pasteurisation may use a range of time/temperature combinations.

In addition, the *Competent Authority* may permit low risk waste to be disposed of by other means, or used for any other purposes, following an *assessment of the risk* from such methods or uses.

Article 4.7.9.

Mass mortality events

Mass mortality of *aquatic animals* can arise from natural events or killing for disease control purposes (refer to Chapter 7.4.). This may lead to the need for disposal of large numbers of dead *aquatic animals* and is often subject to intense public and media scrutiny. The *Competent Authority* should conduct disposal operations within acceptable scientific principles that will address the *risks* of spread of the *pathogenic agent*, and public and environmental concerns.

1. Preparedness

Successful disposal with minimum delay is achieved by advance planning and preparation:

- a) Preparedness planning should engage other relevant government agencies and stakeholders such as industry organisations, animal welfare organisations, emergency response organisations, and media.
- b) Standard operating procedures should be developed (including documented decision-making processes, training of staff).
- c) Pre-arranged mechanisms to access emergency funding for the disposal operation.
- d) Information sharing with officials involved in the disposal operation, stakeholders, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.
- e) Resource readiness planning should address such items as personnel, transport, storage facilities, equipment, fuel, protective clothing and logistical support. Special equipment, such as well boats, may be required.

2. Critical elements

Critical elements which need to be considered in planning and implementation include:

- a) rapid disposal of the dead *aquatic animals*;
- b) methods of treatment and disposal should address capacity issues and the *risks* of spread of *pathogenic agents*;
- c) adequate funding and staff resources;
- d) addressing the *risk* of spread of *pathogenic agents* by vectors and fomites;
- e) stakeholder cooperation;
- f) safety of personnel;
- g) environmental concerns;
- h) societal acceptance.

3. Choice of disposal methods

The *Competent Authority* may determine the dead *aquatic animals* to be either high risk waste or low risk waste and select an appropriate disposal method in accordance with the risk (refer to Articles 4.7.7. and 4.7.8.).

Should the chosen disposal option be applied near the border of a neighbouring country, the *Competent Authority* of that country should be informed.

CHAPTER 4.8.

CONTROL OF PATHOGENIC AGENTS IN AQUATIC ANIMAL FEED

Article 4.8.1.

Introduction

Feed can be a source of infectious *disease* in *aquatic animals*.

Because *aquatic animals* are often a principal ingredient in *feed* for *aquatic animals*, and because the use of semi-processed, raw and live *feed* continues to be a common practice, the *risk* of *disease* transmission via *feed* should be addressed.

Article 4.8.2.

Purpose and scope

The purpose of this chapter is to address transmission of infectious *diseases* of *aquatic animals* via *feed* to prevent entry and spread into a country, *zone* or *compartment* free from *pathogenic agents* of concern.

This chapter applies to the production and use of all products destined for *feed* and *feed ingredients* whether produced commercially or on farm.

Risk analysis principles (in accordance with Chapter 2.1.) should be applied to determine the *risks* associated with the production and use of *feed* in *aquatic animals*.

This chapter is complementary to guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

Article 4.8.3.

Responsibilities

The responsibilities of the *Competent Authority* include setting and enforcing regulatory requirements related to animal *feed*, and verifying that these requirements are met. This also includes raising awareness about *risks* related to use of unprocessed or semi-processed *feed* in *aquaculture*.

Feed producers have the responsibility to ensure that production of *feed* is performed in a manner to prevent the spread of *diseases* of *aquatic animals*. Records and contingency plans should be in place, as appropriate, to enable the tracing, recall, or destruction of non-compliant products. All personnel involved in the harvest, manufacture, transport, storage and handling of *feed* and *feed ingredients* should be adequately trained and aware of their role and responsibility in preventing the spread of infectious *diseases* of *aquatic animals*. Equipment for producing, storing and transporting *feed* and *feed ingredients* should be kept clean and maintained in good working order.

Owners and managers of *aquaculture establishments* should adhere to regulatory requirements and implement *biosecurity plans* on their farms in order to manage *risks* related to the use of semi-processed, raw and live *feed*. This can be done through identification of *disease* free sources and record keeping for traceability purposes, implementation of on farm *risk* mitigation measures, and early detection of infectious *diseases*.

Private veterinarians and other *aquatic animal health professionals* providing specialist services to producers and to the *feed* industry may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. *disease* reporting, quality standards, transparency).

Article 4.8.4.

Hazards associated with aquatic animal feed

Biological hazards that may be present in *feed* and *feed ingredients* include *pathogenic agents* such as bacteria, viruses, fungi, and parasites. The scope of these recommendations covers *listed diseases* and other *pathogenic agents* that cause an adverse effect on *aquatic animal* health.

Chemical and physical hazards associated with *feed* and *feed ingredients* are not addressed in this chapter.

Antimicrobial resistance arising from the use of *antimicrobial agents* in *feed* is addressed in Section 6.

Article 4.8.5.

Risk pathways and exposure

Feed may be contaminated with *pathogenic agents* present at the time of harvesting, transport, storage and processing of *commodities* used as *feed ingredients*. Contamination may also occur during manufacture, transport, storage and use of *feed*. Poor hygienic practices during processing and manufacture, transport and storage are potential sources of contamination with *pathogenic agents*.

Aquatic animals can be directly exposed to *pathogenic agents* in *feed*. *Aquatic animals* can also be indirectly exposed through contamination of the environment by *feed*.

Article 4.8.6.

Risk management

1. Use of safe feed and feed ingredients

Some *commodities* undergo significant processing such as heat treatment, acidification, extrusion and extraction. There may be a negligible likelihood that *pathogenic agents* will survive in such products if they have been produced in accordance with Good Manufacturing Practice.

Criteria provided in Chapter 5.4. may be used to assess the safety of *commodities* to be used as *feed* or *feed ingredients*.

Articles X.X.3. of all *disease-specific* chapters in Sections 8 to 11 list *commodities* considered safe for any purpose including use as *feed* or *feed ingredients*.

Competent Authorities should also consider sourcing *feed* and *feed ingredients* from a country, *zone* or *compartment* free from *pathogenic agents* of concern.

2. Use of feed and feed ingredients from sources that may not be free from pathogenic agents of concern

When using *feed* and *feed ingredients* from sources that may not be free from *pathogenic agents* of concern, *Competent Authorities* should consider the following *risk* mitigation measures:

- a) treatment (e.g. by heating or acidification) of the *commodity* using a method approved by the *Competent Authority* to inactivate *pathogenic agent(s)* as per Articles X.X.10. (for Chapter 10.4. the relevant Article is 10.4.14.) of all *disease-specific* chapters in Sections 8 to 11; or
- b) confirmation (e.g. by testing) that *pathogenic agents* are not present in the *commodity*; or
- c) use of *feed* only in populations that are not susceptible to the *pathogenic agent(s)* in question and where *susceptible species* will not come into contact with the *feed* or its waste products.

3. Feed production

To prevent contamination by *pathogenic agents* during processing, manufacture, storage and transport of *feed* and *feed ingredients*, the following is recommended:

- a) flushing, sequencing or physical cleaning-out of manufacturing lines and storage facilities should be performed between batches as appropriate;
- b) buildings and equipment for processing and transporting *feed* and *feed ingredients* should be constructed in a manner that facilitates hygienic operation, maintenance and cleaning and prevents contamination;

- c) *feed* manufacturing plants should be designed and operated in a manner that avoids cross-contamination between batches;
 - d) processed *feed* and *feed ingredients* should be stored separately from unprocessed *feed ingredients*, under appropriate storage conditions;
 - e) *feed* and *feed ingredients*, manufacturing equipment, storage facilities and their immediate surroundings should be kept clean;
 - f) measures to inactivate *pathogenic agents*, such as heat treatment, should be used where appropriate;
 - g) labelling should provide for the identification of *feed* and *feed ingredients* as to the batch, place and date of production to assist in tracing *feed* and *feed ingredients*.
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SECTION 5.

TRADE MEASURES, IMPORTATION/EXPORTATION PROCEDURES AND HEALTH CERTIFICATION

CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

Article 5.1.1.

A combination of factors should be taken into account to facilitate *international trade* in *aquatic animals* and *aquatic animal products*, without incurring unacceptable *risks* to human and *aquatic animal* health.

Because of differences between countries in their *aquatic animal* health situations, various options are offered by the *Aquatic Code*. The *aquatic animal* health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements for trade. To maximise harmonisation of the *aquatic animal* health aspects of *international trade*, *Competent Authorities* of Member Countries should base their import requirements on OIE standards.

These requirements should be included in the certificates drawn up in accordance with the model *international aquatic animal health certificates* provided for in Chapter 5.11.

Certificates should be exact and concise, and should clearly address the requirements of the *importing country*. For this purpose, prior consultation between *Competent Authorities* of *importing* and *exporting countries* may be necessary. This consultation helps to determine the exact requirements of the certification.

Certificates should be issued and signed by a *certifying official* authorised by the *Competent Authority* to perform inspections, and endorsed through signature and/or official stamp of the *Competent Authority*. The certification requirements should not include conditions for *diseases* that are not transmitted by the *commodity* concerned. The certificate should be signed in accordance with the provisions of Chapter 5.2.

When officials of a *Competent Authority* wish to visit another country for matters of professional interest to the *Competent Authority* of the other country, the latter should be informed prior to any such visit. This visit should be mutually agreed upon between *Competent Authorities*.

Article 5.1.2.

Responsibilities of the importing country

- 1) The import requirements included in the *international aquatic animal health certificate* should assure that *commodities* introduced into the *importing country* comply with OIE standards. *Importing countries* should align their requirements with the recommendations in the relevant standards of the OIE. If there are no such recommendations or if the country chooses a level of protection requiring measures more stringent than the standards of the OIE, these should be based on an import *risk analysis* conducted in accordance with Chapter 2.1.

- 2) The *international aquatic animal health certificate* should not include requirements for the exclusion of *pathogenic agents* or *aquatic animal diseases* that are present in the *importing country* and are not subject to any official control programme. The measures imposed on imports to manage the *risks* posed by a *pathogenic agent* or *aquatic animal disease* should not be more stringent than those applied as part of the official control programme operating within the *importing country*.
- 3) The *international aquatic animal health certificate* should not include measures against *pathogenic agents* or *diseases* that are not OIE listed, unless the *importing country* has demonstrated through an *import risk analysis*, carried out in accordance with Section 2, that the *pathogenic agent* or *disease* poses a significant *risk* to the *importing country*.
- 4) The transmission of the requirements of the *importing country* or certificates from the *Competent Authority* of the *importing country* and the communication of import requirements to persons other than the *Competent Authority* of another country necessitates that copies of these documents be also sent to the *Competent Authority* of the *exporting country*. This important procedure avoids delays and difficulties that may arise between traders and *Competent Authorities* when the authenticity of the certificates or permits is not established.

The transmission of this information is the responsibility of *Competent Authorities* of the *exporting country*. However, it can be issued by private sector *veterinarians* at the place of origin of the *commodities* when this practice is the subject of appropriate approval and authentication by *Competent Authorities*.
- 5) Situations may arise that result in changes to the consignee, identification of the means of transportation, or *frontier post* after a certificate is issued. If it is determined that these do not change the *aquatic animal* health or public health status of the consignment, then they should not prevent the acceptance of the certificate.

Article 5.1.3.

Responsibilities of the exporting country

- 1) An *exporting country* should, on request, supply the following to *importing countries*:
 - a) information on the aquatic animal health situation and national aquatic animal health information systems to determine whether that country is free or has *zones* or *compartments* free from *listed diseases*, and on the pathway followed to achieve disease freedom e.g. historical freedom, absence of *susceptible species* or *targeted surveillance*, including the regulations and procedures in force to maintain the free status;
 - b) regular and prompt information on the occurrence of *listed diseases*;
 - c) details of the country's ability to apply measures to control and prevent *listed diseases*;
 - d) information on the structure of the *Competent Authority* and the authority that they exercise;
 - e) technical information, particularly on biological tests and vaccines applied in all or part of the country.
- 2) *Competent Authorities* of *exporting countries* should:
 - a) have official procedures for the authorisation of *certifying officials*, defining their functions and duties as well as conditions of oversight and accountability, including possible suspension and termination of the authorisation;
 - b) ensure that relevant instructions and training are provided to *certifying officials*;
 - c) monitor the activities of the *certifying officials* to verify their integrity and impartiality.
- 3) The *Competent Authority* of the *exporting country* is ultimately accountable for certification used in *international trade*.

Article 5.1.4.

Responsibilities in case of an incident related to importation

- 1) *International trade* involves a continuing ethical responsibility. Therefore, if within a reasonable period subsequent to an export taking place, the *Competent Authority* becomes aware of the appearance or reappearance of a *disease* that has been specifically included in the *international aquatic animal health certificate* or other *disease* of potential epidemiological importance to the *importing country* there is an obligation for the *Competent Authority* to notify the *importing country*, so that the imported *commodities* may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.

- 2) If a *disease* condition appears in imported *aquatic animals* within a reasonable period after importation, the *Competent Authority* of the *exporting country* should be informed so as to enable an investigation to be made, because this may be the first available information on the occurrence of the *disease* in a previously free *aquatic animal* population. The *Competent Authority* of the *importing country* should be informed of the result of the investigation because the source of *infection* may not be in the *exporting country*.
 - 3) If a *disease* appears in *aquatic animals* in an *importing country* and is associated with importation of *commodities*, the *Competent Authority* of the *exporting country* should be informed. This will enable the *exporting country* to investigate as this may be the first available information on the occurrence of the *disease* in a previously free *aquatic animal* population.
 - 4) In case of suspicion, on reasonable grounds, that an *international aquatic animal health certificate* may be fraudulent, the *Competent Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. *Competent Authorities* of all countries involved should fully cooperate with the investigation. If the *international aquatic animal health certificate* is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken in accordance with the relevant legislation.
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CHAPTER 5.2.

CERTIFICATION PROCEDURES

Article 5.2.1.

Protection of the professional integrity of the certifying official

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the *certifying official* should be respected and safeguarded.

It is essential to include in the certificate only those specific statements that can be accurately and honestly signed by a *certifying official*. For example, these requirements should not include certification of an area as being free from *diseases* that are not notifiable in that country, or the occurrence of which the signing *certifying official* is not necessarily informed about. It is unacceptable to ask for certification for events that will take place after the document is signed when these events are not under the direct control and supervision of the signing *certifying official*.

Article 5.2.2.

Certifying officials

Certifying officials should:

- 1) be authorised by the *Competent Authority* of the *exporting country* to sign *international aquatic animal health certificates*;
- 2) only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another party authorised by the *Competent Authority*;
- 3) sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the *certifying official* should have verified or be in possession of that documentation before signing;
- 4) have no conflict of interest in the commercial aspects of the *aquatic animals* or *aquatic animal products* being certified and be independent from the commercial parties.

Article 5.2.3.

Preparation of international aquatic animal health certificates

Certificates should be drawn up in accordance with the following principles:

- 1) Certificates should be designed so as to minimise the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should bear the signature of the *certifying official* and the official identifier (stamp) of the issuing *Competent Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.
- 2) Certificates should be written using terms that are simple, unambiguous and as easy to understand as possible, without losing their legal meaning.
- 3) If so required, certificates should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the *certifying official*.
- 4) Certificates should require appropriate identification of *aquatic animals* and *aquatic animal products* except where this is impractical (e.g. eyed eggs).
- 5) Certificates should not require a *certifying official* to certify matters that are outside his/her knowledge or that he/she cannot ascertain and verify.
- 6) Where appropriate, when presented to the *certifying official*, certificates should be accompanied by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.

- 7) The text of a certificate should not be amended except by deletions that should be signed and stamped by the *certifying official*.
- 8) The signature and stamp should be in a colour different to that of the printing of the certificate. The stamp may be embossed instead of being a different colour.
- 9) Only original certificates should be accepted by the *importing country*.
- 10) Replacement certificates may be issued by a *Competent Authority* to replace original certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These replacements should be provided by the issuing authority and be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.

Article 5.2.4.

Electronic certification

- 1) Certification may be provided by electronic exchange of data sent directly from the *Competent Authority* of the *exporting country* to the *Competent Authority* of the *importing country*.
 - a) Systems providing electronic certificates normally provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The *certifying official* should have access to all necessary information such as origin of *aquatic animals* and laboratory results.
 - b) When exchanging electronic certificates and in order to fully utilise electronic data exchange, *Competent Authorities* should use internationally standardised language, message structure and exchange protocols. Guidance for electronic certification in standardised Extensible Markup Language (XML) as well as secure exchange mechanisms between *Competent Authorities* is provided by the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT).
 - c) A secure method of electronic data exchange should be ensured by digital authentication of the certificates, encryption, non-repudiation mechanisms, controlled and audited access and firewalls.
 - 2) Electronic certificates should carry the same information as conventional certificates.
 - 3) The *Competent Authority* should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.
 - 4) The *certifying official* should be officially responsible for the secure use of his/her electronic signature.
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CHAPTER 5.3.

OIE PROCEDURES RELEVANT TO THE AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES OF THE WORLD TRADE ORGANIZATION

Article 5.3.1.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) encourages the Members of the World Trade Organization to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach of *risk management*.

The SPS Agreement encourages Governments to make a wider use of *risk analysis*: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual *risk* involved.

The SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, *sanitary measures* which may, directly or indirectly, affect *international trade*.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live animals and animal products, including *aquatic animals* and their products.

Article 5.3.2.

Introduction on the judgement of the equivalence of sanitary measures

The importation of *aquatic animals* and *aquatic animal products* involves a degree of *risk* to the *aquatic animal* health status of an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* option(s) are made more difficult by differences among the *aquatic animal* health and production systems in Member Countries. It is now recognised that significantly different *aquatic animal* health and production systems can provide equivalent *aquatic animal* and human health protection for the purpose of *international trade*, with benefits to both the *importing country* and the *exporting country*.

These recommendations are to assist Member Countries to determine whether *sanitary measures* arising from different *aquatic animal* health and production systems may provide the same level of *aquatic animal* and human health protection. They discuss principles which might be utilised in a judgement of equivalence, and outline a step-wise process for trading partners to follow in facilitating a judgement of equivalence. These provisions are applicable whether equivalence applies at the level of specific measures or on a systems-wide basis, and whether equivalence applies to specific areas of trade or *commodities*, or generally.

Article 5.3.3.

General considerations on the judgement of the equivalence of sanitary measures

Before trade in *aquatic animals* or their products may occur, an *importing country* must be satisfied that its *aquatic animal* health status will be appropriately protected. In most cases, the *risk management* measures drawn up will rely in part on judgements made about the *aquatic animal* health and production system(s) in the *exporting country* and the effectiveness of sanitary procedures undertaken there. Systems operating in the *exporting country* may differ from those in the *importing country* and from those in other countries with which the *importing country* has traded. Differences may

be with respect to infrastructure, policies and/or operating procedures, laboratory systems, approaches to the pests and diseases present, border security and internal movement controls.

International recognition of the legitimacy of different approaches to achieving the *importing country's* appropriate level of protection (ALOP) has led to the principle of equivalence being included in trade agreements, including the SPS Agreement of the WTO.

Benefits of applying equivalence may include:

- 1) minimising costs associated with *international trade* by tailoring *aquatic animal* health measures to local circumstances;
- 2) maximising *aquatic animal* health outcomes for a given level of resource input;
- 3) facilitating trade by achieving the required health protection through less trade restrictive *sanitary measures*; and
- 4) decreased reliance on relatively costly *commodity* testing and isolation procedures in bilateral or multilateral agreements.

The *Aquatic Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases* and *pathogenic agents*. Equivalence may be gained, for example, by enhanced *surveillance* and monitoring, by the use of alternative test, treatment or isolation procedures, or by combinations of the above. To facilitate the judgement of equivalence, Member Countries should base their *sanitary measures* on the standards, guidelines and recommendations of the OIE.

It is essential to apply a scientific *risk analysis* to the extent practicable in establishing the basis for a judgement of equivalence.

Article 5.3.4.

Prerequisite considerations in a judgement of equivalence

1. Application of risk assessment

Application of the discipline of *risk assessment* provides a structured basis for judging equivalence among different *sanitary measures* as it allows a close examination to be made of the effect of a measure(s) on a particular step(s) in the importation pathway, and the relative effects of proposed alternative measure(s) on the same or related steps.

A judgement of equivalence needs to assess the *sanitary measure* in terms of its effectiveness regarding the particular *risk* or group of *risks* against which the measure is designed to protect. Such an assessment may include the following elements: the purpose of the measure, the level of protection achieved by the measure and the contribution the measure makes to achieving the ALOP of the *importing country*.

2. Categorisation of sanitary measures

Proposals for equivalence may be in terms of a measure comprising a single component of a measure (e.g. an isolation procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for *commodity*), or a combination of measures. Multiple components or combinations of measures may be applied consecutively or concurrently.

Sanitary measures are those described in each chapter of the *Aquatic Code* which are used for *risk* reduction and are appropriate for particular *diseases*. *Sanitary measures* may be applied either alone or in combination and include test requirements, processing requirements, inspection or certification procedures, quarantine confinements, and sampling procedures.

For the purposes of judging equivalence, *sanitary measures* can be broadly categorised as:

- a) infrastructure: including the legislative base (e.g. *aquatic animal* health law) and administrative systems (e.g. organisation of national and regional *aquatic animal* health authorities, emergency response organisations);
- b) programme design/implementation: including documentation of systems, performance and decision criteria, laboratory capability, and provisions for certification, audit and enforcement;
- c) specific technical requirement: including requirements applicable to the use of secure facilities, treatment (e.g. retorting of cans), specific test (e.g. PCR) and procedures (e.g. pre-export inspection).

A *sanitary measure(s)* proposed for a judgement of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, a comparison of specific technical requirements may suffice. In many instances, however, a judgement as to whether the same level of protection is likely to be achieved may only be able to be determined through an evaluation of all relevant components of an *exporting country's aquatic animal* health and production

system. For example, a judgement of equivalence for a specific *sanitary measure* at the programme design/implementation level may require a prior examination of infrastructure while a judgement of equivalence for a specific measure at the specific technical requirement level may require that the specific measure be judged in its context through examination of infrastructure and programmes.

Article 5.3.5.

Principles for judgement of equivalence

In conjunction with the above considerations, judgement of the equivalence of *sanitary measures* should be based on application of the following principles:

- 1) an *importing country* has the right to set the level of protection it deems appropriate (its ALOP) in relation to human and animal life and health in its *territory*; this ALOP may be expressed in qualitative or quantitative terms;
- 2) the *importing country* should be able to describe the reason for each *sanitary measure* i.e. the level of protection intended to be achieved by application of the identified measure against a *hazard*;
- 3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of providing the same level of protection;
- 4) the *importing country* should, upon request, enter into consultations with the *exporting country* with the aim of facilitating a judgement of equivalence;
- 5) any *sanitary measure* or combination of *sanitary measures* can be proposed for judgement of equivalence;
- 6) an interactive process should be followed that applies a defined sequence of steps, and utilises an agreed process for exchange of information, so as to limit data collection to that which is necessary, minimise administrative burden, and facilitate resolution of claims;
- 7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measure(s)* proposed as equivalent will provide the same level of protection;
- 8) the *exporting country* should present a submission for equivalence in a form that facilitates judgement by the *importing country*;
- 9) the *importing country* should evaluate submissions for equivalence in a timely, consistent, transparent and objective manner and in accordance with appropriate *risk assessment* principles;
- 10) the *importing country* should take into account any knowledge of and prior experience with the *Veterinary Authority* or other *Competent Authority* of the *exporting country*;
- 11) the *exporting country* should provide access to enable the procedures or systems which are the subject of the equivalence judgement to be examined and evaluated upon request of the *importing country*;
- 12) the *importing country* should be the sole determinant of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
- 13) to facilitate a judgement of equivalence, Member Countries should base their *sanitary measures* on relevant OIE standards;
- 14) to allow the judgement of equivalence to be reassessed if necessary, the *importing country* and the *exporting country* should keep each other informed of significant changes to infrastructure, health status or programmes which may bear on the judgement of equivalence; and
- 15) an *importing country* should give positive consideration to a request by an exporting developing country for appropriate technical assistance that would facilitate the successful completion of a judgement of equivalence.

Article 5.3.6.

Sequence of steps to be taken in judgement of equivalence

There is no single sequence of steps which must be followed in all judgements of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. The interactive sequence of steps described below may be useful for all *sanitary measures* irrespective of their categorisation as infrastructure, programme design/implementation or specific technical requirement components of an *aquatic animal* health and production system.

This sequence assumes that the *importing country* is meeting its obligations under the WTO SPS Agreement and has in place a transparent measure based either on an international standard or a *risk analysis*.

Recommended steps are:

- 1) the *exporting country* identifies the measure(s) for which it wishes to propose an alternative measure(s), and requests from the *importing country* a reason for its *sanitary measure* in terms of the level of protection intended to be achieved against a *hazard(s)*;
- 2) the *importing country* explains the reason for the measure(s), in terms which would facilitate comparison with an alternative *sanitary measure(s)* and consistent with the principles set out in these provisions;
- 3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure(s)* in a form which facilitates analysis by an *importing country*;
- 4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;
- 5) judgement of equivalence by the *importing country* takes into account as appropriate:
 - a) the impact of biological variability and uncertainty;
 - b) the expected effect of the alternative *sanitary measure(s)* on all relevant *hazards*;
 - c) OIE standards;
 - d) application of solely qualitative frameworks where it is not possible or reasonable to conduct quantitative risk assessment;
- 6) the *importing country* notifies the *exporting country* of its judgement and the underlying reasons within a reasonable period of time:
 - a) recognition of the equivalence of the *exporting country's* alternative *sanitary measure(s)*;
 - b) request for further information; or
 - c) rejection of the case for equivalence of the alternative *sanitary measure(s)*;
- 7) an attempt should be made to resolve any differences of opinion over judgement of a case, either interim or final, by using an agreed mechanism to reach consensus (e.g. the OIE informal procedure for dispute mediation), or by referral to an agreed expert;
- 8) depending on the category of measures involved, the *importing country* and the *exporting country* may enter into a formal equivalence agreement giving effect to the judgement or a less formal acknowledgement of the equivalence of a specific measure(s) may suffice.

An *importing country* recognising the equivalence of an *exporting country's* alternative *sanitary measure(s)* needs to ensure that it acts consistently with regard to applications from third countries for recognition of equivalence applying to the same or very similar measure(s). Consistent action does not mean however that a specific measure(s) proposed by several *exporting countries* should always be judged as equivalent as a measure(s) should not be considered in isolation but as part of a system of infrastructure, policies and procedures.

Article 5.3.7.

Sequence of steps to be taken in establishing a zone/compartiment and having it recognised for international trade purposes

There is no single sequence of steps which should be followed in establishing a *zone* or a *compartiment*. The steps that the Veterinary Services or *Aquatic Animal Health Services* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. For zoning
 - a) The *exporting country* identifies a geographical area within its *territory*, which it considers to contain an *aquatic animal subpopulation* with a distinct health status with respect to a specific *disease/specific diseases*, based on *surveillance*.
 - b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its *territory*, in accordance with the recommendations in the *Aquatic Code*.
 - c) The *exporting country* provides:
 - i) the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separate *zone* for *international trade* purposes;
 - ii) access to enable the procedures or systems that establish the *zone* to be examined and evaluated upon request by the *importing country*.

- d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:
 - i) an evaluation of the *exporting country's* Veterinary Services or *Aquatic Animal Health Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards.
- e) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
 - i) recognition of the *zone*; or
 - ii) request for further information; or
 - iii) rejection of the area as a *zone* for *international trade* purposes.
- f) An attempt should be made to resolve any differences over recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- g) The *Veterinary Authorities* or other *Competent Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *zone*.

2. For compartmentalisation

- a) Based on discussions with the relevant industry, the *exporting country* identifies within its *territory* a *compartment* comprising an *aquatic animal subpopulation* contained in one or more establishments or other premises operating under common management practices related to *biosecurity*. The *compartment* contains an identifiable *aquatic animal subpopulation* with a distinct health status with respect to specific *disease(s)*. The *exporting country* describes how this status is maintained through a partnership between the relevant industry and the *Veterinary Authority* or other *Competent Authority* of the *exporting country*.
- b) The *exporting country* examines the *compartment's biosecurity plan* and confirms through an audit that:
 - i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and
 - ii) the *surveillance* and monitoring programme in place is appropriate to verify the status of such a *subpopulation* with respect to such *disease(s)*.
- c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Aquatic Code*.
- d) The *exporting country* provides:
 - i) the above information to the *importing country*, with an explanation of why such a *subpopulation* can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
 - ii) access to enable the procedures or systems that establish the *compartment* to be examined and evaluated upon request by the *importing country*.
- e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:
 - i) an evaluation of the *exporting country's* Veterinary Services or *Aquatic Animal Health Services*;
 - ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;
 - iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and
 - iv) other relevant OIE standards.
- f) The *importing country* notifies the *exporting country* of its determination and the underlying reasons, within a reasonable period of time, being:
 - i) recognition of the *compartment*; or
 - ii) request for further information; or
 - iii) rejection of such a *subpopulation* as a *compartment* for *international trade* purposes.
- g) An attempt should be made to resolve any differences over recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus such as the OIE informal procedure for dispute mediation (Article 5.3.8.).
- h) The *Veterinary Authorities* or other *Competent Authorities* of the *importing* and *exporting countries* should enter into a formal agreement recognising the *compartment*.

- i) The *Veterinary Authority* or other *Competent Authority* of the *exporting country* should promptly inform *importing countries* of any occurrence of a *disease* in respect of which the *compartment* was defined.

Article 5.3.8.

The OIE informal procedure for dispute mediation

OIE shall maintain its existing voluntary in-house mechanisms for assisting Member Countries to resolve differences. In-house procedures which will apply are that:

- 1) Both parties agree to give the OIE a mandate to assist them in resolving their differences.
 - 2) If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
 - 3) Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
 - 4) The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
 - 5) The expert or experts shall submit a confidential report to the Director General of the OIE, who will transmit it to both parties.
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CHAPTER 5.4.

CRITERIA TO ASSESS THE SAFETY OF AQUATIC ANIMAL COMMODITIES

In the context of this chapter the word 'safety' is applied only to animal health considerations for *listed diseases*.

Article 5.4.1.

Criteria to assess the safety of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from disease X

In all *disease* chapters, point 1 of Article X.X.3. lists *aquatic animals* and *aquatic animal products* that can be traded for any purpose from a country, *zone* or *compartment* not declared free from *disease X*. The criteria for inclusion of *aquatic animals* and *aquatic animal products* in point 1 of Article X.X.3. are based on the absence of the *pathogenic agent* in the traded *aquatic animals* and *aquatic animal products* or inactivation of the *pathogenic agent* by treatment or processing.

The assessment of the safety of the *aquatic animals* and *aquatic animal products* using the criteria relating to treatment or processing can only be undertaken where treatments or processing are well defined. It may not be necessary to provide details of the entire treatment or process undertaken. However, the steps considered critical in the inactivation of the *pathogenic agent* of concern should be detailed.

It is assumed that treatment or processing (i) uses standardised protocols, which include the steps considered critical in the inactivation of the *pathogenic agent* of concern; (ii) is conducted in accordance with Good Manufacturing Practices; and (iii) that any other steps in the treatment, processing and subsequent handling of the *aquatic animal product* do not jeopardise the safety of the traded *aquatic animal product*.

Criteria

For an *aquatic animal* or *aquatic animal product* to be considered safe for *international trade* under the provisions of Article X.X.3., it should comply with the following criteria:

- 1) Absence of pathogenic agent in the traded aquatic animal or aquatic animal product:
 - a) There is strong evidence that the *pathogenic agent* is not present in the tissues from which the *aquatic animal* or *aquatic animal product* is derived.

AND

- b) The water (including ice) used to process or transport the *aquatic animal* or *aquatic animal product* is not contaminated with the *pathogenic agent* and the processing prevents cross contamination of the *aquatic animal* or *aquatic animal product* to be traded.

OR

- 2) Even if the *pathogenic agent* is present in, or contaminates the tissues from which the *aquatic animal* or *aquatic animal product* is derived, the treatment or processing to produce the *aquatic animal* or *aquatic animal product* to be traded inactivates the *pathogenic agent*:

- a) physical (e.g. temperature, drying, smoking);

AND/OR

- b) chemical (e.g. iodine, pH, salt, smoke);

AND/OR

- c) biological (e.g. fermentation).

Article 5.4.2.

Criteria to assess the safety of aquatic animals or aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from disease X

In all *disease* chapters, point 1 of Article X.X.12. (amphibian and fish *disease* chapters) and Article X.X.11. (crustacean and mollusc *disease* chapters) lists *aquatic animals* or *aquatic animal products* for retail trade for human consumption. The criteria for inclusion of *aquatic animals* or *aquatic animal products* in point 1 of Article X.X.12. (amphibian and fish *disease* chapters) and Article X.X.11. (crustacean and mollusc *disease* chapters) include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely presence of viable *pathogenic agent* in the waste.

For the purpose of this criterion retail means the selling or provision of *aquatic animals* or *aquatic animal products* directly to the consumer with the intended purpose of human consumption. The retail pathway may also include wholesale distribution of the products provided they are not further processed by the wholesale distributor or the retailer, i.e. are not subjected to actions such as gutting, cleaning, filleting, freezing, thawing, cooking, unpacking, packing or repackaging.

It is assumed that: (i) the *aquatic animals* or *aquatic animal products* are used for human consumption only; (ii) waste may not always be handled in an appropriate manner that mitigates the introduction of the *pathogenic agent*; the level of risk is related to the waste disposal practices in each Member's country or territory; (iii) treatment or processing prior to importation is conducted in accordance with Good Manufacturing Practices, and (iv) any other steps in the treatment, processing and subsequent handling of the *aquatic animals* or *aquatic animal products* prior to importation do not jeopardise the safety of the traded *aquatic animals* or *aquatic animal products*.

Criteria

For *aquatic animals* or *aquatic animal products* to be considered for *international trade* under the provisions of point 1 of Article X.X.12. (amphibian and fish *disease* chapters) and Article X.X.11. (crustacean and mollusc *disease* chapters), it should comply with the following criteria:

- 1) the *aquatic animal* or *aquatic animal product* is prepared and packaged for retail trade for human consumption;
AND

EITHER

- 2) it includes only a small amount of raw waste tissues generated by the consumer;

OR

- 3) the *pathogenic agent* is not normally found in the waste tissues generated by the consumer.
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CHAPTER 5.5.

CONTROL OF AQUATIC ANIMAL HEALTH RISKS ASSOCIATED WITH TRANSPORT OF AQUATIC ANIMALS

Article 5.5.1.

General considerations

- 1) These considerations should be used as recommendations when countries introduce measures to control the *aquatic animal* health risks related to the transport of these *aquatic animals* and *aquatic animal products*. These recommendations do not address *aquatic animal* welfare.
- 2) *Vehicles* (or *containers*) used for the transport of *aquatic animals* shall be designed, constructed and fitted in such a way as to withstand the weight of the *aquatic animals* and water and to ensure their safety during transportation. *Vehicles* shall be thoroughly cleansed and disinfected before use in accordance with the recommendations given in the *Aquatic Code*.
- 3) *Vehicles* (or *containers*) in which *aquatic animals* are confined during transport shall be secured to maintain optimal conditions for the *aquatic animals* during transport, and to allow easy access by the attendant.

Article 5.5.2.

Particular considerations for containers

- 1) The construction of *containers* intended for transportation of *aquatic animals* shall be such that the accidental release of water, etc., is prevented during transport.
- 2) In the case of the transportation of *aquatic animals*, provision shall be made to enable preliminary observation of the contents of *containers*.
- 3) *Containers* in transit in which there are *aquatic animal products* shall not be opened unless the *Aquatic Animal Health Service* of the *transit country* consider it necessary. If this is the case, *containers* shall be subject to precautions to prevent contamination.
- 4) *Containers* shall be loaded only with one kind of product or, at least, with products not susceptible to contamination by one another.
- 5) It rests with each country to decide on the facilities it requires for the transport and importation of *aquatic animals* and *aquatic animal products* in *containers*.

Article 5.5.3.

Particular considerations for the transport of aquatic animals by air

- 1) The stocking densities for the transport of *aquatic animals* in *containers* should be determined by taking the following into consideration when transporting by air:
 - a) the total volume of available space for each type of *aquatic animal*;
 - b) the oxygenation capacity available to supply the *containers* while on the ground and during all stages of the flight.

With regard to fish, molluscs and crustaceans, the space reserved for each *aquatic animal* species in *containers* that have been fitted for the separate transportation of several *aquatic animals* or for the *transportation* of groups of *aquatic animals* should comply with acceptable densities specified for the species in question.

- 2) The OIE approved International Air Transport Association (IATA) Regulations for live animals may be adopted if they do not conflict with national legislative arrangements. (Copies of these Regulations are obtainable from IATA, 800 Place Victoria, P.O. Box 113, Montreal, Quebec H4Z 1M1, Canada.)

Article 5.5.4.

Disinfection and other sanitary measures

- 1) *Disinfection* and all zoo-sanitary work should be carried out in order to:
 - a) avoid all unjustified inconvenience and to prevent damage or injury to the health of people and *aquatic animals*;
 - b) avoid damage to the structure of the *vehicle* or its appliances;
 - c) prevent, as far as possible, any damage to *aquatic animal products*.
- 2) On request, the *Aquatic Animal Health Service* shall issue the transporters with a certificate indicating the measures that have been applied to all *vehicles*, the parts of the *vehicle* that have been treated, the methods used and the reasons that led to the application of the measures.
In the case of aircraft, the certificate may be replaced, on request, by an entry in the General Declaration of the aircraft.
- 3) Likewise, the *Aquatic Animal Health Service* shall issue on request:
 - a) a certificate showing the date of arrival and departure of the *aquatic animals*;
 - b) a certificate to the shipper or exporter, the consignee and transporter or their representatives, indicating the measures applied.

Article 5.5.5.

Treatment of transportation water

Water to be used for transportation of *aquatic animals* should be appropriately treated after transport and/or before discharge in order to minimise the *risk* of transferring pathogens. The specific recommendations are provided in the chapter of the *Aquatic Code* on disinfection.

During transportation of *aquatic animals*, the transporter should not be permitted to evacuate and replace the water in the transport tanks except on specifically designated sites in the national *territory*. The waste and rinsing water should not be emptied into a drainage system that is directly connected to an aquatic environment where *aquatic animals* are present. The water from the tanks should therefore either be disinfected by a recognised process (for example, 50 mg iodine or chlorine/litre for one hour), or sprayed over land that does not directly drain into waters containing *aquatic animals*. Each country shall designate the sites in their national *territories* where these operations can be carried out.

Article 5.5.6.

Discharge of infected material

The *Aquatic Animal Health Service* shall take all practical measures to prevent the discharge of any untreated infective material, including transport water, into internal or territorial waters.

Article 5.5.7.

Particular considerations for the transport of live fish by well boat

A well boat is a boat with integrated tanks to carry live fish in sea water that may operate with open valves to allow exchange of sea water. Therefore, well boats can present a *biosecurity* risk if the fish being carried are infected. Well boats are inherently difficult to disinfect.

- 1) Only healthy fish showing no clinical signs of *disease* on the day of loading should be transported. The well boat must have the capability of fully closed containment of fish during its operation if so required.
- 2) The stocking densities should be determined by taking both the total volume of available space for each species of fish and the oxygenation/aeration capacity available to supply the fish during all stages of transport into consideration.
- 3) Fish may be transported by well boat from an infected site if this is part of a disease response plan agreed to by the *Competent Authority*.
- 4) Provision shall be made to enable preliminary observation of the contents in the well, and monitoring equipment should be available where appropriate.

- 5) Access by farm staff to the vessel and from the vessel to the farm cages, including the equipment, should be restricted.
- 6) Transporting fish of different health status at the same time increases the *risk of disease* transfer between those fish and is discouraged.
- 7) Well boats may exchange water in their tanks with the environment except in designated areas in proximity to *aquaculture establishments* or areas with protected wild populations. The *Aquatic Animal Health Service* should designate the areas based upon a *risk assessment*.
- 8) Multiple deliveries of fish during the same trip should be avoided. Where unavoidable the order of deliveries should be made to sites of a higher health status first (e.g. youngest year class), to a single *aquaculture establishment*, or establishments of the same health status.
- 9) In the event of mortality occurring during transport, a *contingency plan* capable of dealing with full containment and disposal of dead fish, via an approved disposal method, should be available. This plan should be prepared in accordance with the recommendations on handling and disposal of carcasses and wastes of *aquatic animals* (in preparation).
- 10) Well boats should not operate in adverse inclement weather conditions that may force the operation to divert from the planned route and schedule of transport.
- 11) The well boat should be cleaned and, where required, disinfected to an acceptable standard before re-use. The level of *disinfection* should be proportional to the risk. Well boats should maintain a *disinfection* checklist which should be kept with the ship's log and should be open to audit. It is essential to ensure that all fish are removed from the system before cleaning. All organic matters should be removed through the process of cleaning before *disinfection* commences. The general principles and specific recommendations as outlined in the *Aquatic Manual* should be consulted for guidance.
- 12) When travelling between areas and zones of different health levels, cleaning and, if required, *disinfection* procedures should be followed and implemented to a standard approved by the *Aquatic Animal Health Service*.

CHAPTER 5.6.

AQUATIC ANIMAL HEALTH MEASURES APPLICABLE BEFORE AND AT DEPARTURE

Article 5.6.1.

- 1) Each country should only authorise the exportation from its *territory* of live *aquatic animals* and *aquatic animal products* that are correctly identified, and inspected in accordance with the procedures outlined in the *Aquatic Code* and *Aquatic Manual*.
- 2) In certain cases, the above-mentioned *aquatic animals* could, in accordance with the wish of the *importing country*, be subjected to certain biological tests or to prophylactic parasitological procedures within limits of a defined period of time before their departure.
- 3) Observation of the above-mentioned *aquatic animals* before leaving the country may be carried out in the establishment where they were reared or at the *frontier post*. When they have been found to be clinically healthy and free from *listed diseases* or any other specified infectious *disease* by a member of the personnel of the *Competent Authority* or a *certifying official* approved by the *importing country* during the period of observation, the *aquatic animals* should be transported to the place of shipment in specially constructed *containers*, previously cleansed and disinfected, without delay and without coming into contact with other susceptible *aquatic animals*, unless these *aquatic animals* have health guarantees similar to those of the transported *aquatic animals*.
- 4) The transportation of *aquatic animals* for breeding or rearing or slaughter shall be carried out directly from the establishment of origin to the place of shipment or to the processing establishment in conformity with the conditions agreed between the *importing* and *exporting countries*.

Article 5.6.2.

Each country should only undertake the exportation of live *aquatic animals* or *eggs* or *gametes* destined for a country or *zone* or *aquaculture establishment* officially declared free from one or more of the *listed diseases*, when the *exporting country* or *zone* or *aquaculture establishment* of origin is itself officially declared free of the same *disease(s)*. If the live *aquatic animals* originate in an infected *aquaculture establishment* or *infected zone*, with respect to the *disease(s)* in question, the *exporting country* should not export the *aquatic animals* if they have been exposed to *infection* by direct or indirect contact of a kind likely to cause transmission of the *pathogenic agent(s)*, without the prior agreement of the *importing country*.

Article 5.6.3.

Each country exporting *aquatic animals* at any stage of development or *aquatic animal products* should inform the country of destination and when necessary the *transit countries* if, after exportation, *diagnosis* of a *listed disease* occurs in the establishment of origin, or in *aquatic animals* that were in the *aquaculture establishment* or natural water body at the same time as the exported animals, within a period of time that indicates that the exported consignment may have been infected.

Article 5.6.4.

Before the departure of the *aquatic animals* and *aquatic animal products*, a member of the personnel of the *Competent Authority* or a *certifying official* approved by the *importing country* should provide an *international aquatic animal health certificate* conforming with the models approved by the OIE (as shown in Chapter 5.11.) and worded in the languages agreed upon between the *exporting country* and the *importing country* and, when necessary, with the *transit countries*.

Article 5.6.5.

- 1) Before the departure of a consignment of *aquatic animals* on an international journey, the *Competent Authority* of the port, airport or district in which the *frontier post* is situated may, if it is considered necessary, have a health examination carried out on the consignment. The time and place of the examination shall be fixed taking into account customs and other formalities and in such a way as not to impede or unreasonably delay departure.
- 2) The *Competent Authority* referred to in point 1 above shall take necessary measures to:
 - a) prevent the shipment of *aquatic animals* showing clinical signs of any *listed disease*;
 - b) avoid entry into the *container* of possible vectors or *pathogenic agents*.

CHAPTER 5.7.

AQUATIC ANIMAL HEALTH MEASURES APPLICABLE DURING TRANSIT FROM THE PLACE OF DEPARTURE IN THE EXPORTING COUNTRY TO THE PLACE OF ARRIVAL IN THE IMPORTING COUNTRY

Article 5.7.1.

- 1) Any country through which the transit of *aquatic animals* has to be made, and that normally conducts commercial transactions with the *exporting country*, should not refuse the transit, subject to the reservations mentioned herein and on condition that notification is made of the proposed transit to the *Competent Authority* in charge of the *frontier posts*.

This notification shall state the species and quantities of *aquatic animals*, the methods of transport and the *frontier posts* of entry and exit in accordance with a previously arranged and authorised itinerary in the *transit country*.

- 2) Any country through which transit has to take place may refuse such transit if, in the *exporting country* or *transit country* that precedes it on the itinerary, certain *diseases* exist that have been specifically included in the *international aquatic animal health certificates* or in bilateral agreements. Alternatively, the *Competent Authority* of the *transit country* may impose conditions with regard to the method, including packaging, and route of transport.
- 3) Any *transit country* may require the presentation of *international aquatic animal health certificates*. Such a country may, in addition, cause an examination to be made by a member of the personnel of the *Aquatic Animal Health Service* on the health status of fish, molluscs or crustaceans in transit, except in cases where transport in sealed *vehicles* or *containers* is a condition of transit.
- 4) Any *transit country* may refuse passage through its *territory* of *aquatic animals* at one of its *frontier posts* if an examination carried out by a member of the personnel of the *Aquatic Animal Health Service* shows that the consignment of *aquatic animals* in transit is affected by or infected with any of the *listed diseases* and if these *diseases* are exotic to that country or the *zone* through which the transportation was to take place, or if there is an enforced control programme for the *disease(s)* in question, or if the *international aquatic animal health certificate* is inaccurate and/or unsigned or does not apply to fish, molluscs or crustaceans.

In these circumstances, the *Competent Authority* of the *exporting country* shall be informed immediately, thereby providing an opportunity for checking the findings or correcting the *certificate*.

If the *diagnosis* of any *listed disease* is confirmed or if the *certificate* cannot be corrected, the consignment of *aquatic animals* in transit shall either be returned to the *exporting country* if there is a common frontier with it, or be slaughtered or destroyed.

Article 5.7.2.

- 1) Any *transit country* may require *vehicles* used for the transit of *aquatic animals* through its *territory* to be constructed to prevent the escape and dispersion of waste water or other contaminated material.
- 2) Unloading of *aquatic animals* shall be permitted in the *territory* of the *transit country* only if an emergency situation arises. The *importing country* shall be informed of any unforeseen unloading in the *transit country* and the reason for it.

Article 5.7.3.

Vessels stopping in a port or passing through a canal or other navigable route situated in the *territory* of a country, on their way to a port situated in the *territory* of another country, must comply with the conditions required by the *Competent Authority*.

Article 5.7.4.

- 1) If, for reasons beyond the control of its captain, a ship or aircraft calls or lands somewhere other than at a port or airport, or at a port or airport other than that at which it should normally call or land, the captain of the ship or aircraft, or his/her deputy, shall immediately notify the nearest *Competent Authority* or any other public authority of the new port of call or landing.
- 2) As soon as the *Competent Authority* is notified of this calling or landing place, it shall take appropriate action.
- 3) The *aquatic animals* on board the ship or aircraft shall not be permitted to leave the vicinity of the docking or landing place and the removal from the vicinity of any equipment or packing material accompanying them shall not be permitted.
- 4) When the measures prescribed by the *Competent Authority* have been carried out, the ship or aircraft shall be permitted, for *aquatic animal* health purposes, to proceed to the port or airport at which it would normally have called or landed or, if there are technical reasons for which this cannot be done, to a port or an airport that is more suitable.

CHAPTER 5.8.

FRONTIER POSTS IN THE IMPORTING COUNTRY

Article 5.8.1.

The *Competent Authority* shall provide specified *frontier posts* with an office comprising personnel, equipment and premises as the case may be and, in particular, means for:

- 1) detecting and isolating *aquatic animal* populations affected with or suspected of being affected with a *disease*;
- 2) carrying out *disinfection* of *vehicles* used to transport *aquatic animals* and *aquatic animal products*;
- 3) making clinical examinations and obtaining specimens of material for diagnostic purposes from live *aquatic animals* or carcasses of *aquatic animals* affected or suspected of being affected with a *disease*, and obtaining specimens of *aquatic animal products* suspected of contamination.

Furthermore, it is preferable that each port and international airport be provided with equipment for the sterilisation or incineration of any material dangerous to *aquatic animal* health.

Article 5.8.2.

When required by international traffic in transit, airports shall be provided, as soon as possible, with areas of direct transit; these must, however, comply with the conditions required by the *Competent Authority*.

Article 5.8.3.

Each *Veterinary Authority* shall keep at the disposal of the OIE *Headquarters* and any interested country on request:

- 1) a list of specified *frontier posts* and processing plants for *aquatic animals* in its *territory* that are approved for *international trade*;
- 2) the period of time required for notice to be given for the application of the arrangements contained in paragraph 2 of Articles 5.9.1. and 5.9.2.;
- 3) a list of airports in its *territory* that are provided with an area of direct transit.

CHAPTER 5.9.

AQUATIC ANIMAL HEALTH MEASURES APPLICABLE ON ARRIVAL

Article 5.9.1.

- 1) An *importing country* should only accept into its *territory* live *aquatic animals* that have been subjected to examination by a member of the personnel of the *Aquatic Animal Health Service* of the *exporting country* or a *certifying official* approved by the *importing country* and that are accompanied by an *international aquatic animal health certificate* (see Model Certificates given in Chapter 5.11.).
- 2) An *importing country* may require sufficient advance notification regarding the proposed date of entry into its *territory* of *aquatic animals*, stating the species, quantity, means of transport and the name of the *frontier post*.
In addition, any *importing country* shall publish a list of the specified *frontier posts* supplied with the equipment required for conducting control operations at importation and enabling the importation and transit procedures to be carried out in the most speedy and efficacious way.
- 3) An *importing country* may prohibit the introduction into its *territory* of *aquatic animals* if these were found, on examination carried out at the *frontier post* by a member of the personnel of the *Aquatic Animal Health Service*, to be affected by a *listed disease* of concern to the *importing country*.

Refusal of entry may also be applied to *aquatic animals* that are not accompanied by an *international aquatic animal health certificate* conforming to the requirements of the *importing country*.

In these circumstances, the *Competent Authority* of the *exporting country* shall be informed immediately, thereby providing an opportunity for checking the findings or correcting the *certificate*.

However, the *importing country* may prescribe that the importation be placed immediately in *quarantine* in order to carry out a clinical observation and biological examinations with a view to establishing a formal *diagnosis*.

If the *diagnosis* of a *listed disease* is confirmed, or if the *certificate* cannot be corrected, the *importing country* may take the following measures:

- a) return the *aquatic animals* involved to the *exporting country* if this rejection does not involve *transit* through a third country;
- b) slaughter and destroy in cases where re-shipment would be dangerous from a health point of view or impossible from a practical point of view.

Article 5.9.2.

- 1) An *importing country* should only accept into its *territory* raw uneviscerated fish of those *species susceptible* to a *listed disease* destined for introduction into an aquatic environment or for human consumption that have been subjected to examination by a member of the personnel of the *Aquatic Animal Health Service* of the *exporting country* or a *certifying official* approved by the *importing country*, and that are accompanied by an *international aquatic animal health certificate* (see Model Certificates given in Chapter 5.11.).
- 2) An *importing country* may require sufficient advance notification regarding the proposed date of entry into its *territory* of a consignment of products of aquatic animal origin destined for human consumption, together with information on the nature, quantity and packaging of the products, as well as the name of the *frontier post*.

Article 5.9.3.

On arrival at a *frontier post* of a *vehicle* transporting *aquatic animals* infected with any specified *listed disease*, the *vehicle* shall be considered to be contaminated and the *Aquatic Animal Health Service* shall apply the following measures:

- 1) unloading of the *vehicle* and immediate transportation of any possibly contaminated material, such as water or ice, to an establishment assigned in advance for its destruction and the strict application of the *aquatic animal* health measures required by the *importing country*;

- 2) *disinfection* of:
- a) outer clothes and boots of the crew on the transporting *vehicle*;
 - b) all parts of the *vehicle* that were used in the transport, moving and unloading of the *aquatic animals*.
-

CHAPTER 5.10.

**MEASURES
CONCERNING INTERNATIONAL TRANSPORT OF
AQUATIC ANIMAL PATHOGENS AND
PATHOLOGICAL MATERIAL**

Article 5.10.1.

Introduction

There is the *risk* that *disease* may occur as a result of the accidental release of *aquatic animal* pathogens during international transport of packaged materials. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied at national borders by prohibiting or controlling the importation of specified *aquatic animal* pathogens or *pathological material*, which may contain them.

Competent Authorities should not require *sanitary measures* for biological samples preserved for diagnostic applications that are treated in such a manner as to inactivate the *pathogenic agent*.

Article 5.10.2.

Importation of aquatic animal pathogens

The importation of a pathogen referred to in the *Aquatic Code*, whether in culture, in *pathological material* or in any other form, should be officially controlled by the *Competent Authority* to ensure appropriate safeguards are in place to manage the *risk* posed by the pathogen. The conditions should be appropriate to the *risk* posed by the pathogen and, in relation to air transport, the appropriate standards of the International Air Transport Association or other relevant transport associations concerning the packaging and transport of dangerous goods as outlined in Article 5.10.3. should apply.

When considering applications to import a pathogen referred to in the *Aquatic Code*, whether in culture, in *pathological material* or in any other form, from other countries, *Competent Authorities* should have regard to the nature of the material, the animal from which it is derived, the susceptibility of that animal to various *diseases* and the animal health situation of the country of origin. It may be advisable to require that material be pretreated before import to minimise the *risk* of inadvertent introduction of a pathogen referred to in the *Aquatic Code*.

Any material that does not satisfy the applied conditions should be rendered safe by the *Aquatic Animal Health Service* of the receiving country.

Article 5.10.3.

Packaging and documentation for transport

The safe transport of a pathogen referred to in the *Aquatic Code*, with respect to the pathogen, the handlers and the environment, is primarily dependent on proper packaging and it is the responsibility of the sender that this is done in accordance with current regulations.

1. Basic triple packaging system

The system consists of three layers as follows:

- a) Primary receptacle: a labelled primary watertight, leak-proof receptacle containing the specimen. The receptacle is wrapped in enough absorbent material to absorb all fluid in case of breakage.
- b) Secondary receptacle: a second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in one secondary receptacle. Sufficient additional absorbent material must be used to cushion multiple primary receptacles.

- c) Outer shipping package: the secondary receptacle is placed in an outer shipping package, which protects it and its contents from outside influences such as physical damage, temperature fluctuations and water while in transit.

Ice or dry ice when used in a shipment must be placed outside the secondary receptacle. If wet ice is used, it should be in a leak-proof *container* and the outer package must also be leak-proof. The secondary receptacle must be secured within the outer package to prevent damage after the refrigerant has melted or dissipated.

Dry ice must NOT be placed inside the primary or secondary receptacle because of the risk of explosions. The outer package must permit the release of carbon dioxide gas if dry ice is used. IATA Packing Instruction 904 must be observed for packages containing dry ice.

2. Documentation

Specimen data forms, letters and other types of information that identify or describe the specimen and also identify the shipper and receiver should be taped to the outside of the secondary receptacle, together with a copy of the recipient's import permit.

Article 5.10.4.

Any sender of a pathogen referred to in the *Aquatic Code* or *pathological material* must ensure that the proposed receiver has obtained the necessary import licence referred to in Article 5.10.2.

Article 5.10.5.

- 1) Every consignment of a pathogen referred to in the *Aquatic Code* or *pathological material* should be notified in advance by the sender to the intended recipient, giving the following information:
 - a) exact nature of the sample and its packaging;
 - b) the number of packages sent and the marks and numbers enabling their identification;
 - c) date of despatch;
 - d) method of transport used for consignment of products (ship, aircraft, railway wagon or road *vehicle*).
- 2) The recipient should notify the sender of the receipt of each consignment of a pathogen referred to in the *Aquatic Code* or *pathological material* on its arrival.
- 3) When a consignment that has been notified by the sender fails to arrive by the anticipated date, the intended recipient should notify the *Competent Authority* of the receiving country and, at the same time, the sender in the country of origin, so that any necessary action can be taken for investigation to be made without delay.

CHAPTER 5.11.

**MODEL HEALTH CERTIFICATES
FOR INTERNATIONAL TRADE
IN LIVE AQUATIC ANIMALS
AND PRODUCTS OF AQUATIC ANIMAL ORIGIN**

Article 5.11.1.

Notes for guidance on the health certificates for international trade in live aquatic animals and products of aquatic animal origin

1. General

Please complete the certificate on paper in capital letters. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

2. Part I. Details of dispatched consignment

Country:	Name of the country that issues the certificate
Box I.1.	Name and full address of the natural or legal entity dispatching the consignment. Information on telephone and fax numbers or e-mail address is recommended.
Box I.2.	The certificate reference number is the number used by the Competent Authority of the country to identify the certificate.
Box I.3.	Name of the Competent Authority.
Box I.4.	Name and full address of the natural or legal entity to whom the consignment is destined at the time the certificate is issued.
Box I.5.	Name of the country from which the live aquatic animals or gametes are being exported. For aquatic animal products, name the country(ies) where the finished products were produced, manufactured or packed. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.6.	Name of the zone or compartment of origin, if relevant, in part II of the certificate.
Box I.7.	Name of the country of destination. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.8.	Name of the zone or compartment of destination, if relevant, in part II of the certificate.
Box I.9.	Name and full address of the place(s) from which the live aquatic animals, gametes or aquatic animal products are being exported; and official approval or registration number when required. For live aquatic animals and gametes: the establishment(s) or place of capture. For products of aquatic animal origin: the premises from which the products are to be dispatched.
Box I.10.	Name of the place from which the live aquatic animals, gametes or aquatic animal products are being shipped (this will be a land, sea or airport).

Box I.11.	Date of departure. For live aquatic animals and gametes include the expected time of departure.
Box I.12.	Details of the means of transport.
	Identification of the means of transport at the time the certificate is issued: for air transport, the flight number; for maritime transport, the name of the vessel; for rail transport, the number of the train and the wagon and for road transport, the registration number of the road vehicle and the number of the trailer where used.
Box I.13.	Name of expected border post and, if available, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).
Box I.14.	CITES permit number(s) if the commodity concerns species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora.
Box I.15.	Describe the commodity or use the titles as they appear in the Harmonised System of the World Customs Organization.
Box I.16.	Heading or HS Code of the Harmonized System set up by the World Customs Organization.
Box I.17.	Total quantity or weight of the commodity.
	For live aquatic animals and gametes give the total count or weight.
	For aquatic animal products give the gross weight and the net weight in kg of the whole consignment.
Box I.18.	Temperature of products for transport and storage.
Box I.19.	For live aquatic animals and gametes give the total number of containers in which they are being transported. For aquatic animal products give the total number of packages.
Box I.20.	Identify the containers/seal numbers where required.
Box I.21.	Identify the type of packaging of products as defined in Recommendation No. 21 – Code of Passengers, Type of Cargo, Package and Packaging Materials of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business).
Box I.22.	Intended use of the imported live aquatic animals or aquatic animal products.
	Breeding: applies to gametes and broodstock.
	Grow out: applies to live aquatic animals, aquatic eggs and aquatic larvae requiring time in culture.
	Slaughter: applies to live aquatic animals for slaughter.
	Restocking: applies to live aquatic animals for the purpose of rebuilding stocks.
	Ornamental: applies to live aquatic animals kept for companionship or enjoyment.
	Competition/display: applies to live aquatic animals used for competition or display purposes.
	Human consumption: applies to live aquatic animals (without further aquaculture involved) or aquatic animals products intended for human consumption.
	Aquatic animal feed: means any product of animal origin (single or multiple), whether processed, semi-processed or raw, that is intended to be fed to aquatic animals.
	Further processing: applies to products of aquatic animal origin that have to be further processed before being suitable for end use.
	Other technical use: applies to aquatic animal products not intended for human or aquatic animal consumption. These include aquatic animal products that are intended for use in the pharmaceutical, medical, cosmetic and other industries. Such products may be subjected to extensive further processing.
Technical use in live aquatic animals: applies to aquatic animal products used in live aquatic animals, e.g. to stimulate ovulation.	

Box I.23.	Mark, if appropriate.
Box I.24.	Details on the nature of the commodity sufficient to identify it.
	For live aquatic animals and gametes: Category (i.e. amphibian, crustacean, fish or mollusc); Wild stocks or cultured stocks; Species (scientific name); and if required, Identification system; Batch number or other identification details; Age; Sex.
	For products of aquatic animal origin: Category (i.e. amphibian, crustacean, fish or mollusc); Wild stocks or cultured stocks; Species (Scientific name); Approval number of establishment(s) (e.g. processing plant; cold store); Lot identification/date code; Number of packages.

3. Part II. Zoosanitary information

Box II.	Complete this part in accordance with the requirements agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations in the Aquatic Code.
Box II.a.	Reference number: see box I.2.
Certifying Official	Name, address, official position, date of signature and official stamp of the Competent Authority.

Article 5.11.2.

Model health certificate for international trade in live aquatic animals and gametes

COUNTRY:

Part I: Details of dispatched consignment	I.1. Consignor: Name: Address:	I.2. Certificate reference number:
		I.3. Competent Authority:
	I.4. Consignee: Name: Address:	
	I.5. Country of origin: ISO Code*:	I.6. Zone or compartment of origin**:
	I.7. Country of destination: ISO Code*:	I.8. Zone or compartment of destination**:
	I.9. Place of origin: Name: Address:	
I.10. Place of shipment:	I.11. Date of departure:	
I.12. Means of transport: Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification:	I.13. Expected border post:	I.14. CITES permit No(s)**:
I.15. Description of commodity:	I.16. Commodity code (ISO code):	I.17. Total quantity:
I.18.	I.19. Total number of packages:	
I.20. Identification of container/seal number:	I.21. Type of packaging:	
I.22. Commodities intended for use as: Breeding <input type="checkbox"/> Grow out <input type="checkbox"/> Slaughter <input type="checkbox"/> Restocking <input type="checkbox"/> Ornamental <input type="checkbox"/> Competition/exhibition <input type="checkbox"/> Other <input type="checkbox"/> If other, specify:		
I.23. For import or admission: Definitive import <input type="checkbox"/> Re-entry <input type="checkbox"/> Temporary admission <input type="checkbox"/>		
I.24. Identification of commodities: Amphibian <input type="checkbox"/> Crustacean <input type="checkbox"/> Fish <input type="checkbox"/> Mollusc <input type="checkbox"/> Wild stock <input type="checkbox"/> Cultured stock <input type="checkbox"/>		
Species (scientific name):	Age*:	
Identification system*:	Batch number*:	
Sex*:		

* Optional. ** If referenced in Part II.

Article 5.11.3.

Model health certificate for international trade in products of aquatic animal origin

COUNTRY:

Part I: Details of dispatched consignment	I.1. Consignor: Name: Address:	I.2. Certificate reference number:
		I.3. Competent Authority:
	I.4. Consignee: Name: Address:	
	I.5. Country of origin: ISO Code*:	I.6. Zone or compartment of origin**:
	I.7. Country of destination: ISO Code*:	I.8. Zone or compartment of destination**:
	I.9. Place of origin: Name: Address:	
	I.10. Place of shipment:	I.11. Date of departure:
	I.12. Means of transport: Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification:	I.13. Expected border post:
		I.14. CITES permit No(s)**:
	I.15. Description of commodity:	I.16. Commodity code (ISO code):
	I.17. Total quantity/weight:	
I.18. Temperature of the product: Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>	I.19. Total number of packages:	
I.20. Identification of container/seal number:	I.21. Type of packages:	
I.22. Commodities intended for use as: Human consumption <input type="checkbox"/> Aquatic animal feed <input type="checkbox"/> Further processing <input type="checkbox"/> Other technical use <input type="checkbox"/> Other <input type="checkbox"/> If other, specify. Technical use in aquatic animals <input type="checkbox"/> If technical use, specify:		
I.23.		
I.24. Identification of commodities: Amphibian <input type="checkbox"/> Crustacean <input type="checkbox"/> Fish <input type="checkbox"/> Mollusc <input type="checkbox"/> Wild stock <input type="checkbox"/> Cultured stock <input type="checkbox"/> Species (scientific name): Approval number of establishments: Lot ID/date code:		

* Optional.

** If referenced in Part II.

SECTION 6.

ANTIMICROBIAL USE IN AQUATIC ANIMALS

CHAPTER 6.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

Article 6.1.1.

Objectives

The purpose of this section is to provide guidance for Member Countries to appropriately address the selection and dissemination of resistant microorganisms and antimicrobial resistance determinants from the use of *antimicrobial agents* in *aquatic animals*.

Antimicrobial agents are essential for human and animal health and welfare. The OIE recognises the need for access to *antimicrobial agents* in veterinary medicine: *antimicrobial agents* are essential for treating and controlling infectious diseases in *aquatic animals*. The OIE therefore considers that ensuring continued access to effective *antimicrobial agents* is important.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of *antimicrobial agents* in humans, animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to address the risk factors for the selection and dissemination of antimicrobial resistance. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Member Countries in regard to risks in the animal sector.

The application of *risk assessment* and *risk management* measures should be based on relevant international standards on *risk analysis* and supported by sound data and information when available. The guidance provided in these chapters should be consulted as part of the standard approach to reduce the risk associated with the selection and dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants.

CHAPTER 6.2.

PRINCIPLES FOR RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN AQUATIC ANIMALS

Article 6.2.1.

Purpose

These principles provide guidance for the responsible and prudent use of *antimicrobial agents* in *aquatic animals*, with the aim of protecting both animal and human health. The *Competent Authorities* responsible for the registration and marketing authorisation of products and the control of all organisations involved in the production, distribution and use of *antimicrobial agents* have specific obligations.

Article 6.2.2.

Objectives of responsible and prudent use

Responsible and prudent use includes a set of practical measures and recommendations intended to reduce the risk associated with the selection and dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants in *aquatic animal* production to:

- 1) maintain the efficacy of *antimicrobial agents* both for veterinary and human medicine and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety;
- 2) comply with the ethical obligation and economic need to keep *aquatic animals* in good health;
- 3) prevent or reduce the transfer of both resistant microorganisms and resistance determinants from *aquatic animals* to humans and terrestrial animals;
- 4) prevent antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food.

Article 6.2.3.

Definition

Pharmacovigilance of antimicrobial agent: means the detection and investigation of the effects of the use of these products, mainly aimed at safety and efficacy in *aquatic animals* and safety in people exposed to the products.

Article 6.2.4.

Responsibilities of Competent Authorities

The *Competent Authorities* responsible for granting marketing authorisation for *antimicrobial agents* have a significant role in specifying the terms of the authorisation and in providing the appropriate information to the *veterinarian* or other *aquatic animal health professional* through product labelling and/or by other means, in support of prudent use of *antimicrobial agents* in *aquatic animals*.

It is the responsibility of *Competent Authorities* to develop up-to-date guidelines on data requirements for evaluation of *antimicrobial agent* applications.

Competent Authorities in cooperation with animal and public health professionals should adopt a proactive approach to promote prudent use of *antimicrobial agents* in *aquatic animals* as an element of a comprehensive strategy for the containment of antimicrobial resistance.

Elements of a comprehensive strategy should include good animal husbandry practices, vaccination policies and development of animal health care at the farm level, and consultation with a *veterinarian* or other *aquatic animal health*

professional, all of which should contribute to reduction of the prevalence of animal *disease* requiring antimicrobial treatment.

Competent Authorities should expeditiously grant marketing authorisations when criteria of quality, efficacy and safety are met.

The examination of marketing authorisation applications should include an assessment of the risks to animals, humans and the environment resulting from the use of *antimicrobial agents* in *aquatic animals*. The evaluation should focus on each individual *antimicrobial agent* and take into consideration the class of antimicrobials to which the particular active substance belongs. The safety evaluation should include consideration of the potential impact of the proposed use in *aquatic animals* on human health, including the human health impact of antimicrobial resistance developing in microorganisms found in *aquatic animals*. An assessment of the impact of the proposed use on the environment should be conducted.

Competent Authorities should aim to ensure that advertising of *antimicrobial agents* complies with relevant legislation and marketing authorisations granted and discourage direct advertising other than to those legally entitled to prescribe the *antimicrobial agent*.

Information collected through pharmacovigilance programmes, including on lack of efficacy, should form part of the *Competent Authority's* comprehensive strategy to minimise antimicrobial resistance.

Competent Authorities should disseminate, to *veterinarians* or other *aquatic animal health professionals*, information on trends in antimicrobial resistance collected during surveillance programmes and should monitor the performance of susceptibility testing laboratories.

Competent Authorities and stakeholders should work together to provide for effective procedures for the safe collection and destruction of unused or out-of-date *antimicrobial agents*.

Article 6.2.5.

Responsibilities of the veterinary pharmaceutical industry

The veterinary pharmaceutical industry has responsibilities for providing information requested by *Competent Authorities* on the quality, efficacy and safety of *antimicrobial agents*. The responsibilities of the veterinary pharmaceutical industry cover pre- and post- marketing phases, including manufacturing, sale, importation, labelling, advertising and pharmacovigilance.

The veterinary pharmaceutical industry has the responsibility to provide the *Competent Authority* with the information necessary to evaluate the amount of *antimicrobial agents* marketed. The veterinary pharmaceutical industry should ensure that the advertising of *antimicrobial agents* directly to the *aquatic animal* producer is discouraged.

Article 6.2.6.

Responsibilities of wholesale and retail distributors

Distributors should ensure that their activities are in compliance with the relevant legislation.

Distributors should ensure that information for the appropriate use and disposal of the *antimicrobial agent* accompany all distributed products and should also be responsible for maintaining and disposing of the product in accordance with the manufacturer recommendations.

Article 6.2.7.

Responsibilities of veterinarians and other aquatic animal health professionals

Responsibilities of *veterinarians* or other *aquatic animal health professionals* include identifying, preventing and treating *aquatic animal diseases*, as well as the promotion of sound animal husbandry methods, hygiene procedures, vaccination and other alternative strategies to minimise the need for antimicrobial use in *aquatic animals*.

Veterinarians or other *aquatic animal health professionals* authorised to prescribe veterinary medicines should only prescribe, dispense or administer a specific course of treatment with an *antimicrobial agent* for *aquatic animals* under their care.

The responsibilities of *veterinarians* or other *aquatic animal health professionals* are to carry out a thorough clinical assessment of the *aquatic animal(s)*, including as appropriate: clinical examination, post-mortem examination, bacteriology with culture and sensitivity, and other laboratory tests to arrive at the most definitive *diagnosis* possible before initiating a specific course of treatment with an *antimicrobial agent*. Evaluation of environmental factors and husbandry at the production site (e.g. water quality) should be considered as potential primary factors leading to *infection* and should be addressed prior to prescribing a course of *antimicrobial agent* treatment.

If therapy with an *antimicrobial agent* is deemed necessary it should be initiated as soon as possible. The selection of the agent should be based on the knowledge and experience of the *veterinarian* or other *aquatic animal health professional* authorised to prescribe veterinary medicines.

As soon as possible, susceptibility testing of the target microorganism should be used to confirm the choice of treatment. Results of all susceptibility tests should be retained and should be available to the *Competent Authority*.

The *veterinarian* or other *aquatic animal health professional* authorised to prescribe veterinary medicines should indicate precisely to the *aquatic animal* producer the treatment regime, including the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of *antimicrobial agents* to be delivered, depending on the dosage and the number of *aquatic animals* to be treated.

The use of *antimicrobial agents* extra-label/off-label may be permitted in appropriate circumstances in conformity with the relevant legislation.

Records on the use of *antimicrobial agents* should be kept in conformity with the relevant legislation. *Veterinarians* or *aquatic animal health professionals* should also periodically review farm records on the use of the *antimicrobial agents* to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens. Suspected adverse reactions, including a lack of efficacy, should be reported to the *Competent Authority*. Associated susceptibility data should accompany the report of lack of efficacy.

Article 6.2.8.

Responsibilities of aquatic animal producers

Aquatic animal producers should implement health programmes on their farms in order to promote *aquatic animal* health and food safety. This can be done through adequate planning of culture strategies to maintain *aquatic animal* health through *biosecurity* programmes, husbandry, nutrition, vaccination, maintenance of good water quality, etc.

Aquatic animal producers should use *antimicrobial agents* only on the prescription of a *veterinarian* or other *aquatic animal health professional* authorised to prescribe veterinary medicines, and follow directions on the dosage, method of application, and withdrawal period.

Aquatic animal producers should ensure that *antimicrobial agents* are properly stored, handled, and disposed.

Aquatic animal producers should keep adequate records of *antimicrobial agents* used, bacteriological and susceptibility tests, and make such records available to the *veterinarian* or other *aquatic animal health professional*.

Aquatic animal producers should inform the *veterinarian* or other *aquatic animal health professional* of recurrent *disease* problems and lack of efficacy of *antimicrobial agent* treatment regimes.

Article 6.2.9.

Training of users of antimicrobial agents

The training of users of *antimicrobial agents* should involve all the relevant organisations, such as relevant regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, and veterinary professional organisations and other approved users such as *aquatic animal* owners.

Article 6.2.10.

Research

To address the significant lack of information for numerous species of *aquatic animals*, the relevant regulatory authorities and other stakeholders should encourage public-funded and industry-funded research.

CHAPTER 6.3.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIAL AGENTS USED IN AQUATIC ANIMALS

Article 6.3.1.

Purpose

The purpose of these recommendations is to describe approaches to the monitoring of quantities of *antimicrobial agents* used in *aquatic animals*, including species reared for food and ornamental purposes.

These recommendations are intended for use in the collection of objective and quantitative information to evaluate usage patterns by antimicrobial class, route of administration and *aquatic animal* species in order to evaluate exposure of microorganisms to *antimicrobial agents*.

The collection of data on the use of *antimicrobial agents* in *aquaculture* may be constrained in some countries by the lack of available resources, lack of accurately labelled products, poorly documented distribution channels and lack of professional consultation or supervision. This chapter may therefore be seen as indicating the direction in which countries should develop with regard to collecting data and information on the use of *antimicrobial agents* in *aquatic animals*.

Article 6.3.2.

Objectives

The information provided in these recommendations is essential for conducting *risk analyses* and for planning purposes. This information can be helpful in interpreting antimicrobial resistance surveillance data and can assist in the ability to respond to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information would help identify trends in the use of *antimicrobial agents* in *aquatic animals* and the potential association with antimicrobial resistance in *aquatic animal* bacteria, including potentially zoonotic bacteria. This information may also assist in *risk management* when evaluating the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies and indicate where alteration of prescribing practices for *antimicrobial agents* in *aquatic animals* might be appropriate. The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.3.3.

Development and standardisation of monitoring systems for antimicrobial agents

Competent Authorities may, for reasons of cost and administrative efficiency, collect medical, agricultural, aquacultural and other *antimicrobial agents* use data in a single programme. Where livestock and *aquatic animal* industries are under multiple authorities in a single country, collaboration between the authorities to develop a coordinated monitoring system is necessary to facilitate the collection of data. Additionally, a consolidated programme would facilitate the comparison of *aquatic animal* use data with human use data necessary for a comprehensive *risk analysis*.

Systems to monitor usage of *antimicrobial agents* may consist of the following elements:

1. Sources of data on antimicrobial agents

a) Basic sources

Data from basic sources may include general information without specific attribution (such as, weight, quantity and class of *antimicrobial agents*).

Sources of data will vary from country to country. Such sources may include customs, import, export, manufacturing and sales data.

b) Direct sources

Data from direct sources may include more specific information (such as target *aquatic animal* species, route of administration and active ingredient).

Data from veterinary medicinal product registration authorities, manufacturers, wholesalers, retailers, feed stores and feed mills might be useful sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by veterinary antimicrobial manufacturers to the registration authority one of the requirements of marketing authorisation (registration of the *antimicrobial agent*).

c) End-use sources

Data from end-use sources has the advantage of providing more detailed information on the type and purpose of use and can be complimentary to the other sources.

End-use sources of data may include *veterinarians*, *aquatic animal health professionals* and *aquatic animal* producers. End-use sources may be useful when more accurate and locally specific information is needed (such as extra-/off-label use).

Collection of this type of information can be resource intensive; therefore, periodic collection of this type of information may be sufficient. Data collection should be targeted to the most relevant period of use.

In some countries end-use sources may be the only practical source of information.

d) Other sources

Pharmaceutical industry associations and *aquatic animal* producer associations, veterinary and allied health professional associations, and other stakeholders with indirect knowledge of the quantities of *antimicrobial agents* used may be another source of this information.

Non-conventional sources including Internet sales data related to *antimicrobial agents* may be collected where available. Internet sales data may be particularly useful with respect to ornamental species.

2. Elements for data collection and reporting

a) Basic data to be collected should include:

- i) the absolute amount in kilograms of the active ingredient of the *antimicrobial agent(s)* used per year, divided into antimicrobial class/subclass;

for active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded; for *antimicrobial agents* expressed in International Units, the calculation required to convert these units to mass of active entity should be stated; it may be possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, export/import data or any combination of these;

- ii) the total number of *aquatic animals* treated and their weight in kilograms.

b) Additional data may be collected to further categorise the exposure of microorganisms to *antimicrobial agents* and may include:

- i) species of fish, crustaceans, molluscs or amphibians treated;

- ii) purpose e.g. *aquatic animals* for human consumption, use as ornamental species and baitfish;

- iii) route of administration (medicated feed, bath treatment, parenteral delivery) and the method used to calculate the dose (biomass of *aquatic animals*, volume of water treated);

- iv) indication for use.

The *antimicrobial agents*/classes/sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity / antimicrobial resistance mechanism.

Nomenclature of *antimicrobial agents* should comply with international standards where available.

When making information publically available, the *Competent Authority* should ensure confidentiality and anonymity of individual enterprises.

3. Considerations for data collection

Antimicrobial usage data may be collected on a routine basis and / or at a specific point in time depending on availability of resources and / or the need to monitor usage of *antimicrobial agents* or address a specific antimicrobial resistance problem.

Registration of products with labelling that accurately reflects the intended use of the *antimicrobial agent* will facilitate collection of information on the quantities and usage patterns.

Collection, storage and processing of data from end-use sources requires careful design but should have the advantage of producing accurate and targeted information.

Article 6.3.4.

Elements for interpretation of data on the use of antimicrobial agents

When available, the following information may support the interpretation of antimicrobial usage data and further characterisation of exposure pathways:

- 1) type of aquaculture system (extensive or intensive, ponds or tanks, flow-through or recirculating, hatchery or grow-out, integrated system);
- 2) animal movements (transfer between facilities or from wild to the facility, grading);
- 3) species, life stage, and/or stage of the production cycle;
- 4) environmental and culture parameters (seasonality, temperature, salinity, pH);
- 5) geographical location, specific rearing units;
- 6) weight/biomass, dosage regimes and duration of treatment with *antimicrobial agents*;
- 7) basis for treatment (historical, empirical, clinical, clinical with laboratory confirmation and sensitivity testing).

Factors such as the number/percentage of animals / culture units treated, treatment regimens, type of use and route of administration are key elements to consider for *risk assessment*.

When comparing use of *antimicrobial agents* over time, changes in size and composition of animal populations should also be taken into account.

Regarding data coming from end-user sources, analysis of the use of *antimicrobial agents* may be possible at the regional, local, farm, and the level of the individual *veterinarian* or other *aquatic animal health professional*.

CHAPTER 6.4.

DEVELOPMENT AND HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES FOR AQUATIC ANIMALS

Article 6.4.1.

Purpose

This chapter provides criteria relevant to *aquatic animals* and *aquatic animal products* intended for human consumption for:

- 1) the development of national antimicrobial resistance surveillance and monitoring programmes and
- 2) the harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes.

Article 6.4.2.

Objective of surveillance and monitoring programmes

Competent Authorities should conduct active antimicrobial resistance surveillance and monitoring programmes for *aquatic animals*.

Surveillance and monitoring of antimicrobial resistance is necessary to:

- 1) establish baseline data on the prevalence of antimicrobial resistant microorganisms and determinants;
- 2) collect information on antimicrobial resistance trends in relevant microorganisms;
- 3) explore the potential relationship between antimicrobial resistance in *aquatic animal* microorganisms and the use of *antimicrobial agents*;
- 4) detect the emergence of antimicrobial resistance mechanisms;
- 5) conduct *risk analyses* as relevant to *aquatic animal* and human health;
- 6) provide recommendations on human health and *aquatic animal* health policies and programmes;
- 7) provide information to facilitate prudent use, including guidance for professionals prescribing the use of *antimicrobial agents* in *aquatic animals*.

Cooperation at a regional level between countries conducting antimicrobial resistance surveillance should be encouraged.

The findings of surveillance and monitoring programmes should be shared at the regional and international level to maximise understanding of the global risks to *aquatic animal* health and human health. The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.4.3.

General considerations for the design of surveillance and monitoring programmes

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in microorganisms from *aquatic animals*, *aquatic animal products* intended for human consumption, and humans constitutes a critical part of *aquatic animal* health and public health strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of *antimicrobial agents* used in therapy.

For *aquaculture* it is important to conduct surveillance and monitoring of microorganisms that infect *aquatic animals* and microorganisms, including human pathogens, present on food derived from *aquatic animals*.

Article 6.4.4.

Design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect aquatic animals

An important consideration for the design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect *aquatic animals* is the lack of standardised and validated antimicrobial testing methods for a significant number of bacterial species of aquatic importance. When validated methods are available they should be used. Any deviations from standard methodology should always be clearly reported. For tests performed on bacterial species for which standard methods have not been developed full details of the methods used should be provided.

A preliminary requirement for the development of a surveillance and monitoring programme may be the identification and prioritisation of bacteria isolated from *aquatic animals* for methods development.

1. Selection of microorganisms

Information on the occurrence of antimicrobial resistance in microorganisms that infect *aquatic animals* should be derived from regular monitoring of isolates obtained from diagnostic laboratories. These isolates should have been identified as primary causal agents of significant disease epizootics in *aquatic animals*.

It is important that monitoring programmes focus on microorganisms that are associated with the commonly encountered *infections* of the major aquatic species farmed in the region / local growing area.

Selection should be designed to minimise bias resulting from over representation of isolates obtained from severe epizootics or epizootics associated with therapeutic failures.

Microorganisms belonging to a specific species or group may be selected for intensive study in order to provide information on a particular problem.

2. Methods used to analyse microorganism susceptibility to antimicrobial agents

Participating laboratories may perform disc diffusion, minimum inhibitory concentration (MIC) or other susceptibility tests to monitor frequencies of resistance. Protocols that have been standardised internationally and validated for application to the study of microorganisms isolated from *aquatic animals* should always be used.

3. Requirements for laboratories involved in monitoring resistance

Laboratories involved in national or regional monitoring of antimicrobial resistance should be of sufficient capability and have relevant expertise to comply with all the quality control requirements of the standardised test protocols. They should also be capable of participating in all necessary inter-laboratory calibration studies and method standardisation trials.

4. Choice of antimicrobial agents

Representatives of all major classes of *antimicrobial agents* used to treat *disease* in *aquatic animal* species should be included in susceptibility testing.

5. Reporting of results

The results of surveillance and monitoring programmes, including susceptibility data, should be published and made available for use by relevant stakeholders. Both primary quantitative data and the interpretive criteria used should be reported.

6. Surveillance and monitoring for epidemiological purposes

For epidemiological surveillance purposes, use of the epidemiological cut-off value (also referred to as microbiological breakpoint), which is based on the distribution of MICs or inhibition zone diameters of the specific microbial species tested, is preferred.

When reporting interpretations made by application of epidemiological cut-off values, the resultant categories should be referred to as wild type (WT) or non-wild type (NWT). When interpretations are made by the application of breakpoints the resultant categories should be referred to as sensitive, intermediate or resistant.

For microbial species and *antimicrobial agent* combinations, where internationally agreed epidemiological cut-off values have not been set, laboratories may establish their own laboratory-specific values provided the methods they use are clearly reported.

7. Surveillance and monitoring for clinical purposes

The application of clinical breakpoints may be appropriate when the aim of the programme is to provide information to facilitate prudent use, including guidance for professionals in prescribing *antimicrobial agents* in *aquatic animals*.

Selecting *antimicrobial agents* for therapeutic administration on the basis of information gained from the application of validated clinical breakpoints to antimicrobial susceptibility test data for microorganisms isolated from *aquatic animals* is an important element in the prudent use of these agents.

Use of these clinical breakpoints allows microorganisms to be identified as unlikely to respond to the *in vivo* concentrations of *antimicrobial agents* achieved by a given standard therapeutic regime. In order to facilitate the development of these breakpoints, data is required that allows clinical correlation to be completed. For this purpose, where possible, data that relates *in vitro* susceptibility of isolates to the clinical outcome of treatments with specified dose regimes under specific environmental conditions should be collected and reported.

Valuable information with respect to setting clinical breakpoints can be gained from situations where therapeutic failure is reported. The *Competent Authority* should include, in a surveillance and monitoring programme, systems for capturing details of failed treatments and the laboratory susceptibility test of the microorganisms involved.

Article 6.4.5.

Design of surveillance and monitoring programmes for microorganisms in or on aquatic animal products intended for human consumption

For details of the sampling protocols and analytical procedures required for surveillance and monitoring programmes for antimicrobial resistance in microorganisms present in *aquatic animal products* intended for human consumption, Chapter 6.7. of the OIE *Terrestrial Animal Health Code* should be consulted.

It is important to note that the word 'commensal' as used in Chapter 6.7. of the OIE *Terrestrial Animal Health Code* has less relevance due to the transient nature of the intestinal microflora of *aquatic animals*. The inclusion of intestinal microflora in surveillance and monitoring programmes should only be considered when there is evidence that these are resident for sufficient time to be a risk factor affected by *antimicrobial agents*.

When designing a sampling programme it is important to consider that contamination of *aquatic animal products* with resistant microorganisms that are capable of infecting humans may arise from sources other than the *aquatic animal*. All sources of contamination should be taken into account, for example entry of raw manure into the aquatic environment. The number of such microorganisms associated with *aquatic animals* is much less than that found in terrestrial animals. However the following species should be included, as a minimum, in a surveillance and monitoring programme:

- 1) *Salmonella* spp.;
- 2) *Vibrio parahaemolyticus*;
- 3) *Listeria monocytogenes*.

CHAPTER 6.5.

RISK ANALYSIS FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIAL AGENTS IN AQUATIC ANIMALS

Article 6.5.1.

Recommendations for analysing the risks to aquatic animal health and human health from antimicrobial resistant microorganisms of aquatic animal origin

1. Introduction

Antimicrobial resistance is a naturally occurring phenomenon influenced by many factors. However, problems related to antimicrobial resistance are inherently related to *antimicrobial agent* use in any environment, including human and non-human uses.

Antimicrobial resistance associated with the use of *antimicrobial agents* for therapeutic and non-therapeutic purposes has led to the selection and dissemination of antimicrobial resistant microorganisms, with a resulting loss of therapeutic efficacy in animal and human medicine of *antimicrobial agents*.

2. Objective

For the purposes of this chapter, the principal aim of *risk analysis* is to provide Member Countries with a transparent, objective and scientifically defensible method of assessing and managing the human and *aquatic animal* health risks associated with the selection and dissemination of resistance arising from the use of *antimicrobial agents* in *aquatic animals*.

Guidance on the issue of foodborne antimicrobial resistance related to the non-human use of *antimicrobial agents* is covered by the Codex Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL77-2011).

3. Definitions

For the purposes of this chapter, the *hazard* is the resistant microorganism or resistance determinant that emerges as a result of the use of a specific *antimicrobial agent* in *aquatic animals*. This definition reflects the potential for resistant microorganisms to cause adverse health effects, as well as the potential for horizontal transfer of genetic determinants between microorganisms. The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *aquatic animals* could become exposed to an antimicrobial resistant pathogen, fall ill and then be treated with an *antimicrobial agent* that is no longer effective.

For the purposes of this chapter, risk to *aquatic animal* health relates to the *infection* of *aquatic animals* with microorganisms in which resistance has emerged due to *antimicrobial agent* usage in *aquaculture*, and resulting in the loss of benefit of antimicrobial therapy used to manage *aquatic animal diseases*.

For the purposes of this chapter, risk to human health relates to the *infection* of humans with microorganisms in which resistance has emerged due to *antimicrobial agent* usage in *aquatic animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the human *infection*.

4. The risk analysis process

The components of *risk analysis* described in this chapter are *hazard* identification, *risk assessment*, *risk management* and *risk communication*.

The chapter includes factors to be considered at various steps of the *risk analysis* process. These factors are not intended to be exhaustive and not all elements may be applicable in all situations.

5. Risk assessment

The assessment of the risk to human and *aquatic animal* health from antimicrobial resistant microorganisms resulting from the use of *antimicrobial agents* in *aquatic animals* should examine:

- a) the likelihood of emergence of resistant microorganisms arising from the use of an *antimicrobial agent*, or more particularly dissemination of the resistance determinants if transmission is possible between microorganisms;

- b) all pathways and their contribution to the likelihood of humans and *aquatic animals* being exposed to these resistant microorganisms or resistance determinants;
- c) the consequences of exposure in terms of risks to human and *aquatic animal* health.

The general principles of *risk assessment* as defined in Article 2.1.3. apply equally to both qualitative and quantitative *risk assessment*.

Article 6.5.2.

Special considerations for conducting antimicrobial resistance risk analysis in aquaculture

1. Introduction

Antimicrobial resistance (AMR) *risk analysis* in *aquaculture* is challenged by a variety of factors that impact both *risk assessment* and *risk management*, including the diversity of *aquaculture*, relative lack of methods for culture and antimicrobial susceptibility testing (AST), relative lack of information on use of drugs, and potential for the development of a reservoir of resistant microorganisms and resistance determinants with a potential for horizontal transmission.

Nevertheless, the fundamental principles of *risk analysis* (*risk assessment*, *risk management*, *risk communication*) provide a framework just as valuable for *aquaculture* as for terrestrial animal production.

2. Data needs

Special care is required in the design of data collection programmes for *risk assessment* to take account of possible confounding factors.

Because many types of *aquaculture* operations (in particular, open systems) intersect with terrestrial animal production and human environments, it is especially important to clearly identify the risk to be assessed. The selection and dissemination of resistant microorganisms or resistant determinants may be associated with the use of *antimicrobial agents* on *aquatic animals* or it may be the result of antimicrobial use in nearby terrestrial animal production operations or the presence of *antimicrobial agents* in human waste water.

3. Diversity of aquaculture

The range of species under culture, the number and type of different culture systems, and the range of *antimicrobial agents* and their routes of administration impact elements of the *risk assessment*, particularly the entry assessment. Therefore, careful attention should be used when grouping seemingly similar sectors of the *aquaculture* industry.

Identification, selection and monitoring of *risk management* options are also influenced by the diversity of *aquaculture*.

4. Lack of standardised methods for antimicrobial susceptibility testing

Currently, standardised methods for antimicrobial susceptibility testing (AST) for many relevant *aquaculture* species are lacking resulting in inability to quantify specific risks. Standardised AST methods should be used where available; or when standardised methods are not available, well-described and scientifically sound approaches should be applied.

5. Lack of approved drugs

The small number of approved *antimicrobial agents* for use in *aquaculture* challenges *risk analysis*, both in terms of *risk assessment* and *risk management*.

The collection and use of thorough information on the types and quantities of *antimicrobial agents* that are in use in *aquaculture* and relevant to the *risk assessment* is important. In some circumstances legal extra or off-label and illegal uses may also need to be considered. See Chapter 6.3.

For *risk management*, the small number of approved drugs in combination with a range of regulatory and *aquatic animal* health infrastructure in countries engaged in *aquaculture* presents additional challenges. *Risk management* options should be practical and take into account the ability for enforcement and compliance.

For monitoring and *surveillance* programmes, a lack of approved drugs means systems for collection of data and information on the quantities of *antimicrobial agents* used may need to consider not only licensed distribution of approved drugs, but information on the use of unapproved drugs.

6. Potential for development of a reservoir (horizontal transmission)

Microorganisms inhabiting the environment represent the fundamental reservoir of resistant determinants in the biosphere. This reservoir represents the basic origin of all *antimicrobial agent* resistance determinants encountered in human and veterinary medicine. The frequency of resistance determinants in environmental microorganisms is maintained by intrinsic, non-anthropogenic factors; all human uses of *antimicrobial agents*, including in *aquaculture*, have the potential to increase the size of the reservoir.

There is a risk that the use of *antimicrobial agents* in *aquaculture* will result in a rise in the frequency of resistance determinants in the environmental microbiome. This may result in an increase in the frequency with which determinants are transferred to microorganisms capable of infecting humans, animals or *aquatic animals*. The assessment and management of this risk are extremely complex. The biological pathways both for the entry assessment and the exposure assessment are myriad and at present no specific guidelines can be offered.

Article 6.5.3.

Analysis of risks to human health

1. Definition of the risk

The *infection* of humans with microorganisms in which resistance has emerged due to *antimicrobial agent* usage in *aquatic animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the human *infection*.

2. Hazard

- Microorganisms that have acquired resistance (including multiple resistance) arising from the use of an *antimicrobial agent* in *aquatic animals*.
- Microorganisms having obtained a resistance determinant from other microorganisms which have acquired resistance arising from the use of an *antimicrobial agent* in *aquatic animals*.

The identification of the *hazard* should include consideration of the class or subclass of the *antimicrobial agent*. This definition should be read in conjunction with point 3 of Article 6.5.1.

3. Entry assessment

An entry assessment describes the biological pathways by which the use of a specific *antimicrobial agent* in *aquatic animals* leads to the entry of resistant microorganisms or resistance determinants into a particular environment. This assessment includes estimating qualitatively or quantitatively the probability of that complete process occurring. The entry assessment describes the probability of the entry of each of the *hazards* under each specified set of conditions with respect to amounts and timing.

The following factors should be considered in the entry assessment:

- species of *aquatic animals* treated with the *antimicrobial agent(s)* in question;
- *aquaculture* production system (intensive or extensive, net pens, tanks, raceways, ponds, other);
- number of *aquatic animals* treated, their age and their geographical distribution;
- prevalence of *disease* for which the *antimicrobial agent* is indicated or is used in the target *aquatic animal* population;
- data on trends in *antimicrobial agent* use and changes in *aquaculture* production systems;
- data on potential extra-label or off-label use;
- methods and routes of administration of the *antimicrobial agent*;
- dosage regimen (dose, dosing interval and duration of the treatment);
- pharmacokinetics and relevant pharmacodynamics of the *antimicrobial agent*;
- site and type of *infection*;
- development of resistant microorganisms;
- prevalence of *pathogenic agents* that are likely to develop resistance in an *aquatic animal* species;
- mechanisms and pathways of direct or indirect transfer of resistance;
- potential linkage of virulence attributes and resistance;
- cross-resistance or co-resistance with other *antimicrobial agents*;

- data on trends and occurrence of resistant microorganisms obtained through *surveillance* of *aquatic animals* and *aquatic animal products* and waste products.

The following confounding factors should be considered in the entry assessment:

- resistant microorganisms or resistant determinants associated with *aquatic animals* or *aquatic animal products* that are a result of terrestrial contamination of the aquatic environment, *feed* contamination or contamination during post-harvest processing.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant microorganisms or resistance determinants released from a given *antimicrobial agent's* use in *aquatic animals*, and estimates the probability of exposures occurring. The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

- human demographics, including population subgroups, food consumption patterns, and traditions and cultural practices with respect to the preparation and storage of food;
- prevalence of resistant microorganisms in food at the point of consumption;
- microbial load in contaminated food at the point of consumption;
- environmental contamination with resistant microorganisms;
- transfer of resistant microorganisms and their resistance determinants between humans, *aquatic animals*, and the environment;
- measures taken for microbial decontamination of food;
- survival capacity and dissemination of resistant microorganisms during the food production process (including slaughtering, processing, storage, transportation and retailing);
- disposal practices for waste products and the likelihood for human exposure to resistant microorganisms or resistance determinants through those waste products;
- capacity of resistant microorganisms to become established in humans;
- human-to-human transmission of the microorganisms under consideration;
- capacity of resistant microorganisms to transfer resistance to human commensal microorganisms and zoonotic agents;
- amount and type of *antimicrobial agents* used to treat humans;
- pharmacokinetics, such as metabolism, bioavailability, distribution to the gastrointestinal flora;
- level of direct contact of workers in the *aquaculture* or processing industries to the antimicrobial resistant organisms.

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant microorganisms or resistance determinants and the consequences of those exposures. A causal process should exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- microbial dose and subsequent host response interactions;
- variation in susceptibility of exposed populations or subgroups of the population;
- variation and frequency of human health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs (e.g. illness and hospitalisation);
- potential linkage of virulence attributes and resistance;
- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary risks;
- interference with antimicrobial therapy in humans;
- importance of the *antimicrobial agent* in animal health and human health (see OIE List of Antimicrobial Agents of Veterinary Importance and WHO List of Critically Important Antimicrobials);
- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A risk estimation integrates the results from the entry assessment, exposure assessment and consequence assessment to produce overall estimates of risks associated with the *hazards*. Thus, risk estimation takes into account the whole of the risk pathway from *hazard* identification to the unwanted consequences.

7. Risk management

Risk management consists of the steps described below.

a) Risk evaluation

Risk evaluation - the process of comparing the risk estimated in the *risk assessment* with the reduction in risk expected from the proposed *risk management* measures.

b) Option evaluation

A range of *risk management* options is available to minimise the emergence and dissemination of antimicrobial resistance and these include both regulatory and non-regulatory options, such as the development of codes of practice for the use of *antimicrobial agents* in *aquaculture*.

Risk management decisions need to consider fully the implications of these different options for human health and *aquatic animal* health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of *aquatic animal diseases* can have the dual benefits of reducing the risks to human health associated with both the bacterial pathogen under consideration and antimicrobial resistance.

c) Implementation

Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when. *Competent Authorities* should ensure an appropriate regulatory framework and infrastructure.

d) Monitoring and review

Risk management options should be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

8. Risk communication

Communication with all interested parties should be promoted at the earliest opportunity and integrated into all phases of *risk analysis*. This will provide all interested parties, including risk managers, with a better understanding of *risk management* approaches. *Risk communication* should be also well documented.

Article 6.5.4.

Analysis of risks to aquatic animal health

1. Definition of the risk

The *infection of aquatic animals* with microorganisms in which resistance has emerged due to antimicrobial usage in *aquatic animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the *aquatic animal infection*.

2. Hazard

- Microorganisms that have acquired resistance (including multiple resistance) arising from the use of an *antimicrobial agent* in *aquatic animals*.
- Microorganisms having obtained a resistance determinant from another microorganism which has acquired resistance arising from the use of an *antimicrobial agent* in *aquatic animals*.

The identification of the *hazard* should include considerations of the class or subclass of the *antimicrobial agent*. This definition should be read in conjunction with point 3 of Article 6.5.1.

3. Entry assessment

The following factors should be considered in the entry assessment:

- *aquatic animal* species treated with the *antimicrobial agent* in question;
- *aquaculture* production system (intensive or extensive, net pens, tanks, raceways, ponds, other);
- number of *aquatic animals* treated, and their age, geographical distribution and, where appropriate, sex;
- prevalence of *disease* for which the *antimicrobial agent* is indicated or is used in the target *aquatic animal* population;

- data on trends in *antimicrobial agent* use or sales and changes in *aquaculture* production systems;
- data on potential extra-label or off-label use;
- methods and routes of administration of the *antimicrobial agent*;
- dosage regimen (dose, dosing interval and duration of the treatment);
- the pharmacokinetics and pharmacodynamics of the *antimicrobial agent*;
- type and site of *infection*;
- development of resistant microorganisms;
- prevalence of *pathogenic agents* that are likely to develop resistance in an *aquatic animal* species;
- mechanisms and pathways of direct or indirect transfer of resistance;
- cross-resistance or co-resistance with other *antimicrobial agents*;
- data on trends and occurrence of resistant microorganisms obtained through *surveillance* of *aquatic animals*, *aquatic animal products* and waste products.

The following confounding factors should be considered in the entry assessment:

- resistant microorganisms or resistant determinants associated with *aquatic animals* or their products that are a result of terrestrial contamination of the aquatic environment, *feed* contamination or contamination during post-harvest processing.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant microorganisms in clinically ill and clinically unaffected *aquatic animals*;
- prevalence of resistant microorganisms in *feed* and in the *aquatic animal* environment;
- animal-to-animal transmission of the resistant microorganisms and their resistance determinants (*aquatic animal* husbandry practices, movement of *aquatic animals*);
- number or percentage of *aquatic animals* treated;
- quantity and trends of *antimicrobial agent* used in *aquatic animals*;
- survival capacity and spread of resistant microorganisms;
- exposure of wildlife to resistant microorganisms;
- disposal practices for waste products and the likelihood for *aquatic animal* exposure to resistant microorganisms or resistance determinants through those products;
- capacity of resistant microorganisms to become established in *aquatic animals*;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;
- pharmacokinetics, such as metabolism, bioavailability, distribution to relevant flora - considering the gastrointestinal flora of many aquatic species may be transient;
- transfer of resistant microorganisms and resistance determinants between humans, *aquatic animals*, and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- microbial dose and subsequent host response interactions;
- variation in *disease* susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of *aquatic animal* health effects resulting from loss of efficacy of *antimicrobial agents* and associated costs;
- potential linkage of virulence attributes and resistance;
- importance of the *antimicrobial agent* in *aquatic animal* health and human health (see OIE List of Antimicrobial Agents of Veterinary Importance and WHO List of Critically Important Antimicrobials);
- additional burden of *disease* due to antimicrobial resistant microorganisms;
- number of therapeutic failures due to antimicrobial resistant microorganisms;
- increased severity and duration of infectious *disease*;
- impact on *aquatic animal* welfare;
- estimation of the economic impact and cost on *aquatic animal* health and production;
- deaths (total per year; probability per year for a random member of the population or a member of a specific more exposed sub-population) linked to antimicrobial resistant microorganisms when compared with deaths linked to sensitive microorganisms of the same species;

- availability of alternative antimicrobial therapy;
- potential impact of switching to an alternative *antimicrobial agent* e.g. alternatives with potential increased toxicity.

6. Risk estimation

A risk estimation integrates the results from the entry assessment, exposure assessment and consequence assessment to produce overall estimates of risks associated with the *hazards*. Thus, risk estimation takes into account the whole of the risk pathway from *hazard* identification to the unwanted consequences.

7. Risk management

The relevant provisions in point 7 of Article 6.5.3. apply.

8. Risk communication

The relevant provisions in point 8 of Article 6.5.3. apply.

SECTION 7.

WELFARE OF FARMED FISH

CHAPTER 7.1.

**INTRODUCTION TO RECOMMENDATIONS FOR THE
WELFARE OF FARMED FISH**

Article 7.1.1.

Guiding principles

- 1) Considering that:
 - a) the use of fish in harvest or capture fisheries, in research and for recreation (e.g. ornamentals and aquaria), makes a major contribution to the wellbeing of people; and
 - b) there is a critical relationship between fish health and fish welfare; and
 - c) improvements in farmed fish welfare can often improve productivity and hence lead to economic benefits.
- 2) The OIE will develop recommendations for the welfare of farmed fish (excluding ornamental species) during transport, slaughter, and destruction for disease control purposes. In developing these, the following principles will apply:
 - a) The use of fish carries with it an ethical responsibility to ensure the welfare of such animals to the greatest extent practicable.
 - b) The scientific assessment of fish welfare involves both scientifically derived data and value-based assumptions that need to be considered together, and the process of making these assessments should be made as explicit as possible.

Article 7.1.2.

Scientific basis for recommendations

- 1) The basic requirements for the welfare of farmed fish include handling methods appropriate to the biological characteristics of the fish and a suitable environment to fulfil their needs.
 - 2) There are many species of fish in farming systems and these have different biological characteristics. It is not practicable to develop specific recommendations for each of these species. These OIE recommendations therefore address the welfare of farmed fish at a general level.
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CHAPTER 7.2.

WELFARE OF FARMED FISH DURING TRANSPORT

Article 7.2.1.

Scope

This chapter provides recommendations to minimise the effect of transport on the welfare of farmed fish (hereafter referred to as fish). It applies to their transport by air, by sea or on land within a country and between countries, and only considers the issues related to their welfare.

Recommendations for measures to control the *aquatic animal* health risks related to the transport of fish are included in Chapter 5.5.

Article 7.2.2.

Responsibilities

All personnel handling fish throughout the transportation process are responsible for ensuring that consideration is given to the potential impact on the welfare of the fish.

- 1) The responsibilities of the *Competent Authority* for the exporting and importing jurisdiction include:
 - a) establishing minimum standards for fish welfare during transport, including examination before, during and after their transport, appropriate certification, record keeping, awareness and training of personnel involved in transport;
 - b) ensuring implementation of the standards, including possible accreditation of transport companies.
- 2) Owners and managers of fish at the start and at the end of the journey are responsible for:
 - a) the general health of the fish and their fitness for transport at the start of the journey and to ensure the overall welfare of the fish during the transport regardless of whether these duties are subcontracted to other parties;
 - b) ensuring trained and competent personnel supervise operations at their facilities for fish to be loaded and unloaded in a manner that avoids injury and causes minimum stress;
 - c) having a *contingency plan* available to enable humane killing of the fish at the start and at the end of the journey, as well as during the journey, if required;
 - d) ensuring fish have a suitable environment to enter at their destination that ensures their welfare is maintained.
- 3) Transporters, in cooperation with the farm owner/manager, are responsible for planning the transport to ensure that the transport can be carried out in accordance with fish health and welfare standards including:
 - a) using a well maintained *vehicle* that is appropriate to the species to be transported;
 - b) ensuring trained and competent staff are available for loading and unloading, and to ensure swift humane killing of the fish, if required;
 - c) having *contingency plans* to address emergencies and minimise stress during transport;
 - d) selecting suitable equipment for loading and unloading of the *vehicle*.
- 4) The person in charge of supervising the transport is responsible for all documentation relevant to the transport, and practical implementation of recommendations for welfare of fish during transport.

Article 7.2.3.

Competence

All parties supervising transport activities, including loading and unloading, should have an appropriate knowledge and understanding to ensure that the welfare of the fish is maintained throughout the process. Competence may be gained through formal training and/or practical experience.

- 1) All persons handling live fish, or who are otherwise responsible for live fish during transport, should be competent in accordance with their responsibilities listed in Article 7.2.2.

- 2) *Competent Authority*, farm owners/managers, and transport companies have a responsibility in providing training to their respective staff and other personnel.
- 3) Any necessary training should address species-specific knowledge and may include practical experience on:
 - a) fish behaviour, physiology, general signs of *disease* and poor welfare;
 - b) operation and maintenance of equipment relevant to fish health and welfare;
 - c) water quality and suitable procedures for water exchange;
 - d) methods of live fish handling during transport, loading and unloading (species-specific aspects when relevant);
 - e) methods for inspection of the fish, management of situations frequently encountered during transport such as changes in water quality parameters, adverse weather conditions, and emergencies;
 - f) methods for the humane killing of fish in accordance with Chapter 7.4.;
 - g) logbooks and record keeping.

Article 7.2.4.

Planning the transport1. General considerations

Adequate planning is a key factor affecting the welfare of fish during transportation. The pre-transport preparation, the duration and route of a transport should be determined by the purpose of the transport e.g. *biosecurity* issues, transport of fish for stocking farms or resource enhancement, for slaughter/killing for disease control purposes. Before the transport starts, plans should be made in relation to:

- a) type of *vehicle* and transport equipment required;
- b) route – such as distance, expected weather and/or sea conditions;
- c) nature and duration of the transport;
- d) assessment of the need for acclimatisation of fish to water quality at the site of unloading;
- e) need for care of the fish during the transport;
- f) emergency response procedures related to fish welfare;
- g) assessment of the necessary *biosecurity* level (e.g. washing and *disinfection* practices, safe places for changing water, treatment of transport water) (refer to Chapter 5.5.).

2. Vehicle design and maintenance, including handling equipment

- a) *Vehicles* and *containers* used for transport of fish should be appropriate to the species, size, weight and number of fish to be transported.
- b) *Vehicles* and *containers* should be maintained in good mechanical and structural condition to prevent predictable and avoidable damage of the *vehicle* that may directly or indirectly affect the welfare of transported fish.
- c) *Vehicles* (if relevant) and *containers* should have adequate circulation of water and equipment for oxygenation as required to meet variations in the conditions during the journey and the needs of the animals being transported, including the closing of valves in well boats for *biosecurity* reasons.
- d) The fish should be accessible to inspection en route, if necessary, to ensure that fish welfare can be assessed.
- e) Documentation that focuses on fish welfare and thus carried with the *vehicle* should include a transport logbook of stocks received, contact information, mortalities and disposal/storage logs.
- f) Equipment used to handle fish, for example nets and dip nets, pumping devices and brailing devices, should be designed, constructed and maintained to minimise physical injuries.

3. Water

- a) Water quality (e.g. oxygen, CO₂ and NH₃ level, pH, temperature, salinity) should be appropriate for the species being transported and method of transportation.
- b) Equipment to monitor and maintain water quality may be required depending on the length of the transport.

4. Preparation of fish for the transport

- a) Prior to transport, feed should be withheld from the fish, taking into consideration the fish species and life stage to be transported.

- b) The ability of the fish to cope with the stress of transport should be assessed based on health status, previous handling and recent transport history of the fish. Generally, only fish that are fit for transport should be loaded. Transport for disease control purposes should be in accordance with Chapter 7.4.
- c) Reasons for considering of unfitness of fish for transport include:
 - i) displaying clinical signs of *disease*;
 - ii) significant physical injuries or abnormal behaviour, such as rapid ventilation or abnormal swimming;
 - iii) recent exposure to stressors that adversely affect behaviour or physiological state (for example extreme temperatures, chemical agents);
 - iv) insufficient or excessive length of fasting.

5. Species-specific recommendations

Transport procedures should take account of variations in the behaviour and specific needs of the transported fish species. Handling procedures that are successful with one species may be ineffective or dangerous for another species.

Some species or life stages may need to be physiologically prepared prior to entering a new environment, such as by feed deprivation or osmotic acclimatisation.

6. Contingency plans

There should be a *contingency plan* that identifies the important adverse fish welfare events that may be encountered during the transport, the procedures for managing each event and the action to be taken in such an event. For each event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Article 7.2.5.

Documentation

- 1) Fish should not be loaded until the required documentation is complete.
- 2) The documentation accompanying the consignment (the transport log) should include:
 - a) description of the consignment (e.g. date, time, and place of loading, species, biomass load);
 - b) description of the transport plan (e.g. including route, water exchanges, expected time, date and place of arrival and unloading and receiver contact information).
- 3) The transport log should be made available to the dispatcher and the receiver of the consignment as well as to the *Aquatic Animal Health Service* upon request. Transport logs from previous journeys should be kept after completion of the transport for a period of time as specified by the *Aquatic Animal Health Service*.

Article 7.2.6.

Loading the fish

- 1) The issues which should be addressed to avoid injury and unnecessary stress to the fish include:
 - a) crowding procedure in farm pond, tank, net or cage prior to loading;
 - b) equipment (such as nets, pumps, pipes and fittings) that are improperly constructed (e.g. sharp bends or protrusions) or improperly operated (e.g. overloading with fish of incorrect size or number of fish);
 - c) water quality - some species of fish should be acclimatised if there is a likelihood of the fish being transported in water of a significantly different temperature or other water parameters.
- 2) The density of fish in a *vehicle* and/or *container* should be in accordance with scientific data where available and not exceed what is generally accepted for a given species and a given situation.
- 3) Loading should be carried out, or supervised, by operators with knowledge and experience of the behaviour and other characteristics of the fish species being loaded to ensure that the welfare of the fish is maintained.

Article 7.2.7.

Transporting the fish

1. General considerations

- a) Periodic inspections should take place during the transport to verify that acceptable welfare is being maintained.
- b) Ensure that water quality is monitored and the necessary adjustments made to avoid extreme conditions.
- c) Travel in a manner that minimises uncontrolled movements of the fish that may lead to stress and cause injury.

2. Sick or injured fish

- a) In the event of a fish health emergency during transport, the *vehicle* operator should initiate the *contingency plan* (see point 6 of Article 7.2.4.).
- b) If the killing of fish is necessary during the transport, it should be carried out humanely in accordance with Chapter 7.4.

Article 7.2.8.

Unloading the fish

- 1) The principles of good fish handling during loading apply equally during unloading.
- 2) Fish should be unloaded as soon as possible after arrival at the destination, allowing sufficient time to ensure that the unloading procedure does not cause harm to the fish. Some species of fish should be acclimatised if there is a likelihood of the fish being unloaded into water of a significantly different quality (such as temperature, salinity, pH).
- 3) Moribund or seriously injured fish should be removed and humanely killed in accordance with Chapter 7.4.

Article 7.2.9.

Post-transport activities

- 1) The person in charge of receiving the fish should closely observe them during the post-transport period, and keep appropriate records.
 - 2) Fish showing abnormal clinical signs should be humanely killed in accordance with Chapter 7.4. or isolated and examined by a *veterinarian* or other qualified personnel, who may recommend treatment.
 - 3) Significant problems associated with transport should be evaluated to prevent recurrence of such problems.
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CHAPTER 7.3.

WELFARE ASPECTS OF STUNNING AND KILLING OF FARMED FISH FOR HUMAN CONSUMPTION

Article 7.3.1.

Scope

These recommendations apply to the stunning and killing of farmed fish species for human consumption.

These recommendations address the need to ensure the welfare of farmed fish, intended for human consumption, during stunning and killing including transport and holding immediately prior to stunning.

This chapter describes general principles that should be applied to ensure the welfare of fish for stunning and killing for human consumption and also applies to farmed fish killed for disease control purposes. Other measures applicable to emergency killing for disease control purposes are addressed in Chapter 7.4.

As a general principle, farmed fish should be stunned before killing, and the stunning method should ensure immediate and irreversible loss of consciousness. If the stunning is not irreversible, fish should be killed before consciousness is recovered.

Article 7.3.2.

Personnel

Persons engaged in the handling, stunning and killing of fish play an important role in their welfare. Personnel handling fish for stunning and killing should be experienced and competent in the handling of fish, and understand their behaviour patterns as well as the underlying principles necessary to carry out their tasks. Some stunning and killing methods may pose a risk to the personnel; therefore training should cover occupational health and safety implications of any methods used.

Article 7.3.3.

Transport

If fish are to be transported prior to stunning and killing, this should be done in accordance with OIE recommendations on the welfare of farmed fish during transport (see Chapter 7.2.).

Article 7.3.4.

Design of holding facilities

- 1) The holding facilities should be designed and specifically constructed to hold a certain fish species or group of fish species.
- 2) The holding facilities should be of a size that allows holding a certain number of fish for processing in a given timeframe without compromising the welfare of the fish.
- 3) Operations should be conducted with minimal injury and stress to the fish.
- 4) The following recommendations may help to achieve this:
 - a) nets and tanks should be designed and maintained to minimise physical injuries;
 - b) water quality should be suitable for the fish species and stocking density;
 - c) equipment for transferring fish, including pumps and pipes, should be designed and maintained to minimise injury.

Article 7.3.5.

Unloading, transferring and loading

- 1) Fish should be unloaded, transferred and loaded under conditions that minimise injury and stress to the fish.
- 2) The following points should be considered:
 - a) Water quality (e.g. temperature, oxygen and CO₂ levels, pH and salinity) should be assessed on arrival of fish prior to their unloading, and corrective action taken if required.
 - b) Where possible any injured or moribund fish should be separated and killed humanely.
 - c) The crowding periods of fish should be as short and infrequent as possible to avoid stressful conditions arising.
 - d) The handling of fish during transfers should be minimised and preferably fish should not be handled out of water. If fish need to be removed from water, this period should be kept as short as possible.
 - e) Where feasible, and when applicable, fish should be allowed to swim directly into a stunning device without handling to avoid handling stress.
 - f) Equipment used to handle fish, for example nets and dip nets, pumping devices and brailing devices, should be designed, constructed and operated to minimise physical injuries (e.g. pumping height, pressure and speed are important factors to consider).
 - g) Fish should not be fasted (deprived of food) before killing for longer than is necessary, e.g. to clear the gut or to reduce undesirable organoleptic properties.
 - h) There should be a *contingency plan* to address emergencies and minimise stress during unloading, transferring and loading fish.

Article 7.3.6.

Stunning and killing methods

1. General considerations

- a) The choice of method should take account of species-specific information where available.
- b) All handling, stunning and killing equipment should be maintained and operated appropriately; it should be tested on a regular basis to ensure that performance is adequate.
- c) Effective stunning should be verified by the absence of consciousness.
- d) A backup stunning system is necessary. Any fish mis-stunned, or regaining consciousness before death, should be re-stunned as soon as possible.
- e) Stunning should not take place if killing is likely to be delayed such that the fish will recover or partially recover consciousness.
- f) While absence of consciousness may be difficult to recognise, signs of correct stunning include i) loss of body and respiratory movement (loss in opercular activity); ii) loss of visual evoked response (VER); iii) loss of vestibulo-ocular reflex (VOR, eye rolling).

2. Mechanical stunning and killing methods

- a) Percussive stunning is achieved by a blow of sufficient strength to the head applied above or immediately adjacent to the brain in order to damage the brain. Mechanical stunning may be achieved either manually or using specially developed equipment.
- b) Spiking or coring are irreversible stunning and killing methods of fish based on physical damage to the brain by inserting a spike or core into the brain.
- c) Shooting using a free bullet may be used for killing large fish (such as tuna). The fish may either be crowded in a net and shot in the head from the surface, or individual fish may be killed by shooting in the head from under the water (commonly called lupara).
- d) Unconsciousness following mechanical stunning is generally irreversible if correctly applied. In cases where the loss of consciousness is transient, fish should be killed before consciousness is recovered.

3. Electrical stunning and killing methods

- a) Electrical stunning involves the application of an electrical current of sufficient strength and duration, and suitable frequency to cause immediate loss of consciousness and insensibility of the fish. The conductivity of fresh and brackish water varies, so it is essential to establish the parameters of the electrical current to ensure proper stunning at the site of stunning.
- b) The electrical stunning device should be constructed and used for the specific fish species and their environment.
- c) Unconsciousness following electrical stunning may be reversible. In such cases fish should be killed before consciousness is recovered.
- d) Fish should be confined beneath the surface of the water, and there should be a uniform distribution of electrical current in the stunning tank or chamber.
- e) In semi-dry electrical stunning systems, fish should enter the device head first to ensure rapid and efficient stunning.

4. Other killing methods

The following methods are known to be used for killing fish: chilling with ice in holding water, carbon dioxide (CO₂) in holding water; chilling with ice and CO₂ in holding water; salt or ammonia baths; asphyxiation by removal from water; exsanguination without stunning. However, they have been shown to result in poor fish welfare. Therefore, these methods should not be used if it is feasible to use the methods described in points 2 and 3 of this article, as appropriate to the fish species.

Article 7.3.7.

Summary table of some stunning/killing methods for fish and their respective welfare issues

A combination of methods described in the table below may be used.

Stunning/ killing method	Specific method	Key fish welfare concerns/requirements	Advantages	Disadvantages
Mechanical	Percussive stunning	The blow should be of sufficient force and delivered above or adjacent to the brain in order to render immediate unconsciousness. Fish should be quickly removed from the water, restrained and given a quick blow to the head, delivered either manually by a club or by automated percussive stunning. The effectiveness of stunning should be checked, and fish be re-stunned if necessary. It can be a stun / kill method.	Immediate loss of consciousness. Suitable for medium to large sized fish.	Hand operated equipment may be hampered by uncontrolled movement of the fish. Mis-stunning may result from a too weak blow. Injuries may occur. Manual percussive stunning is only practicable for the killing of a limited number of fish of a similar size.
	Spiking or coring	The spike should be aimed on the skull in a position to penetrate the brain of the fish and the impact of the spike should produce immediate unconsciousness. Fish should be quickly removed from the water, restrained and the spike immediately inserted into the brain. It is a stun / kill method.	Immediate loss of consciousness. Suitable for medium to large sized fish. For small tuna, spiking under the water avoids exposure of fish to air. The pineal window of tuna facilitates spiking for this species.	Inaccurate application may cause injuries. Difficult to apply if fish agitated. It is only practicable for the killing of a limited number of fish.
	Free bullet	The shot should be carefully aimed at the brain. The fish should be positioned correctly and the shooting range should be as short as practicable. It is a stun / kill method.	Immediate loss of consciousness. Suitable for large sized fish (e.g. large tuna).	Shooting distance; calibre need to be adapted. Excessive crowding and noise of guns may cause stress reaction. Contamination of the working area due to release of body fluids may present a biosecurity risk. May be hazardous to operators.

Stunning/ killing method	Specific method	Key fish welfare concerns/requirements	Advantages	Disadvantages
Electrical	Electrical stunning	Involves the application of an electrical current of sufficient strength, frequency and duration to cause immediately unconsciousness. It can be a stun / kill method. Equipment should be designed and maintained correctly.	Immediate loss of consciousness. Suitable for small to medium sized fish. Suitable for large numbers of fish, and the fish do not have to be removed from the water.	Difficult to standardise for all species. Optimal control parameters are unknown for some species. May be hazardous to operators.
	Semi-dry electrical stunning	The head of the fish should enter the system first so electricity is applied to the brain first. Involves the application of an electrical current of sufficient strength, frequency and duration to cause immediately unconsciousness. Equipment should be designed and maintained correctly.	Good visual control of stunning and the ability for re-stunning of individual fish.	Misplacement of the fish may result in improper stunning. Optimal control parameters are unknown for some species. Not suitable for mixed sizes of fish.

[Note: the terms small, medium and large fish should be interpreted relative to the species in question.]

Article 7.3.8.

Examples of stunning/killing methods for fish groups

The following methods enable humane killing for the following fish groups:

- 1) percussive stunning: carp, salmonids;
- 2) spiking or coring: tuna;
- 3) free bullet: tuna;
- 4) electrical stunning: carp, eel, salmonids.

CHAPTER 7.4.

KILLING OF FARMED FISH FOR DISEASE CONTROL PURPOSES

Article 7.4.1.

Scope

These recommendations are based on the premise that a decision to kill the farmed fish for disease control purposes has been made, and address the need to ensure the welfare of the farmed fish until they are dead.

The culling of individual farmed fish, in the course of farming operations (i.e. sorting, grading, or background morbidity), is out of the scope of this chapter.

Account should also be taken of the guidance given in the following chapters in the *Aquatic Code*: 4.5. Contingency planning; Chapter 4.7. Handling, disposal and treatment of aquatic animal waste; Chapter 5.5. Control of aquatic animal health risks associated with transport; Chapter 7.2. Welfare of farmed fish during transport and Chapter 7.3. Welfare aspects of stunning and killing of farmed fish for human consumption.

Article 7.4.2.

General principles

- 1) Fish welfare considerations should be addressed within *contingency plans* for disease control (refer to Chapter 4.5.).
- 2) The killing method should be selected taking into consideration fish welfare and *biosecurity* requirements as well as safety of the personnel.
- 3) When fish are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or the least aversive possible and should not cause avoidable pain, distress or suffering in fish.
- 4) The methods described in Chapter 7.3. can also be used for disease control purposes.
- 5) Some of the methods recommended for disease control purposes (e.g. anaesthetic overdose, maceration) may render the fish unsuitable for human consumption, and this should be specified in the *contingency plan*.
- 6) Depending on the situation, emergency killing of fish may be carried out on site or after fish are transported to an approved killing facility.

Article 7.4.3.

Operational guidelines for affected premises and approved killing facilities

- 1) The following should apply when killing fish:
 - a) Operational procedures should be adapted to the specific circumstances on the premises and should address fish welfare and *biosecurity* specific to the *disease* of concern.
 - b) Killing of fish should be carried out without delay by appropriately qualified personnel with all due consideration made to increased *biosecurity* protocols.
 - c) Handling of fish should be kept to a minimum to avoid stress and to prevent spread of *disease*. This should be done in accordance with the articles described below.
 - d) Methods used to kill the fish should render them unconscious until death or kill them in the shortest time possible, and should not cause avoidable pain or distress.

- e) There should be continuous monitoring of the procedures to ensure they are consistently effective with regard to *biosecurity* and fish welfare.
- f) Standard operating procedures (SOP's) should be available and followed at the premises.
- 2) Procedures for the killing of fish on affected premises for disease control purposes should be developed by the operator and approved by the *Competent Authority*, taking into consideration fish welfare and *biosecurity* requirements as well as safety of the personnel and should include consideration of:
 - a) handling and movement of fish;
 - b) species, number, age and size of fish to be killed;
 - c) methods for killing the fish;
 - d) availability of anaesthetic agents suitable to kill the fish;
 - e) equipment needed to kill the fish;
 - f) any legal issues (e.g. the use of anaesthetic agents suitable for killing fish);
 - g) presence of other nearby *aquaculture* premises;
 - h) disposal of killed fish in accordance with Chapter 4.7.

Article 7.4.4.

Competencies and responsibilities of the operational team

The operational team is responsible for planning, implementation of, and reporting on the killing of the fish.

1. Team leader

- a) Competencies
 - i) Ability to assess fish welfare, especially relating to the effectiveness of the stunning and killing techniques selected and utilised in the fish killing operations, to detect and correct any deficiencies;
 - ii) ability to assess *biosecurity* risks and mitigation measures being applied to prevent spread of *disease*;
 - iii) skills to manage all activities on premises and deliver outcomes on time;
 - iv) awareness of the psychological impact on fish farmers, team members and general public;
 - v) effective communication skills.
- b) Responsibilities
 - i) Determine most appropriate killing method(s) to ensure that the fish are killed without avoidable pain and distress while balancing *biosecurity* considerations;
 - ii) plan overall operations on the affected premises;
 - iii) determine and address requirements for fish welfare, operator safety and *biosecurity*;
 - iv) organise, brief and manage a team of people to facilitate killing of the relevant fish in accordance with national *contingency plans* for disease control;
 - v) determine logistics required;
 - vi) monitor operations to ensure that fish welfare, operator safety and *biosecurity* requirements are met;
 - vii) report upwards on progress and problems;
 - viii) provide a written report summarising the killing practices utilised in the operation and their effect on fish welfare and subsequent *biosecurity* outcomes. The report should be archived and be accessible for a period of time defined by the *Competent Authority*;
 - ix) review on-site facilities in terms of their appropriateness for mass destruction.

2. On-site personnel responsible for killing of fish

- a) Competencies
 - i) Specific knowledge of fish, their behaviour and environment;
 - ii) trained and competent in fish handling, stunning and killing procedures;
 - iii) trained and competent in the operation and maintenance of equipment.
- b) Responsibilities
 - i) Ensure killing of fish through effective stunning and killing techniques;
 - ii) assist team leader as required;
 - iii) design and construct temporary fish handling facilities, when required.

Article 7.4.5.

Killing by an overdose of an anaesthetic agent

This article refers to killing methods using an overdose of an anaesthetic agent.

1. Use of anaesthetic agents

- a) Anaesthetic agents used for killing fish should kill the fish effectively, not merely have an anaesthetic effect.
- b) When using anaesthetic agents, the operating personnel should ensure that the solution has the correct concentration for the water in which it is to be administered, and that water of appropriate quality for the species and life stage of fish is used.
- c) Fish should be kept in the anaesthetic solution until they are dead.

2. Advantages

- a) Large numbers of fish may be killed in one batch.
- b) Handling is not required until fish are dead.
- c) Use of anaesthetic agents is a non-invasive technique and thus reduces *biosecurity* risks.

3. Disadvantages

- a) The method may fail to cause death in fish, e.g. dilution of the anaesthetic solution with prolonged use. In such circumstances, fish that are anaesthetised should be killed before they regain consciousness.
- b) Some anaesthetic agents may induce a transient aversive reaction in the fish.
- c) Care is essential in the preparation and provision of treated water, and in the disposal of water and/or fish carcasses that have been treated with anaesthetic agents.

Article 7.4.6.

Mechanical killing methods

1. Decapitation

- a) Decapitation, using a sharp device, such as a guillotine or knife, may be used but should be preceded by stunning or, if appropriate, anaesthesia.
- b) The required equipment should be kept in good working order.
- c) Contamination of the working area by blood, body fluids and other organic material may present a *biosecurity* risk and is the major disadvantage of this method.

2. Maceration

- a) Maceration by a mechanical device with rotating blades or projections causes immediate fragmentation and death in newly hatched fish and embryonated eggs, as well as fertilised/unfertilised eggs of fish. It is a suitable method for the processing of such material. A large number of eggs/newly hatched fry can be killed quickly.
- b) Maceration requires specialised equipment which should be kept in good working order. The rate of introducing material into the device should be such that the cutting blades continue to rotate at their fully functional rate and that they do not fall below the defined critical speed defined by the manufacturer.
- c) Contamination of the working area by blood, body fluids and other organic material may present a *biosecurity* risk and is the major disadvantage of this method.

SECTION 8.
DISEASES OF AMPHIBIANS

CHAPTER 8.1.
INFECTION WITH *BATRACHOCHYTRIUM*
DENDROBATIDIS

Article 8.1.1.

For the purposes of the *Aquatic Code*, infection with *Batrachochytrium dendrobatidis* means *infection* with the freshwater fungus *B. dendrobatidis* (Fungi, Chytridiomycota, Rhizophydiales).

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 8.1.2.

Scope

The recommendations in this chapter apply to: all species of *Anura* (frogs and toads), *Caudata* (salamanders, newts and sirens) and *Gymnophiona* (caecilians). The recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 8.1.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *B. dendrobatidis*, regardless of the *infection* with *B. dendrobatidis* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 8.1.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed amphibian products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) cooked amphibian products that have been subjected to heat treatment at 100°C for at least one minute (or any time/temperature equivalent which has been demonstrated to inactivate *B. dendrobatidis*);
 - c) pasteurised amphibian products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate *B. dendrobatidis*);
 - d) mechanically dried amphibian products (i.e. a heat treatment of 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate *B. dendrobatidis*);
 - e) amphibian skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 8.1.2., other than those referred to in point 1 of Article 8.1.3., *Competent Authorities* should require the conditions prescribed in Articles 8.1.7. to 8.1.12. relevant to the *infection* with *B. dendrobatidis* status of the *exporting country, zone or compartment*.

- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 8.1.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with *B. dendrobatidis*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 8.1.4.

Country free from infection with *B. dendrobatidis*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with *B. dendrobatidis* if all the areas covered by the *zone* are declared *infection* with *B. dendrobatidis* free (see Article 8.1.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with *B. dendrobatidis* if:

- 1) none of the *susceptible species* referred to in Article 8.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 8.1.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the *disease* status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. dendrobatidis*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *B. dendrobatidis* and subsequently lost its *disease* free status due to the detection of *infection* with *B. dendrobatidis* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. dendrobatidis*.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 8.1.5.

Article 8.1.5.

Zone or compartment free from infection with *B. dendrobatidis*

If a *zone* or *compartment* extends over more than one country, it can only be declared an *infection* with *B. dendrobatidis* free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *B. dendrobatidis* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 8.1.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 8.1.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with *B. dendrobatidis*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *B. dendrobatidis* and subsequently lost its *disease free status* due to the detection of *infection* with *B. dendrobatidis* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. dendrobatidis*.

Article 8.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *B. dendrobatidis* following the provisions of points 1 or 2 of Articles 8.1.4. or 8.1.5. (as relevant) may maintain its status as free from *infection* with *B. dendrobatidis* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *B. dendrobatidis* following the provisions of point 3 of Articles 8.1.4. or 8.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *B. dendrobatidis* provided that conditions that are conducive to clinical expression of *infection* with *B. dendrobatidis*, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *B. dendrobatidis*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 8.1.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *B. dendrobatidis*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 8.1.2. from a country, *zone* or *compartment* declared free from *infection* with *B. dendrobatidis*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 8.1.4. or 8.1.5. (as applicable) and 8.1.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with *B. dendrobatidis*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 8.1.3.

Article 8.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

- 1) When importing, for aquaculture, live *aquatic animals* of species referred to in Article 8.1.2. from a country, zone or compartment not declared free from infection with *B. dendrobatidis*, the *Competent Authority* of the *importing country* should assess the *risk* and apply *risk* mitigation measures such as:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment;
 - b) the treatment of water and equipment used in transport and of all effluent and waste materials in a manner that inactivates *B. dendrobatidis*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *B. dendrobatidis*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for infection with *B. dendrobatidis* and perform general examinations for pests and general health/disease status;
 - g) if infection with *B. dendrobatidis* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as infection with *B. dendrobatidis* free or specific pathogen free (SPF) for infection with *B. dendrobatidis*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, zone or compartment.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 8.1.3.

Article 8.1.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 8.1.2. from a country, zone or compartment not declared free from infection with *B. dendrobatidis*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 8.1.3., or products described in point 1 of Article 8.1.12., or other products authorised by the *Competent Authority*, and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *B. dendrobatidis* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 8.1.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 8.1.2. from a country, *zone* or *compartment* not declared free from *infection* with *B. dendrobatidis*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment be delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water and equipment used in transport and all effluent and waste materials from the processing facility be treated in a manner that inactivates *B. dendrobatidis*.

This Article does not apply to *commodities* referred to in point 1 of Article 8.1.3.

Article 8.1.11.

Importation of live aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

When importing, for use in laboratories or zoos, live *aquatic animals* of species referred to in Article 8.1.2. from a country, *zone* or *compartment* not declared free from *infection* with *B. dendrobatidis*, the *Competent Authority* of the *importing country* should ensure:

- 1) the direct delivery to and lifelong holding of the consignment in *quarantine* facilities authorised by the *Competent Authority*; and
- 2) the treatment of water and equipment used in transport and of all effluent and waste materials in a manner that inactivates *B. dendrobatidis*; and
- 3) the disposal of carcasses in accordance with Chapter 4.7.

Article 8.1.12.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *B. dendrobatidis*, regardless of the *infection* with *B. dendrobatidis* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of amphibian meat (skin off and fresh or frozen) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 8.1.2. from a country, *zone* or *compartment* not declared free from *infection* with *B. dendrobatidis*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 8.2.

INFECTION WITH RANAVIRUS

Article 8.2.1.

For the purposes of the *Aquatic Code*, infection with ranavirus means *infection* with any member virus species of the genus *Ranavirus* in the family *Iridoviridae* with the exception of epizootic haematopoietic necrosis virus and European catfish virus.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 8.2.2.

Scope

The recommendations in this chapter apply to: all species of *Anura* (frogs and toads) and *Caudata* (salamanders and newts). The recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 8.2.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with ranavirus

- 1) *Competent Authorities* should not require any conditions related to *infection* with ranavirus, regardless of the *infection* with ranavirus status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 8.2.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed amphibian products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) cooked amphibian products that have been subjected to heat treatment at 65°C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate all virus species of the genus *Ranavirus* in the family *Iridoviridae* [with the exception of epizootic haematopoietic necrosis virus and European catfish virus]);
 - c) pasteurised amphibian products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate all virus species of the genus *Ranavirus* in the family *Iridoviridae* [with the exception of epizootic haematopoietic necrosis virus and European catfish virus]);
 - d) mechanically dried amphibian products (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate all virus species of the genus *Ranavirus* in the family *Iridoviridae* [with the exception of epizootic haematopoietic necrosis virus and European catfish virus]).
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 8.2.2., other than those referred to in point 1 of Article 8.2.3., *Competent Authorities* should require the conditions prescribed in Articles 8.2.7. to 8.2.12. relevant to the *infection* with ranavirus status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 8.2.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with ranavirus, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 8.2.4.

Country free from infection with ranavirus

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with ranavirus if all the areas covered by the *zone* are declared free from *infection* with ranavirus (see Article 8.2.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with ranavirus if:

- 1) none of the *susceptible species* referred to in Article 8.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 8.2.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with ranavirus;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with ranavirus and subsequently lost its *disease* free status due to the detection of *infection* with ranavirus but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with ranavirus.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 8.2.5.

Article 8.2.5.

Zone or compartment free from infection with ranavirus

If a *zone* or *compartment* extends over more than one country, it can only be declared an *infection* with ranavirus free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with ranavirus may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 8.2.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 8.2.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with ranavirus;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from *infection* with ranavirus and subsequently lost its *disease free status* due to the detection of the *infection* with ranavirus in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with ranavirus.

Article 8.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with ranavirus following the provisions of points 1 or 2 of Articles 8.2.4. or 8.2.5. (as relevant) may maintain its status as free from *infection* with ranavirus provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with ranavirus following the provisions of point 3 of Articles 8.2.4. or 8.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with ranavirus provided that conditions that are conducive to clinical expression of *infection* with ranavirus, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with ranavirus, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 8.2.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with ranavirus

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 8.2.2. from a country, *zone* or *compartment* declared free from *infection* with ranavirus, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 8.2.4. or 8.2.5. (as applicable) and 8.2.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with ranavirus.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 8.2.3.

Article 8.2.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with ranavirus

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 8.2.2. from a country, zone or compartment not declared free from infection with ranavirus, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of ranavirus.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for ranavirus, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with ranavirus and perform general examinations for pests and general health/disease status;
 - g) if *infection* with ranavirus is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as free of *infection* with ranavirus or specific pathogen free (SPF) for *infection* with ranavirus;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, zone or compartment.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 8.2.3.

Article 8.2.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with ranavirus

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 8.2.2. from a country, zone or compartment not declared free from infection with ranavirus, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 8.2.3., or products described in point 1 of Article 8.2.12., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ranavirus or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 8.2.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with ranavirus

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of the species referred to in Article 8.2.2. from a country, *zone* or *compartment* not declared free from *infection* with ranavirus, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment be delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water and equipment used in transport and all effluent and waste materials from the processing facility be treated in a manner that inactivates ranavirus.

This Article does not apply to *commodities* referred to in point 1 of Article 8.2.3.

Article 8.2.11.

Importation of live aquatic animals intended for use in laboratories or zoos, from a country, zone or compartment not declared free from infection with ranavirus

When importing, for use in laboratories or zoos, live *aquatic animals* of species referred to in Article 8.2.2. from a country, *zone* or *compartment* not declared free from *infection* with ranavirus, the *Competent Authority* of the *importing country* should ensure:

- 1) the direct delivery to and lifelong holding of the consignment in *quarantine* facilities authorised by the *Competent Authority*; and
- 2) the treatment of water and equipment used in transport and of all effluent and waste materials in a manner that inactivates ranavirus; and
- 3) the disposal of carcasses in accordance with Chapter 4.7.

Article 8.2.12.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with ranavirus

- 1) *Competent Authorities* should not require any conditions related to *infection* with ranavirus, regardless of the *infection* with ranavirus status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:
 - no *commodities* listed.
- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 8.2.2. from a country, *zone* or *compartment* not declared free from *infection* with ranavirus, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

SECTION 9.
DISEASES OF CRUSTACEANS

CHAPTER 9.1.
CRAYFISH PLAGUE
(*APHANOMYCES ASTACI*)

Article 9.1.1.

For the purposes of the *Aquatic Code*, crayfish plague means *infection* with *Aphanomyces astaci* Schikora. This organism is a member of a group commonly known as the water moulds (the *Oomycetida*). Common synonyms are listed in the corresponding chapter of the *Aquatic Manual*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.1.2.

Scope

The recommendations in this chapter apply to all species of crayfish in all three crayfish families (*Cambaridae*, *Astacidae* and *Parastacidae*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 9.1.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from crayfish plague

- 1) *Competent Authorities* should not require any conditions related to crayfish plague, regardless of the crayfish plague status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.1.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crayfish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time /temperature equivalent);
 - b) cooked crayfish products that have been subjected to heat treatment at 100°C for at least one minute (or any time/temperature equivalent which has been demonstrated to inactivate *A. astaci*);
 - c) pasteurised crayfish products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate *A. astaci*);
 - d) frozen crayfish products that have been subjected to minus 20°C or lower temperatures for at least 72 hours;
 - e) crayfish oil;
 - f) crayfish *meal*;
 - g) chemically extracted chitin.

- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.1.2., other than those referred to in point 1 of Article 9.1.3., *Competent Authorities* should require the conditions prescribed in Articles 9.1.7. to 9.1.11. relevant to the crayfish plague status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.1.2. but which could reasonably be expected to pose a *risk* of spread of crayfish plague, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.1.4.

Country free from crayfish plague

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from crayfish plague if all the areas covered by the shared water bodies are declared countries or *zones* free from crayfish plague (see Article 9.1.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from crayfish plague if:

- 1) none of the *susceptible species* referred to in Article 9.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.1.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last 25 years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last 10 years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last five years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last five years without detection of crayfish plague;

OR

- 4) it previously made a *self-declaration of freedom* from crayfish plague and subsequently lost its *disease free status* due to the detection of crayfish plague but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last five years without detection of crayfish plague.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 9.1.5.

Article 9.1.5.

Zone or compartment free from crayfish plague

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from crayfish plague if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from crayfish plague may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.1.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.1.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last 25 years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last 10 years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last five years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last five years without detection of crayfish plague;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from crayfish plague and subsequently lost its *disease free status* due to the detection of crayfish plague in the *zone* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last five years without detection of crayfish plague.

Article 9.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of points 1 or 2 of Articles 9.1.4. or 9.1.5. (as relevant) may maintain its status as free from crayfish plague provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of point 3 of Articles 9.1.4. or 9.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from crayfish plague provided that conditions that are conducive to clinical expression of crayfish plague, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of crayfish plague, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.1.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from crayfish plague

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.1.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require that

the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.1.4. or 9.1.5. (as applicable) and 9.1.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.1.3.

Article 9.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from crayfish plague

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.1.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *A. astaci*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *A. astaci*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *A. astaci* and perform general examinations for pests and general health/disease status;
 - g) if *A. astaci* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as crayfish plague free or specific pathogen free (SPF) for *A. astaci*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.1.3.

Article 9.1.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from crayfish plague

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.1.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.1.3., or products described in point 1 of Article 9.1.11., or other products authorised by the *Competent Authority*, and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *A. astaci* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.1.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from crayfish plague

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.1.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*, and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *A. astaci*.

This Article does not apply to *commodities* referred to in point 1 of Article 9.1.3.

Article 9.1.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from crayfish plague

- 1) *Competent Authorities* should not require any conditions related to crayfish plague, regardless of the crayfish plague status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:
 - no *commodities* listed.
- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.1.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 9.2.

INFECTION WITH YELLOW HEAD VIRUS

Article 9.2.1.

For the purposes of the *Aquatic Code*, infection with yellow head virus (YHD) means *infection* with yellow head virus genotype 1 (YHV). YHV is classified as a species in the genus *Okavirus*, family *Roniviridae* and order *Nidovirales*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.2.2.

Scope

The recommendations in this chapter apply to: giant tiger prawn (*Penaeus monodon*), brown tiger prawn (*P. esculentus*) and Kuruma prawn (*P. japonicus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 9.2.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with yellow head virus

- 1) *Competent Authorities* should not require any conditions related to *infection* with YHD, regardless of the *infection* with YHD status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.2.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);
 - b) cooked crustacean products that have been subjected to heat treatment at 60°C for at least 15 minutes (or any time/temperature equivalent which has been demonstrated to inactivate YHV);
 - c) pasteurised crustacean products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate YHV);
 - d) crustacean oil;
 - e) crustacean *meal*;
 - f) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.2.2., other than those referred to in point 1 of Article 9.2.3., *Competent Authorities* should require the conditions prescribed in Articles 9.2.7. to 9.2.11. relevant to the *infection* with YHD status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.2.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with YHD, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.2.4.

Country free from infection with yellow head virus

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom from infection* with YHD if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with YHD (see Article 9.2.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom from infection* with YHD if:

- 1) none of the *susceptible species* referred to in Article 9.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.2.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*; and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with YHD;

OR

- 4) it previously made a *self-declaration of freedom from infection* with YHD and subsequently lost its *disease free* status due to the detection of *infection* with YHD but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with YHD.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 9.2.5.

Article 9.2.5.

Zone or compartment free from infection with yellow head virus

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with YHD if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with YHD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.2.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.2.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with YHD;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with YHD for a *zone* and subsequently lost its disease status due to the detection of *infection* with YHD in the *zone* but the following conditions have been met:
- on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with YHD.

Article 9.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with YHD following the provisions of points 1 or 2 of Articles 9.2.4. or 9.2.5. (as relevant) may maintain its status as free from *infection* with YHD provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with YHD following the provisions of point 3 of Articles 9.2.4. or 9.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with YHD provided that conditions that are conducive to clinical expression of *infection* with YHD, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with YHD, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.2.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with yellow head virus

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.2.2. from a country, *zone* or *compartment* declared free from *infection* with YHD, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.2.4. or 9.2.5. (as applicable) and 9.2.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with YHD.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.2.3.

Article 9.2.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with yellow head virus

- When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.2.2. from a country, *zone* or *compartment* not declared free from *infection* with YHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - the treatment of water used in transport and all effluent and waste materials in a manner that ensures inactivation of YHV.

- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for YHV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with YHD and perform general examinations for pests and general health/disease status;
 - g) if *infection* with YHD is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as *infection* with YHD free or specific pathogen free (SPF) for *infection* with YHD;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.2.3.

Article 9.2.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with yellow head virus

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.2.2. from a country, *zone* or *compartment* not declared free from *infection* with YHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.2.3., or products described in point 1 of Article 9.2.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of YHV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.2.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with yellow head virus

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.2.2. from a country, *zone* or *compartment* not declared free from *infection* with YHD, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of YHV.

This Article does not apply to *commodities* referred to in point 1 of Article 9.2.3.

Article 9.2.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with yellow head virus

- 1) *Competent Authorities* should not require any conditions related to *infection* with YHD, regardless of the *infection* with YHD status of the *exporting country, zone or compartment*, when authorising the importation or transit of frozen peeled shrimp or decapod crustacea (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.2.2. from a country, *zone or compartment* not declared free from *infection* with YHD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 9.3.

INFECTIOUS HYPODERMAL AND HAEMATOPOIETIC NECROSIS

Article 9.3.1.

For the purposes of the *Aquatic Code*, infectious hypodermal and haematopoietic necrosis (IHHN) means *infection* with infectious hypodermal and haematopoietic necrosis virus (IHHNV). IHHNV is classified as the species *Penaeus stylirostris densovirus* in the genus *Brevidensovirus* in the family *Parvoviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.3.2.

Scope

The recommendations in this chapter apply to: giant tiger prawn (*Penaeus monodon*), Pacific white shrimp (*P. vannamei*) and blue shrimp (*P. stylirostris*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this chapter, the terms shrimp and prawn are used interchangeably.

Article 9.3.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from IHHN

- 1) *Competent Authorities* should not require any conditions related to IHHN, regardless of the IHHN status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.3.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) cooked crustacean products that have been subjected to heat treatment at 90°C for at least 20 minutes (or any time/temperature equivalent which has been demonstrated to inactivate IHHNV);
 - c) crustacean oil;
 - d) crustacean *meal*.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.3.2., other than those referred to in point 1 of Article 9.3.3., *Competent Authorities* should require the conditions prescribed in Articles 9.3.7. to 9.3.11. relevant to the IHHN status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.3.2. but which could reasonably be expected to pose a *risk* of spread of IHHN, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.3.4.

Country free from infectious hypodermal and haematopoietic necrosis

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from IHHN if all the areas covered by the shared water bodies are declared countries or *zones* free from IHHN (see Article 9.3.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from IHHN if:

- 1) none of the *susceptible species* referred to in Article 9.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.3.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IHHN;

OR

- 4) it previously made a *self-declaration of freedom* from IHHN and subsequently lost its *disease free* status due to the detection of IHHN but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IHHN.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 9.3.5.

Article 9.3.5.

Zone or compartment free from infectious hypodermal and haematopoietic necrosis

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from IHHN if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with IHHN may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.3.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.3.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of IHHN;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from IHHN and subsequently lost its *disease free* status due to the detection of IHHN in the *zone* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IHHN.

Article 9.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from IHHN following the provisions of points 1 or 2 of Articles 9.3.4. or 9.3.5. (as relevant) may maintain its status as free from IHHN provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from IHHN following the provisions of point 3 of Articles 9.3.4. or 9.3.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from IHHN provided that conditions that are conducive to clinical expression of IHHN, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of IHHN, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.3.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infectious hypodermal and haematopoietic necrosis

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.3.2. from a country, *zone* or *compartment* declared free from IHHN, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.3.4. or 9.3.5. (as applicable) and 9.3.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from IHHN.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.3.3.

Article 9.3.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.3.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation* measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of IHHNV.

- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for IHHNV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for IHHNV and perform general examinations for pests and general health/disease status;
 - g) if IHHNV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as IHHN free or specific pathogen free (SPF) for IHHNV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.3.3.

Article 9.3.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.3.2. from a country, *zone or compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.3.3., or products described in point 1 of Article 9.3.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of IHHNV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.3.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.3.2. from a country, *zone or compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of IHHNV.

This Article does not apply to *commodities* referred to in point 1 of Article 9.3.3.

Article 9.3.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

- 1) *Competent Authorities* should not require any conditions related to IHHN, regardless of the IHHN status of the *exporting country, zone or compartment*, when authorising the importation or transit of frozen peeled shrimp (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.3.2. from a country, zone or compartment not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 9.4.

INFECTIOUS MYONECROSIS

Article 9.4.1.

For the purposes of the *Aquatic Code*, infectious myonecrosis (IMN) means *infection* with infectious myonecrosis virus (IMNV). This virus is similar to members of the family *Totiviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.4.2.

Scope

The recommendations in this chapter apply to: Pacific white shrimp (*Penaeus vannamei*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this chapter, the terms shrimp and prawn are used interchangeably.

Article 9.4.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infectious myonecrosis

- 1) *Competent Authorities* should not require any conditions related to IMN, regardless of the IMN status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.4.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) cooked crustacean products that have been subjected to heat treatment at 60°C for at least three minutes (or any time/temperature equivalent which has been demonstrated to inactivate IMNV);
 - c) crustacean oil;
 - d) crustacean *meal*;
 - e) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.4.2., other than those referred to in point 1 of Article 9.4.3., *Competent Authorities* should require the conditions prescribed in Articles 9.4.7. to 9.4.11. relevant to the IMN status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.4.2. but which could reasonably be expected to pose a *risk* of spread of IMN, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.4.4.

Country free from infectious myonecrosis

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from IMN if all the areas covered by the shared water bodies are declared countries or *zones* free from IMN (see Article 9.4.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from IMN if:

- 1) none of the *susceptible species* referred to in Article 9.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.4.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IMN;

OR

- 4) it previously made a *self-declaration of freedom* from IMN and subsequently lost its *disease free status* due to the detection of IMN but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IMN.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 9.4.5.

Article 9.4.5.

Zone or compartment free from infectious myonecrosis

If a *zone* or *compartment* extends over more than one country, it can only be declared an IMN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from IMN may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.4.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.4.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of IMN;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from IMN and subsequently lost its *disease free* status due to the detection of IMN in the *zone* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IMN.

Article 9.4.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from IMN following the provisions of points 1 or 2 of Articles 9.4.4. or 9.4.5. (as relevant) may maintain its status as free from IMN provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from IMN following the provisions of point 3 of Articles 9.4.4. or 9.4.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from IMN provided that conditions that are conducive to clinical expression of IMN, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of IMN, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.4.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infectious myonecrosis

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.4.2. from a country, *zone* or *compartment* declared free from IMN, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.4.4. or 9.4.5. (as applicable) and 9.4.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from IMN.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.4.3.

Article 9.4.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infectious myonecrosis

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation* measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of IMNV.

- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for IMNV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for IMNV and perform general examinations for pests and general health/disease status;
 - g) if IMNV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as IMN free or specific pathogen free (SPF) for IMNV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.4.3.

Article 9.4.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infectious myonecrosis

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.4.2. from a country, *zone or compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.4.3., or products described in point 1 of Article 9.4.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of IMNV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.4.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infectious myonecrosis

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.4.2. from a country, *zone or compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of IMNV.

This Article does not apply to *commodities* referred to in point 1 of Article 9.4.3.

Article 9.4.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infectious myonecrosis

- 1) *Competent Authorities* should not require any conditions related to IMN, regardless of the IMN status of the *exporting country, zone or compartment*, when authorising the importation or transit of frozen peeled shrimp (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.4.2. from a country, zone or compartment not declared free from IMN, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.
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CHAPTER 9.5.

NECROTISING HEPATOPANCREATITIS

Article 9.5.1.

For the purposes of the *Aquatic Code*, necrotising hepatopancreatitis (NHP) means *infection* with *Candidatus Hepatobacter penaei*. This obligate intracellular bacterium is a member of the order α -Proteobacteria.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.5.2.

Scope

The recommendations in this chapter apply to: Pacific white shrimp (*Penaeus vannamei*), blue shrimp (*P. stylirostris*), northern white shrimp (*P. setiferus*) and northern brown shrimp (*P. aztecus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this chapter, the terms shrimp and prawn are used interchangeably.

Article 9.5.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from necrotising hepatopancreatitis

- 1) *Competent Authorities* should not require any conditions related to NHP, regardless of the NHP status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.5.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) cooked crustacean products that have been subjected to heat treatment at 100°C for at least three minutes (or any time/temperature equivalent which has been demonstrated to inactivate *Candidatus Hepatobacter penaei*);
 - c) pasteurised crustacean products that have been subjected to heat treatment at 63°C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate *Candidatus Hepatobacter penaei*);
 - d) crustacean oil;
 - e) crustacean *meal*;
 - f) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.5.2., other than those referred to in point 1 of Article 9.5.3., *Competent Authorities* should require the conditions prescribed in Articles 9.5.7. to 9.5.11. relevant to the NHP status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.5.2. but which could reasonably be expected to pose a *risk* of spread of NHP, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.5.4.

Country free from necrotising hepatopancreatitis

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from NHP if all the areas covered by the shared water bodies are declared countries or *zones* free from NHP (see Article 9.5.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from NHP if:

- 1) none of the *susceptible species* referred to in Article 9.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.5.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of NHP;

OR

- 4) it previously made a *self-declaration of freedom* from NHP and subsequently lost its *disease* free status due to the detection of NHP but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of NHP.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 9.5.5.

Article 9.5.5.

Zone or compartment free from necrotising hepatopancreatitis

If a *zone* or *compartment* extends over more than one country, it can only be declared an NHP free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from NHP may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.5.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.5.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of NHP;

OR

- 4) it previously made a *self-declaration of freedom* in the *zone* from NHP and subsequently lost its *disease free status* due to the detection of NHP in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of NHP.

Article 9.5.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from NHP following the provisions of points 1 or 2 of Articles 9.5.4. or 9.5.5. (as relevant) may maintain its status as free from NHP provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from NHP following the provisions of point 3 of Articles 9.5.4. or 9.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from NHP provided that conditions that are conducive to clinical expression of NHP, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of NHP, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.5.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.5.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.5.4. or 9.5.5. (as applicable) and 9.5.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from NHP.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.5.3.

Article 9.5.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from necrotising hepatopancreatitis

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *Candidatus Hepatobacter penaei*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *Candidatus Hepatobacter penaei*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *Candidatus Hepatobacter penaei* and perform general examinations for pests and general health/disease status;
 - g) if *Candidatus Hepatobacter penaei* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as NHP free or specific pathogen free (SPF) for *Candidatus Hepatobacter penaei*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.5.3.

Article 9.5.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from necrotising hepatopancreatitis

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.5.3., or products described in point 1 of Article 9.5.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *Candidatus Hepatobacter penaei* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.5.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from necrotising hepatopancreatitis

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *Candidatus Hepatobacter penaei*.

This Article does not apply to *commodities* referred to in point 1 of Article 9.5.3.

Article 9.5.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from necrotising hepatopancreatitis

- 1) *Competent Authorities* should not require any conditions related to NHP, regardless of the NHP status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of frozen peeled shrimp (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 9.6.

TAURA SYNDROME

Article 9.6.1.

For the purposes of the *Aquatic Code*, Taura syndrome (TS) means *infection* with Taura syndrome virus (TSV). Taura syndrome virus is classified as a species in the family *Dicistroviridae*. Common synonyms are listed in the corresponding chapter of the *Aquatic Manual*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.6.2.

Scope

The recommendations in this chapter apply to: Pacific white shrimp or whiteleg shrimp (*Penaeus vannamei*), blue shrimp (*P. stylirostris*), northern white shrimp (*P. setiferus*), southern white shrimp (*P. schmitti*), greasyback prawn (*Metapenaeus ensis*) and giant tiger prawn (*P. monodon*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this chapter, the terms shrimp and prawn are used interchangeably.

Article 9.6.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from Taura syndrome

- 1) *Competent Authorities* should not require any conditions related to TS, regardless of the TS status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.6.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/ temperature equivalent);
 - b) cooked crustacean products that have been subjected to heat treatment at 70°C for at least 30 minutes (or any time/ temperature equivalent which has been demonstrated to inactivate TSV);
 - c) pasteurised crustacean products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time / temperature equivalent which has been demonstrated to inactivate TSV);
 - d) crustacean oil;
 - e) crustacean *meal*;
 - f) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.6.2., other than those referred to in point 1 of Article 9.6.3., *Competent Authorities* should require the conditions prescribed in Articles 9.6.7. to 9.6.11. relevant to the TS status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.6.2. but which could reasonably be expected to pose a *risk* of spread of TS, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.6.4.

Country free from Taura syndrome

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from TS if all the areas covered by the shared water bodies are declared countries or *zones* free from TS (see Article 9.6.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from TS if:

- 1) none of the *susceptible species* referred to in Article 9.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.6.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of TS;

OR

- 4) it previously made a *self-declaration of freedom* from TS and subsequently lost its *disease* free status due to the detection of TS but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of TS.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 9.6.5.

Article 9.6.5.

Zone or compartment free from Taura syndrome

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from TS if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from TS may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.6.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.6.2. are present in the *zone* or *compartment* and the following conditions have been made:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been made:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of TS;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from TS and subsequently lost its *disease free status* due to the detection of TS in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of TS.

Article 9.6.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from TS following the provisions of points 1 or 2 of Articles 9.6.4. or 9.6.5. (as relevant) may maintain its status as free from TS provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from TS following the provisions of point 3 of Articles 9.6.4. or 9.6.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from TS provided that conditions that are conducive to clinical expression of TS, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of TS, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.6.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from Taura syndrome

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.6.2. from a country, *zone* or *compartment* declared free from TS, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.6.4. or 9.6.5. (as applicable) and 9.6.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from TS.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.6.3.

Article 9.6.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from Taura syndrome

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.6.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of TSV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for TSV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for TSV and perform general examinations for pests and general health/disease status;
 - g) if TSV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as TS free or specific pathogen free (SPF) for TSV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.6.3.

Article 9.6.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from Taura syndrome

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.6.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.6.3., or products described in point 1 of Article 9.6.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of TSV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.6.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from Taura syndrome

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.6.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of TSV.

This Article does not apply to *commodities* referred to in point 1 of Article 9.6.3.

Article 9.6.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Taura syndrome

- 1) *Competent Authorities* should not require any conditions related to TS, regardless of the TS status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of frozen peeled shrimp or decapod crustacea (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.6.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.
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CHAPTER 9.7.

WHITE SPOT DISEASE

Article 9.7.1.

For the purposes of the *Aquatic Code*, white spot disease (WSD) means *infection* with white spot syndrome virus (WSSV). White spot syndrome virus 1 is classified as a species in the genus *Whispovirus* of the family *Nimaviridae*. Common synonyms are listed in the corresponding chapter of the *Aquatic Manual*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.7.2.

Scope

The recommendations in this chapter apply to all decapod (order *Decapoda*) crustaceans from marine, brackish and freshwater sources. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this chapter, the terms shrimp and prawn are used interchangeably.

Article 9.7.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from white spot disease

- 1) *Competent Authorities* should not require any conditions related to WSD, regardless of the WSD status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.7.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) cooked crustacean products that have been subjected to heat treatment at 60°C for at least one minute (or any time/temperature equivalent which has been demonstrated to inactivate WSSV);
 - c) pasteurised crustacean products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate WSSV);
 - d) crustacean oil;
 - e) crustacean *meal*;
 - f) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.7.2., other than those referred to in point 1 of Article 9.7.3., *Competent Authorities* should require the conditions prescribed in Articles 9.7.7. to 9.7.11. relevant to the WSD status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.7.2. but which could reasonably be expected to pose a *risk* of spread of WSD, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.7.4.

Country free from white spot disease

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from WSD if all the areas covered by the shared water bodies are declared countries or *zones* free from WSD (see Article 9.7.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from WSD if:

- 1) none of the *susceptible species* referred to in Article 9.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.7.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of WSD;

OR

- 4) it previously made a *self-declaration of freedom* from WSD and subsequently lost its *disease* free status due to the detection of WSD but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of WSD.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 9.7.5.

Article 9.7.5.

Zone or compartment free from white spot disease

If a *zone* or *compartment* extends over more than one country, it can only be declared a WSD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from WSD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.7.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.7.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of WSD;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from WSD and subsequently lost its *disease free status* due to the detection of WSD in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of WSD.

Article 9.7.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from WSD following the provisions of points 1 or 2 of Articles 9.7.4. or 9.7.5. (as relevant) may maintain its status as free from WSD provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from WSD following the provisions of point 3 of Articles 9.7.4. or 9.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from WSD provided that conditions that are conducive to clinical expression of WSD, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of WSD, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.7.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from white spot disease

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.7.2. from a country, *zone* or *compartment* declared free from WSD, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.7.4. or 9.7.5. (as applicable) and 9.7.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from WSD.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.7.3.

Article 9.7.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from white spot disease

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.7.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of WSSV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for WSSV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for WSSV and perform general examinations for pests and general health/disease status;
 - g) if WSSV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as WSD free or specific pathogen free (SPF) for WSSV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.7.3.

Article 9.7.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from white spot disease

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.7.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.7.3., or products described in point 1 of Article 9.7.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of WSSV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.7.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from white spot disease

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.7.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of WSDV.

This Article does not apply to *commodities* referred to in point 1 of Article 9.7.3.

Article 9.7.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from white spot disease

- 1) *Competent Authorities* should not require any conditions related to WSD, regardless of the WSD status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of frozen peeled shrimp or decapod crustacea (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.7.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.
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CHAPTER 9.8.

WHITE TAIL DISEASE

Article 9.8.1.

For the purposes of the *Aquatic Code*, white tail disease (WTD) means *infection* with macrobrachium nodavirus (MrNV). This virus has yet to be formally classified.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.8.2.

Scope

The recommendations in this chapter apply to: the giant fresh water prawn (*Macrobrachium rosenbergii*). Other common names are listed in the *Aquatic Manual*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this chapter, the terms shrimp and prawn are used interchangeably.

Article 9.8.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from white tail disease

- 1) *Competent Authorities* should not require any conditions related to WTD, regardless of the WTD status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 9.8.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) cooked crustacean products that have been subjected to heat treatment at 60°C for at least 60 minutes (or any time/temperature equivalent which has been demonstrated to inactivate MrNV);
 - c) pasteurised crustacean products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent that has been shown to inactivate MrNV);
 - d) crustacean oil;
 - e) crustacean *meal*;
 - f) chemically extracted chitin.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.8.2., other than those referred to in point 1 of Article 9.8.3., *Competent Authorities* should require the conditions prescribed in Articles 9.8.7. to 9.8.11. relevant to the WTD status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 9.8.2. but which could reasonably be expected to pose a *risk* of spread of WTD, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 9.8.4.

Country free from white tail disease

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from WTD if all the areas covered by the shared water bodies are declared countries or *zones* free from WTD (see Article 9.8.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from WTD if:

- 1) none of the *susceptible species* referred to in Article 9.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.8.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of WTD;

OR

- 4) it previously made a *self-declaration of freedom* from WTD and subsequently lost its *disease free* status due to the detection of WTD but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of WTD.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 9.8.5.

Article 9.8.5.

Zone or compartment free from white tail disease

If a *zone* or *compartment* extends over more than one country, it can only be declared a WTD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from WTD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 9.8.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 9.8.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of WTD;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from WTD and subsequently lost its *disease free* status due to the detection of WTD in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of WTD.

Article 9.8.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from WTD following the provisions of points 1 or 2 of Articles 9.8.4. or 9.8.5. (as relevant) may maintain its status as free from WTD provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from WTD following the provisions of point 3 of Articles 9.8.4. or 9.8.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from WTD provided that conditions that are conducive to clinical expression of WTD, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of WTD, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 9.8.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from white tail disease

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 9.8.2. from a country, *zone* or *compartment* declared free from WTD, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 9.8.4. or 9.8.5. (as applicable) and 9.8.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from WTD.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* listed in point 1 of Article 9.8.3.

Article 9.8.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from white tail disease

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.8.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of WTDV.

- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for WTDV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for WTD and perform general examinations for pests and general health/disease status;
 - g) if WTDV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as WTD free or specific pathogen free (SPF) for WTDV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.8.3.

Article 9.8.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from white tail disease

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 9.8.2. from a country, *zone or compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.8.3., or products described in point 1 of Article 9.8.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of WTDV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 9.8.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from white tail disease

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 9.8.2. from a country, *zone or compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of WTDV.

This Article does not apply to *commodities* referred to in point 1 of Article 9.8.3.

Article 9.8.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from white tail disease

- 1) *Competent Authorities* should not require any conditions related to WTD, regardless of the WTD status of the *exporting country, zone or compartment*, when authorising the importation or transit of frozen peeled shrimp (shell off, head off) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 9.8.2. from a country, *zone or compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.
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SECTION 10.
DISEASES OF FISH

CHAPTER 10.1.
EPIZOOTIC HAEMATOPOIETIC NECROSIS

Article 10.1.1.

For the purposes of the *Aquatic Code*, epizootic haematopoietic necrosis (EHN) means *infection* with EHN virus (EHNV) of the genus *Ranavirus* of the family *Iridoviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 10.1.2.

Scope

The recommendations in this chapter apply to: redfin perch (*Perca fluviatilis*) and rainbow trout (*Oncorhynchus mykiss*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.1.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

- 1) *Competent Authorities* should not require any conditions related to EHN, regardless of the EHN status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.1.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to heat treatment at 90°C for ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate EHNV);
 - c) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate EHNV);
 - d) fish oil;
 - e) fish *meal*;
 - f) fish skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of species referred to in Article 10.1.2., other than those referred to in point 1 of Article 10.1.3., *Competent Authorities* should require the conditions prescribed in Articles 10.1.7. to 10.1.11. relevant to the EHN status of the *exporting country, zone or compartment*.

- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of species not covered in Article 10.1.2. but which could reasonably be expected to pose a *risk* of spread of EHN, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.1.4.

Country free from epizootic haematopoietic necrosis

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from EHN if all the areas covered by the shared water bodies are declared countries or *zones* free from EHN (see Article 10.1.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from EHN if:

- 1) none of the *susceptible species* referred to in Article 10.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.1.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the past ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of EHN;

OR

- 4) it previously made a *self-declaration of freedom* from EHN and subsequently lost its *disease free status* due to the detection of EHN but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of EHN.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 10.1.5.

Article 10.1.5.

Zone or compartment free from epizootic haematopoietic necrosis

If a *zone* or *compartment* extends over more than one country, it can only be declared an EHN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from EHN may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.1.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.1.2. are present in the *zone* or *compartment* and the following conditions have been met:
- a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of EHN;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from EHN and subsequently lost its *disease free* status due to the detection of EHN in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of EHN.

Article 10.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from EHN following the provisions of points 1 or 2 of Articles 10.1.4. or 10.1.5. (as relevant) may maintain its status as free from EHN provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from EHN following the provisions of point 3 of Articles 10.1.4. or 10.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from EHN provided that conditions that are conducive to clinical expression of EHN, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of EHN, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.1.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from epizootic haematopoietic necrosis

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.1.2. from a country, *zone* or *compartment* declared free from EHN, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.1.4. or 10.1.5. (as applicable) and 10.1.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from EHN.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.1.3.

Article 10.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of EHN.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for EHN, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for EHN and perform general examinations for pests and general health/disease status;
 - g) if EHN is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as EHN free or specific pathogen free (SPF) for EHN;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.1.3.

Article 10.1.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.1.3., or products described in point 1 of Article 10.1.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of EHN or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.1.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held, in *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of EHN.

This Article does not apply to *commodities* referred to in point 1 of Article 10.1.3.

Article 10.1.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

- 1) *Competent Authorities* should not require any conditions related to EHN, regardless of the EHN status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of fish fillets or steaks (chilled or frozen) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 10.2.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

Article 10.2.1.

For the purposes of the *Aquatic Code*, infection with *Aphanomyces invadans* means all infections caused by the Oomycete fungus *A. invadans* (syn. *A. piscicida*). The disease was previously referred to as epizootic ulcerative syndrome.

Standards for *diagnostic* tests are described in the *Aquatic Manual*.

Article 10.2.2.

Scope

The recommendations in this chapter apply to: yellowfin seabream (*Acanthopagrus australis*), climbing perch (*Anabas testudineus*), eels (*Anguillidae*), bagrid catfishes (*Bagridae*), silver perch (*Bidyanus bidyanus*), Atlantic menhaden (*Brevoortia tyrannus*), jacks (*Caranx* spp.), catla (*Catla catla*), striped snakehead (*Channa striatus*), mrigal (*Cirrhinus mrigala*), torpedo-shaped catfishes (*Clarius* spp.), halfbeaks flying fishes (*Exocoetidae*), tank goby (*Glossogobius giuris*), marble goby (*Oxyeleotris marmoratus*), gobies (*Gobiidae*), rohu (*Labeo rohita*), rhinofishes (*Labeo* spp.), barramundi and giant sea perch (*Lates calcarifer*), striped mullet (*Mugil cephalus*), mullets (*Mugilidae*) (*Mugil* spp. and *Liza* spp.), ayu (*Plecoglossus altivelis*), pool barb (*Puntius sophore*), barcoo grunter (*Scortum barcoo*), sand whiting (*Sillago ciliata*), wells catfishes (*Siluridae*), snakeskin gourami (*Trichogaster pectoralis*), common archer fish (*Toxotes chatareus*), silver barb (*Puntius gonionotus*), spotted scat (*Scatophagus argus*), giant gourami (*Osphronemus goramy*), dusky flathead (*Platycephalus fuscus*), spiny turbot (*Psettodes* sp.), Tairiku-baratanago (*Rhodeus ocellatus*), Keti-Bangladeshi (*Rohtee* sp.), rudd (*Scaridinius erythrophthalmus*), theraon (*Terapon* sp.) and three-spot gouramy (*Trichogaster trichopterus*). These recommendations also apply to any other susceptible species referred to in the *Aquatic Manual* when traded internationally.

Article 10.2.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *A. invadans*

- 1) *Competent Authorities* should not require any conditions related to infection with *A. invadans*, regardless of the infection with *A. invadans* status of the exporting country, zone or compartment, when authorising the importation or transit of the following aquatic animals and aquatic animal products from the species referred to in Article 10.2.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate *A. invadans*);
 - c) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate *A. invadans*);
 - d) fish oil;
 - e) fish meal;
 - f) frozen eviscerated fish;
 - g) frozen fish fillets or steaks.

- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.2.2., other than those referred to in point 1 of Article 10.2.3., *Competent Authorities* should require the conditions prescribed in Articles 10.2.7. to 10.2.11. relevant to *infection* with *A. invadans* status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country, zone or compartment* not declared free from *infection* with *A. invadans* of a species not covered in Article 10.2.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with *A. invadans*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *exporting country* should be informed of the outcome of this assessment.

Article 10.2.4.

Country free from infection with *A. invadans*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with *A. invadans* if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with *A. invadans* (see Article 10.2.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with *A. invadans* if:

- 1) a country where there has been no observed occurrence of *infection* with *A. invadans* for at least the last ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may make a *self-declaration of freedom* from *infection* with *A. invadans* when *basic biosecurity conditions* have been continuously met in the country for at least the last ten years;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *A. invadans*;

OR

- 3) it previously made a *self-declaration of freedom* from *infection* with *A. invadans* and subsequently lost its *disease free status* due to the detection of *infection* with *A. invadans* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *A. invadans*.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 2 of Article 10.2.5.

Article 10.2.5.

Zone or compartment free from infection with *A. invadans*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with *A. invadans* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *A. invadans* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) a *zone* or *compartment* where the species referred to in Article 10.2.2. are present but there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may be declared free from *infection* with *A. invadans* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the last ten years;

OR

- 2) the *disease* status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with *A. invadans*;

OR

- 3) it previously made a *self-declaration of freedom* for a *zone* from *infection* with *A. invadans* and subsequently lost its *disease* free status due to the detection of *infection* with *A. invadans* in the *zone* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *A. invadans*.

Article 10.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *A. invadans* following the provisions of point 1 of Articles 10.2.4. or 10.2.5. (as relevant) may maintain its status as free from *infection* with *A. invadans* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *A. invadans* following the provisions of point 2 of Articles 10.2.4. or 10.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *A. invadans* provided that conditions that are conducive to clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *A. invadans*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.2.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *A. invadans*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.2.2. from a country, *zone* or *compartment* declared free from *infection* with *A. invadans*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.2.4. or 10.2.5. (as applicable) and 10.2.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with *A. invadans*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.2.3.

Article 10.2.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *A. invadans*

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.2.2. from a country, *zone* or *compartment* not declared free from *infection* with *A. invadans*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *A. invadans*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *A. invadans*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with *A. invadans* and perform general examinations for pests and general health/disease status;
 - g) if *infection* with *A. invadans* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as *infection* with *A. invadans* free or specific pathogen free (SPF) for *infection* with *infection* with *A. invadans*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.2.3.

Article 10.2.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *A. invadans*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.2.2. from a country, *zone* or *compartment* not declared free from *infection* with *A. invadans*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.2.3., or products described in point 1 of Article 10.2.11., or other products authorised by the *Competent Authority*, and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *A. invadans* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.2.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *A. invadans*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.2.2. from a country, *zone* or *compartment* not declared free from *infection* with *A. invadans*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *A. invadans*.

This Article does not apply to *commodities* referred to in point 1 of Article 10.2.3.

Article 10.2.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *A. invadans*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *A. invadans*, regardless of the *infection* with *A. invadans* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of fish fillets or steaks (chilled) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.2.2. from a country, *zone* or *compartment* not declared free from *infection* with *A. invadans*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 10.3.

INFECTION WITH *GYRODACTYLUS SALARIS*

Article 10.3.1.

For the purposes of the *Aquatic Code*, gyrodactylosis means *infection* with the viviparous freshwater ectoparasite *G. salaris* (*G. salaris*) (Phylum *Platyhelminthes*; Class *Monogenea*).

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 10.3.2.

Scope

The recommendations in this chapter apply to: Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), Arctic char (*Salvelinus alpinus*), North American brook trout (*Salvelinus fontinalis*), grayling (*Thymallus thymallus*), North American lake trout (*Salvelinus namaycush*) and brown trout (*Salmo trutta*). The recommendations also apply to other fish species in waters where the parasite is present, because these species may carry the parasite and act as vectors.

Article 10.3.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *G. salaris*

- 1) *Competent Authorities* should not require any related conditions related to *infection* with *G. salaris*, regardless of the *infection* with *G. salaris* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.3.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to a heat treatment at 63°C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate *G. salaris*);
 - c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate *G. salaris*);
 - d) naturally dried, eviscerated fish (i.e. sun-dried or wind-dried);
 - e) frozen eviscerated fish that have been subjected to minus 18°C or lower temperatures;
 - f) frozen fish fillets or steaks that have been subjected to minus 18°C or lower temperatures;
 - g) chilled eviscerated fish that have been harvested from seawater with a salinity of at least 25 parts per thousand (ppt);
 - h) chilled fish fillets or steaks derived from fish that have been harvested from seawater with a salinity of at least 25 ppt;
 - i) chilled fish products from which the skin, fins and gills have been removed;
 - j) fish roe;
 - k) fish oil;
 - l) fish *meal*;
 - m) fish skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.3.2., other than those referred to in point 1 of Article 10.3.3., *Competent Authorities* should require the conditions prescribed in Articles 10.3.7. to 10.3.11. relevant to the *infection* with *G. salaris* status of the *exporting country, zone or compartment*.

- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 10.3.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with *G. salaris*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.3.4.

Country free from infection with *G. salaris*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with *G. salaris* if all the areas covered by the shared watercourse(s) are declared countries or *zones* free from *infection* with *G. salaris* (see Article 10.3.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with *G. salaris* if:

- 1) none of the *susceptible species* referred to in Article 10.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.3.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the *disease* status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last five years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last five years without detection of *infection* with *G. salaris*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *G. salaris* and subsequently lost its *disease* free status due to the detection of *infection* with *G. salaris* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed, or the waters containing the infected fish have been treated by chemicals that kill the parasite; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last five years without detection of *infection* with *G. salaris*.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 10.3.5.

Article 10.3.5.

Zone or compartment free from infection with *G. salaris*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with *G. salaris* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *G. salaris* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.3.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.3.2. are present in the *zone* or *compartment* and the following conditions have been met:
- a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last five years;

OR

- 3) a *zone* or *compartment* supplied with seawater with a salinity of at least 25 ppt may be declared free from *infection* with *G. salaris* provided that no live *aquatic animals* of species referred to in Article 10.3.2. are introduced from a site of a lesser health status for *G. salaris* during the 14 days prior to any live fish transfers from the *zone* or *compartment*;

OR

- 4) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last ten years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last five years without detection of *infection* with *G. salaris*;

OR

- 5) it previously made a *self-declaration of freedom* for a *zone* from *infection* with *G. salaris* and subsequently lost its *disease free status* due to the detection of *infection* with *G. salaris* in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed, or the waters containing the infected fish have been treated by chemicals that kill the parasite; and
 - c) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed, or the waters containing the infected fish have been treated by chemicals that kill the parasite; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last five years without detection of *infection* with *G. salaris*.

Article 10.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *G. salaris* following the provisions of points 1 or 2 of Articles 10.3.4. or 10.3.5. (as relevant) may maintain its status as free from *infection* with *G. salaris* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *G. salaris* following the provisions of point 3 of Article 10.3.4. or point 4 of 10.3.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *G. salaris* provided that conditions that are conducive to clinical expression of *infection* with *G. salaris*, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *G. salaris*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.3.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *G. salaris*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.3.2. from a country, zone or compartment declared free from infection with *G. salaris*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.3.4. or 10.3.5. (as applicable) and 10.3.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, zone or compartment declared free from infection with *G. salaris*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.3.3.

Article 10.3.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *G. salaris*

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.3.2. from a country, zone or compartment not declared free from infection with *G. salaris*, the *Competent Authority* of the *importing country* should:
 - a) require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that:
 - i) the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days; and
 - ii) no other live *aquatic animals* of the species referred to in Article 10.3.2. have been introduced during that period;OR
 - iii) in the case of eyed eggs, the eggs have been disinfected by a method demonstrated to be effective against *G. salaris*;
 - OR
 - b) assess the *risk* and apply *risk* mitigation measures such as:
 - i) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment;
 - ii) if breeding from the imported fish, *disinfection* of the fertilised eggs by a method demonstrated to be effective against *G. salaris*, and complete separation of the hatched progeny from the imported animals;
 - iii) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *G. salaris*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock's health and disease history;
 - c) take and test samples for *G. salaris*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for infection with *G. salaris* and perform general examinations for pests and general health/disease status;
 - g) if infection with *G. salaris* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*,

the F-1 stock may be defined as *infection* with *G. salaris* free or specific pathogen free (SPF) for *infection* with *G. salaris*;

- h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.3.3.

Article 10.3.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *G. salaris*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.3.2. from a country, *zone* or *compartment* not declared free from *infection* with *G. salaris*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.3.3., or products described in point 1 of Article 10.3.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *G. salaris* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.3.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *G. salaris*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.3.2. from a country, *zone* or *compartment* not declared free from *infection* with *G. salaris*, the *Competent Authority* of the *importing country* should:

- 1) require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 ppt for a continuous period of at least 14 days, and no other live *aquatic animals* of the species referred to in Article 10.3.2. have been introduced during that period;

OR

- 2) require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing into one of the products referred to in point 1 of Article 10.3.3. or other products authorised by the *Competent Authority*, and water used in transport and all effluent and waste materials be treated in a manner that ensures inactivation of *G. salaris*.

This Article does not apply to *commodities* referred to in point 1 of Article 10.3.3.

Article 10.3.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *G. salaris*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *G. salaris*, regardless of the *infection* with *G. salaris* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:
 - no *commodities* listed.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.3.2. from a country, *zone* or *compartment* not declared free from *infection* with *G. salaris*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.
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CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

Article 10.4.1.

For the purposes of the *Aquatic Code*, infection with infectious salmon anaemia virus (ISAV) means *infection* with HPR0 (non-deleted highly polymorphic region) or HPR-deleted ISAV of the genus *Isavirus* of the family *Orthomyxoviridae*. Both genotypes should be notified in accordance with the *Aquatic Code*.

There is a link between non-pathogenic HPR0 ISAV and pathogenic HPR-deleted ISAV, with some *outbreaks* potentially occurring as a result of the emergence of HPR-deleted from HPR0.

The provisions in this chapter are provided in recognition of three possible levels of disease status with respect to ISAV:

- 1) HPR0 ISAV and HPR-deleted ISAV free;
- 2) HPR0 ISAV endemic (but HPR-deleted ISAV free);
- 3) HPR0 ISAV and HPR-deleted ISAV endemic.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.4.2.

Scope

The recommendations in this chapter apply to: Atlantic salmon (*Salmo salar*), brown trout (*S. trutta*) and rainbow trout (*Oncorhynchus mykiss*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.4.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to ISAV are for any detectable ISAV, including HPR0 ISAV.

- 1) *Competent Authorities* should not require any conditions related to *infection* with ISAV, regardless of the *infection* with ISAV status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.4.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to a heat treatment at 90°C for at least ten minutes (or to any time/temperature equivalent which has been demonstrated to inactivate ISAV);
 - c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate ISAV);
 - d) fish oil;
 - e) fish *meal*;
 - f) fish skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.4.2., other than those referred to in point 1 of Article 10.4.3., *Competent Authorities* should require the conditions prescribed in Articles 10.4.10. to 10.4.16. relevant to the ISAV status of the *exporting country, zone or compartment*.

- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 10.4.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with ISAV, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.4.4.

Country free from infection with infectious salmon anaemia virus

In this article, all statements referring to a country free from *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom from infection* with ISAV if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with ISAV (see Article 10.4.6.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom from infection* with ISAV if:

- 1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:

- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with ISAV;

OR

- 3) it previously made a *self-declaration of freedom from infection* with ISAV and subsequently lost its *disease free* status due to the detection of *infection* with ISAV but the following conditions have been met:

- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with ISAV.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 10.4.6.

The pathway for *self-declaration of freedom from infection* with ISAV HPR0 based on absence of clinical disease (referred to as historical freedom in Article 1.4.6.) cannot be achieved because *infection* with ISAV HPR0 is unlikely to cause any clinical signs.

Article 10.4.5.

Country free from infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country free from *infection* with HPR-deleted ISAV but not necessarily free from *infection* with HPR0 ISAV.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom from infection* with HPR-deleted ISAV if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with HPR-deleted ISAV (see Article 10.4.7.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from infection with HPR-deleted ISAV if:

- 1) any of the *susceptible species* referred to in Article 10.4.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of *infection* with HPR-deleted ISAV for at least the last ten years despite conditions that are conducive to clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with HPR-deleted ISAV;

OR

- 3) it previously made a *self-declaration of freedom* from infection with HPR-deleted ISAV and subsequently lost its *disease free status* due to the detection of *infection* with HPR-deleted ISAV but the following conditions have been met:
 - a) on detection of *infection* with HPR-deleted ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of HPR-deleted ISAV, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with HPR-deleted ISAV.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 10.4.7.

Article 10.4.6.

Zone or compartment free from infection with infectious salmon anaemia virus

In this article, all statements referring to a *zone* or *compartment* free from *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with ISAV if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with ISAV may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.4.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with ISAV;

OR

- 3) it previously made a *self-declaration of freedom* for a *zone* from *infection* with ISAV and subsequently lost its *disease free status* due to the detection of *infection* with ISAV in the *zone* but the following conditions have been met:
 - a) on detection of *infection* with ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and

- b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
- c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
- d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with ISAV.

Article 10.4.7.

Zone or compartment free from infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a *zone* or *compartment* free from *infection* with HPR-deleted ISAV but not necessarily free from *infection* with HPR0 ISAV.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with HPR-deleted ISAV if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with HPR-deleted ISAV may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) any of the *susceptible species* referred to in Article 10.4.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has been no observed occurrence of *infection* with HPR-deleted ISAV for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with HPR-deleted ISAV;

OR

- 3) it previously made a *self-declaration of freedom* for a *zone* from *infection* with HPR-deleted ISAV and subsequently lost its *disease free* status due to the detection of *infection* with HPR-deleted ISAV in the *zone* but the following conditions have been met:
 - a) on detection of *infection* with HPR-deleted ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least two years without detection of *infection* with HPR-deleted ISAV.

Article 10.4.8.

Maintenance of free status for infection with infectious salmon anaemia virus

In this article, all statements referring to a country, *zone* or *compartment* free from *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

A country, *zone* or *compartment* that is declared free from *infection* with ISAV following the provisions of point 1 of Articles 10.4.4. or 10.4.6. (as relevant) may maintain its status as free from *infection* with ISAV provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with ISAV following the provisions of point 2 of Articles 10.4.4. or 10.4.6. (as relevant) may maintain its status as free from *infection* with ISAV provided that *targeted surveillance* is continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*, and *basic biosecurity conditions* are continuously maintained.

Article 10.4.9.

Maintenance of free status for infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country, *zone* or *compartment* free from *infection* with HPR-deleted ISAV, but not necessarily free from *infection* with HPR0 ISAV.

A country, *zone* or *compartment* that is declared free from *infection* with HPR-deleted ISAV following the provisions of points 1 or 2 of Articles 10.4.5. or 10.4.7. (as relevant) may maintain its status as free from *infection* with ISAV provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with HPR-deleted ISAV following the provisions of point 3 of Articles 10.4.5. or 10.4.7. (as relevant) may discontinue *targeted surveillance* and maintain its free status provided that conditions that are conducive to clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in an infected country and in all cases where conditions are not conducive to clinical expression, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.4.10.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to a country, *zone* or *compartment* free from *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.4.2. from a country, *zone* or *compartment* declared free from *infection* with ISAV, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.4.4. or 10.4.6. (as applicable) and 10.4.8., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with ISAV.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.4.3.

Article 10.4.11.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country, *zone* or *compartment* free from *infection* with HPR-deleted ISAV, but not necessarily free from *infection* with HPR0 ISAV.

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.4.2. from a country, *zone* or *compartment* declared free from *infection* with HPR-deleted ISAV, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.4.5. or 10.4.7. (as applicable) and 10.4.9., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with HPR-deleted ISAV.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.4.3.

Article 10.4.12.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.4.2. from a country, zone or compartment not declared free from *infection* with ISAV, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of ISAV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for ISAV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for ISAV and perform general examinations for pests and general health/disease status;
 - g) if ISAV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as *infection* with ISAV free or specific pathogen free (SPF) for ISAV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, zone or compartment.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.4.3.

Article 10.4.13.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.4.2. from a country, zone or compartment not declared free from *infection* with ISAV, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.4.3., or products described in point 1 of Article 10.4.15., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.4.14.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.4.2. from a country, *zone* or *compartment* not declared free from *infection* with ISAV, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* for slaughter and processing into products authorised by the *Competent Authority*, and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV.

This Article does not apply to *commodities* referred to in point 1 of Article 10.4.3.

Article 10.4.15.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

- 1) *Competent Authorities* should not require any conditions related to *infection* with ISAV, regardless of the *infection* with ISAV status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of fish fillets or steaks (frozen or chilled) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.4.2. from a country, *zone* or *compartment* not declared free from *infection* with ISAV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.4.16.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infection with infectious salmon anaemia virus

In this article, all statements referring to *infection* with ISAV are for any detectable ISAV, including HPR0 ISAV.

- 1) When importing disinfected eggs of the species referred to in Article 10.4.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from *infection* with ISAV, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:
 - a) the ISAV status of the water to be used during the *disinfection* of the eggs;
 - b) the level of *infection* with ISAV in broodstock (ovarian fluid and milt); and
 - c) the temperature and pH of the water to be used for *disinfection*.
- 2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should apply the following *risk* mitigation measures including:
 - a) the eggs should be disinfected prior to importing, in accordance with recommendations in Chapter 4.4. or those specified by the *Competent Authority* of the *importing country*, and
 - b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status.

The *Competent Authority* may wish to consider internal measures, such as renewed *disinfection* of the eggs upon arrival in the *importing country*.

- 3) When importing disinfected eggs of the species referred to in Article 10.4.2. for *aquaculture*, from a country, zone or compartment not declared free from *infection* with ISAV, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that the procedures described in point 2 of this article have been fulfilled.
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CHAPTER 10.5.

INFECTION WITH SALMONID ALPHAVIRUS

Article 10.5.1.

General provisions

For the purposes of the *Aquatic Code*, infection with salmonid alphavirus (SAV) means *infection* with any subtype of SAV of the genus *Alphavirus* of the family *Togaviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.5.2.

Scope

The recommendations in this chapter apply to: Atlantic salmon (*Salmo salar*), brown trout (*S. trutta*) and rainbow trout (*Onchorynchus mykiss*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.5.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with salmonid alphavirus

- 1) *Competent Authorities* should not require any conditions related to *infection* with SAV, regardless of the *infection* with SAV status of the *exporting country, zone or compartment* when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.5.2. intended for any purpose and complying with Article 5.4.1.:
 - a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to a heat treatment at 90°C for at least ten minutes (or to any time/temperature equivalent which has been demonstrated to inactivate SAV);
 - c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate SAV);
 - d) fish oil;
 - e) fish meal;
 - f) fish skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.5.2., other than those referred to in point 1 of Article 10.5.3., *Competent Authorities* should require the conditions prescribed in Articles 10.5.7. to 10.5.12. relevant to the SAV status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 10.5.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with SAV, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.5.4.

Country free from infection with salmonid alphavirus

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom from infection* with SAV if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with SAV (see Article 10.5.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom from infection* with SAV if:

- 1) none of the *susceptible species* referred to in Article 10.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.5.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the past ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with SAV;

OR

- 4) it previously made a *self-declaration of freedom from infection* with SAV and subsequently lost its *disease free* status due to the detection of *infection* with SAV but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with SAV.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 10.5.5.

Article 10.5.5.

Zone or compartment free from infection with salmonid alphavirus

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with SAV if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with SAV may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.5.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.5.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with SAV;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from *infection* with SAV and subsequently lost its *disease free status* due to the detection of *infection* with SAV in the *zone* but the following conditions have been met:
- a) on detection of *infection* with SAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with SAV.

Article 10.5.6.

Maintenance of free status for infection with salmonid alphavirus

A country, *zone* or *compartment* that is declared free from *infection* with SAV following the provisions of points 1 or 2 of Articles 10.5.4. or 10.5.5. (as relevant) may maintain its status as free from *infection* with SAV provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with SAV following the provisions of point 3 of Articles 10.5.4. or 10.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with SAV provided that conditions that are conducive to clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in an infected country and in all cases where conditions are not conducive to clinical expression, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.5.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with salmonid alphavirus

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from *infection* with SAV, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.5.4. or 10.5.5. (as applicable) and 10.5.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with SAV.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with salmonid alphavirus

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from *infection* with SAV, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of SAV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for SAV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with SAV and perform general examinations for pests and general health/disease status;
 - g) if *infection* with SAV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as free from *infection* with SAV or specific pathogen free (SPF) for *infection* with SAV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect a low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.5.3.

Article 10.5.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with salmonid alphavirus

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from *infection* with SAV, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.5.3., or products described in point 1 of Article 10.5.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of SAV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.5.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with salmonid alphavirus

When importing, for use in animal *feed* or for agricultural industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from *infection* with SAV, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of SAV.

This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with salmonid alphavirus

- 1) *Competent Authorities* should not require any conditions related to *infection* with SAV, regardless of the *infection* with SAV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of fish fillets or steaks (frozen or chilled) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from *infection* with SAV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.5.12.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infection from infection with salmonid alphavirus

- 1) When importing disinfected eggs of the species referred to in Article 10.5.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from *infection* with SAV, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:
 - a) the SAV status of the water to be used during the *disinfection* of the eggs;
 - b) the level of *infection* with SAV in broodstock; and
 - c) the temperature and pH of the water to be used for *disinfection*.
- 2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should apply the following *risk* mitigation measures including:
 - a) the eggs should be disinfected prior to importing, in accordance with recommendations in Chapter 4.4. or those specified by the *Competent Authority* of the *importing country*; and
 - b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status.

The *Competent Authority* may wish to consider internal measures, such as renewed *disinfection* of the eggs upon arrival in the *importing country*.

- 3) When importing disinfected eggs of the species referred to in Article 10.5.2. for *aquaculture*, from a country, zone or compartment not declared free from *infection* with SAV, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that the procedures described in point 2 of this article have been fulfilled.
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CHAPTER 10.6.

INFECTIOUS HAEMATOPOIETIC NECROSIS

Article 10.6.1.

For the purposes of the *Aquatic Code*, infectious haematopoietic necrosis (IHN) means *infection* with IHN virus (IHNV) of the genus *Novirhabdovirus* of the family *Rhabdoviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 10.6.2.

Scope

The recommendations in this chapter apply to: rainbow trout or steelhead (*Oncorhynchus mykiss*), the Pacific salmon species (chinook [*O. tshawytscha*], sockeye [*O. nerka*], chum [*O. keta*], masou [*O. masou*], pink [*O. rhodurus*] and coho [*O. kisutch*]), and Atlantic salmon (*Salmo salar*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.6.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infectious haematopoietic necrosis

- 1) *Competent Authorities* should not require any conditions related to IHN, regardless of the IHN status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.6.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to a heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate IHNV);
 - c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate IHNV);
 - d) fish oil;
 - e) fish *meal*;
 - f) fish skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.6.2., other than those referred to in point 1 of Article 10.6.3., *Competent Authorities* should require the conditions prescribed in Articles 10.6.7. to 10.6.12. relevant to the IHN status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 10.6.2. but which could reasonably be expected to pose a *risk* of spread of IHN, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.6.4.

Country free from infectious haematopoietic necrosis

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from IHN if all the areas covered by the shared water bodies are declared countries or *zones* free from IHN (see Article 10.6.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from IHN if:

- 1) none of the *susceptible species* referred to in Article 10.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.6.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IHN;

OR

- 4) it previously made a *self-declaration of freedom* from IHN and subsequently lost its *disease free status* due to the detection of IHN but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IHN.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 10.6.5.

Article 10.6.5.

Zone or compartment free from infectious haematopoietic necrosis

If a *zone* or *compartment* extends over more than one country, it can only be declared an IHN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from IHN may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.6.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.6.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of IHN;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from IHN and subsequently lost its *disease free* status due to the detection of IHN in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of IHN.

Article 10.6.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from IHN following the provisions of points 1 or 2 of Articles 10.6.4. or 10.6.5. (as relevant) may maintain its status as free from IHN provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from IHN following the provisions of point 3 of Articles 10.6.4. or 10.6.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from IHN provided that conditions that are conducive to clinical expression of IHN, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of IHN, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.6.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infectious haematopoietic necrosis

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.6.2. from a country, *zone* or *compartment* declared free from IHN, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.6.4. or 10.6.5. (as applicable) and 10.6.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from IHN.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.6.3.

Article 10.6.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infectious haematopoietic necrosis

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.6.2. from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation* measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of IHN.

- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for IHN, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for IHN and perform general examinations for pests and general health/disease status;
 - g) if IHN is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as IHN free or specific pathogen free (SPF) for IHN;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.6.3.

Article 10.6.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infectious haematopoietic necrosis

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.6.2. from a country, *zone or compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.6.3., or products described in point 1 of Article 10.6.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of IHN or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.6.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infectious haematopoietic necrosis

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.6.2. from a country, *zone or compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of IHN.

This Article does not apply to *commodities* referred to in point 1 of Article 10.6.3.

Article 10.6.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infectious haematopoietic necrosis

- 1) *Competent Authorities* should not require any conditions related to IHN, regardless of the IHN status of the *exporting country, zone or compartment*, when authorising the importation or transit of fish fillets or steaks (frozen or chilled) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.6.2. from a country, *zone or compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.6.12.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infectious haematopoietic necrosis

- 1) When importing disinfected eggs of the species referred to in Article 10.6.2. for *aquaculture*, from a country, *zone or compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:
 - a) the IHN virus status of the water to be used during the *disinfection* of the eggs;
 - b) the prevalence of *infection* with IHN virus in broodstock (ovarian fluid and milt); and
 - c) the temperature and pH of the water to be used for *disinfection*.
- 2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should apply the following *risk* mitigation measures including:
 - a) the eggs should be disinfected prior to importing, in accordance with recommendations in Chapter 4.4. or those specified by the *Competent Authority* of the *importing country*; and
 - b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status.

The *Competent Authority* may wish to consider internal measures, such as renewed *disinfection* of the eggs upon arrival in the *importing country*.

- 3) When importing disinfected eggs of species referred to in Article 10.6.2. for *aquaculture*, from a country, *zone or compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that the procedures described in point 2 of Article 10.6.12. have been fulfilled.

CHAPTER 10.7.

KOI HERPESVIRUS DISEASE

Article 10.7.1.

For the purposes of the *Aquatic Code*, koi herpesvirus disease (KHVD) means *infection* with the viral species koi herpesvirus (KHV) tentatively placed in the sub-family *Cyprinid herpesvirus* of the family *Herpesviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 10.7.2.

Scope

The recommendations in this chapter apply to: common carp (*Cyprinus carpio carpio*), ghost carp (*Cyprinus carpio goi*), koi carp (*Cyprinus carpio koi*) and common carp hybrids (e.g. *Cyprinus carpio* x *Carassius auratus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.7.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from koi herpesvirus disease

- 1) *Competent Authorities* should not require any conditions related to KHVD, regardless of the KHVD status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.7.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to heat treatment at 90°C for at least ten minutes (or to any time/temperature equivalent which has been demonstrated to inactivate KHV);
 - c) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate KHV);
 - d) fish oil;
 - e) fish *meal*.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.7.2., other than those referred to in point 1 of Article 10.7.3., *Competent Authorities* should require the conditions prescribed in Articles 10.7.7. to 10.7.11. relevant to the KHVD status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 10.7.2. but which could reasonably be expected to pose a *risk* of spread of KHVD, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.7.4.

Country free from koi herpesvirus disease

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from KHVD if all the areas covered by the shared water bodies are declared countries or *zones* free from KHVD (see Article 10.7.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from KHVD if:

- 1) none of the *susceptible species* referred to in Article 10.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.7.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of KHVD;

OR

- 4) it previously made a *self-declaration of freedom* from KHVD and subsequently lost its *disease free* status due to the detection of KHVD but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of KHVD.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 10.7.5.

Article 10.7.5.

Zone or compartment free from koi herpesvirus disease

If a *zone* or *compartment* extends over more than one country, it can only be declared a KHVD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from KHVD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.7.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.7.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of KHVD;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from KHVD and subsequently lost its *disease free* status due to the detection of KHVD in the *zone* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of KHVD.

Article 10.7.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from KHVD following the provisions of points 1 or 2 of Articles 10.7.4. or 10.7.5. (as relevant) may maintain its status as free from KHVD provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from KHVD following the provisions of point 3 of Articles 10.7.4. or 10.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from KHVD provided that conditions that are conducive to clinical expression of KHVD, as described in the corresponding chapter of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of KHVD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 10.7.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from koi herpesvirus disease

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.7.2. from a country, *zone* or *compartment* declared free from KHVD, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.7.4. or 10.7.5. (as applicable) and 10.7.6., the place of production of *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from KHVD.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.7.3.

Article 10.7.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from koi herpesvirus disease

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.7.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of KHV.

- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for KHV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for KHV and perform general examinations for pests and general health/disease status;
 - g) if KHV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as KHVD free or specific pathogen free (SPF) for KHV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.7.3.

Article 10.7.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from koi herpesvirus disease

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.7.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.7.3., or products described in point 1 of Article 10.7.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of KHV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.7.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from koi herpesvirus disease

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of a species referred to in Article 10.7.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment be delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing be treated in a manner that ensures inactivation of KHV.

This Article does not apply to *commodities* referred to in point 1 of Article 10.7.3.

Article 10.7.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from koi herpesvirus disease

- 1) *Competent Authorities* should not require any conditions related to KHVD, regardless of the KHVD status of the *exporting country, zone or compartment*, when authorising the importation or transit of fish fillets or steaks (frozen or chilled) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.7.2. from a country, *zone or compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 10.8.

RED SEA BREAM IRIDOVIRAL DISEASE

Article 10.8.1.

For the purposes of the *Aquatic Code*, red sea bream iridoviral disease (RSIVD) means *infection* with red sea bream iridovirus (RSIV) of the family *Iridoviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 10.8.2.

Scope

The recommendations in this chapter apply to: red sea bream (*Pagrus major*), yellowtail (*Seriola quinqueradiata*), amberjack (*Seriola dumerili*), sea bass (*Lateolabrax* sp. and *Lates calcarifer*), Albacore (*Thunnus thynnus*), Japanese parrotfish (*Oplegnathus fasciatus*), striped jack (*Caranx delicatissimus*), mandarin fish (*Siniperca chuatsi*), red drum (*Sciaenops ocellatus*), mullet (*Mugil cephalus*) and groupers (*Epinephelus* spp.). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.8.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from red sea bream iridovirus

- 1) *Competent Authorities* should not require any conditions related to RSIVD, regardless of the RSIVD status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.8.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate RSIV);
 - c) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate RSIV);
 - d) fish oil;
 - e) fish *meal*;
 - f) fish skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.8.2., other than those referred to in point 1 of Article 10.8.3., *Competent Authorities* should require the conditions prescribed in Articles 10.8.7. to 10.8.11. relevant to the RSIVD status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 10.8.2. but which could reasonably be expected to pose a *risk* of spread of RSIVD, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.8.4.

Red sea bream iridovirus free country

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from RSIVD if all the areas covered by the shared water bodies are declared countries or *zones* free from RSIVD (see Article 10.8.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from RSIVD if:

- 1) none of the *susceptible species* referred to in Article 10.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.8.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*), and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of RSIVD;

OR

- 4) it previously made a *self-declaration of freedom* from RSIVD and subsequently lost its *disease* free status due to the detection of RSIVD but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of RSIVD.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 10.8.5.

Article 10.8.5.

Red sea bream iridovirus free zone or free compartment

If a *zone* or *compartment* extends over more than one country, it can only be declared a RSIVD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from RSIVD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.8.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been met continuously for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.8.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of RSIVD;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from RSIVD and subsequently lost its *disease free* status due to the detection of RSIVD in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of RSIVD.

Article 10.8.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from RSIVD following the provisions of points 1 or 2 of Articles 10.8.4. or 10.8.5. (as relevant) may maintain its status as free from RSIVD provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from RSIVD following the provisions of point 3 of Articles 10.8.4. or 10.8.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from RSIVD provided that conditions that are conducive to clinical expression of RSIVD, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of RSIVD, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.8.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from red sea bream iridovirus

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.8.2. from a country, *zone* or *compartment* declared free from RSIVD, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.8.4. or 10.8.5. (as applicable) and 10.8.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from RSIVD.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.8.3.

Article 10.8.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from red sea bream iridovirus

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation measures*:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of RSIV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for RSIVD, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for RSIVD and perform general examinations for pests and general health/disease status;
 - g) if RSIVDV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as RSIVD free or specific pathogen free (SPF) for RSIVDV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.8.3.

Article 10.8.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from red sea bream iridovirus

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.8.3., or products described in point 1 of Article 10.8.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of RSIV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.8.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from red sea bream iridovirus

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of RSIV.

This Article does not apply to *commodities* referred to in point 1 of Article 10.8.3.

Article 10.8.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from red sea bream iridovirus

- 1) *Competent Authorities* should not require any RSIVD related conditions, regardless of the RSIVD status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of fish fillets or steaks (chilled or frozen) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* listed above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 10.9.

SPRING VIRAEMIA OF CARP

Article 10.9.1.

For the purposes of the *Aquatic Code*, spring viraemia of carp (SVC) means *infection* with the viral species SVC virus (SVCV) tentatively placed in the genus *Vesiculovirus* of the family *Rhabdoviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 10.9.2.

Scope

The recommendations in this chapter apply to: common carp (*Cyprinus carpio carpio*) and koi carp (*Cyprinus carpio koi*), crucian carp (*Carassius carassius*), sheatfish (also known as European catfish or wels) (*Silurus glanis*), silver carp (*Hypophthalmichthys molitrix*), bighead carp (*Aristichthys nobilis*), grass carp (white amur) (*Ctenopharyngodon idellus*), goldfish (*Carassius auratus*), orfe (*Leuciscus idus*), and tench (*Tinca tinca*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.9.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from spring viraemia of carp

- 1) *Competent Authorities* should not require any conditions related to SVC, regardless of the SVC status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.9.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);
 - b) pasteurised fish products that have been subjected to heat treatment at 90°C for at least ten minutes (or any time/temperature equivalent which has been demonstrated to inactivate SVCV);
 - c) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate SVCV);
 - d) fish oil;
 - e) fish *meal*.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.9.2., other than those referred to in point 1 of Article 10.9.3., *Competent Authorities* should require the conditions prescribed in Articles 10.9.7. to 10.9.11. relevant to the SVC status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 10.9.2. but which could reasonably be expected to pose a *risk* of spread of SVC, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.9.4.

Country free from spring viraemia of carp

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from SVC if all the areas covered by the shared water bodies are declared countries or *zones* free from SVC (see Article 10.9.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from SVC if:

- 1) none of the *susceptible species* referred to in Article 10.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.9.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of SVC;

OR

- 4) it previously made a *self-declaration of freedom* from SVC and subsequently lost its *disease* free status due to the detection of SVC but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of SVC.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 10.9.5.

Article 10.9.5.

Zone or compartment free from spring viraemia of carp

If a *zone* or *compartment* extends over more than one country, it can only be declared an SVC free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from SVC may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 10.9.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 10.9.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last ten years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of SVC;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from SVC and subsequently lost its *disease free status* due to the detection of SVC in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of SVC.

Article 10.9.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from SVC following the provisions of points 1 or 2 of Articles 10.9.4. or 10.9.5. (as relevant) may maintain its status as free from SVC provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from SVC following the provisions of point 3 of Articles 10.9.4. or 10.9.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from SVC provided that conditions that are conducive to clinical expression of SVC, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of SVC, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.9.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from spring viraemia of carp

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.9.2. from a country, *zone* or *compartment* declared free from SVC, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.9.4. or 10.9.5. (as applicable) and 10.9.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from SVC.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.9.3.

Article 10.9.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from spring viraemia of carp

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of SVCV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for SVCV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for SVCV and perform general examinations for pests and general health/disease status;
 - g) if SVCV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as SVC free or specific pathogen free (SPF) for SVCV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.9.3.

Article 10.9.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from spring viraemia of carp

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.9.3., or products described in point 1 of Article 10.9.11., or other products authorised by the *Competent Authority*, and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of SVCV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.9.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from spring viraemia of carp

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of SVCV.

This Article does not apply to *commodities* referred to in point 1 of Article 10.9.3.

Article 10.9.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from spring viraemia of carp

- 1) *Competent Authorities* should not require any conditions related to SVC, regardless of the SVC status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of fish fillets or steaks (chilled or frozen) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.
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CHAPTER 10.10.

VIRAL HAEMORRHAGIC SEPTICAEMIA

Article 10.10.1.

For the purposes of the *Aquatic Code*, viral haemorrhagic septicaemia (VHS) means *infection* with VHS virus (VHSV, synonym: Egtved virus) of the genus *Novirhabdovirus* of the family *Rhabdoviridae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 10.10.2.

Scope

The recommendations in this chapter apply to: rainbow trout (*Oncorhynchus mykiss*), brown trout (*Salmo trutta*), grayling (*Thymallus thymallus*), white fish (*Coregonus* spp.), pike (*Esox lucius*), turbot (*Scophthalmus maximus*), herring and sprat (*Clupea* spp.), Pacific salmon (*Oncorhynchus* spp.), Atlantic cod (*Gadus morhua*), Pacific cod (*G. macrocephalus*), haddock (*G. aeglefinus*) and rockling (*Onos mustelus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.10.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from viral haemorrhagic septicaemia

- 1) *Competent Authorities* should not require any conditions related to VHS, regardless of the VHS status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 10.10.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) pasteurised fish products that have been subjected to a heat treatment at 90°C for at least ten minutes (or to any time/temperature equivalent which has been demonstrated to inactivate VHSV);
 - c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate VHSV);
 - d) naturally dried, eviscerated fish (i.e. sun-dried or wind-dried);
 - e) fish oil;
 - f) fish *meal*;
 - g) fish skin leather.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of species referred to in Article 10.10.2., other than those referred to in point 1 of Article 10.10.3., *Competent Authorities* should require the conditions prescribed in Articles 10.10.7. to 10.10.12. relevant to the VHS status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of species not covered in Article 10.10.2. but which could reasonably be expected to pose a *risk* of spread of VHS, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 10.10.4.

Country free from viral haemorrhagic septicaemia

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from VHS if all the areas covered by the shared water bodies are declared countries or *zones* free from VHS (see Article 10.10.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from VHS if:

- 1) a country where the species referred to in Article 10.10.2. are present but there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may make a *self-declaration of freedom* from VHS when *basic biosecurity conditions* have been continuously met in the country for at least the last ten years;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of VHS;

OR

- 3) it previously made a *self-declaration of freedom* from VHS and subsequently lost its *disease* free status due to the detection of VHS but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of VHS.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 2 of Article 10.10.5.

Article 10.10.5.

Zone or compartment free from viral haemorrhagic septicaemia

If a *zone* or *compartment* extends over more than one country, it can only be declared a VHS free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from VHS may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) a *zone* or *compartment* where the species referred to in Article 10.10.2. are present but there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may be declared free from VHS when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the last ten years;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of VHS;

OR

- 3) it previously made a *self-declaration of freedom* for a *zone* from VHS and subsequently lost its *disease free status* due to the detection of VHS in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of VHS.

Article 10.10.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from VHS following the provisions of point 1 of Articles 10.10.4. or 10.10.5. (as relevant) may maintain its status as free from VHS provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from VHS following the provisions of point 2 of Articles 10.10.4. or 10.10.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from VHS provided that conditions that are conducive to clinical expression of VHS, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of VHS, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 10.10.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from viral haemorrhagic septicaemia

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 10.10.2. from a country, *zone* or *compartment* declared free from VHS, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.10.4. or 10.10.5. (as applicable) and 10.10.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from VHS.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 10.10.3.

Article 10.10.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from viral haemorrhagic septicaemia

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 10.10.2. from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation measures*:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of VHSV (under study).

- 2) If the intention of the introduction is the establishment of a new stock, the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following main points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for VHSV, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for VHSV and perform general examinations for pests and general health/disease status;
 - g) if VHSV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as VHS free or specific pathogen free (SPF) for VHSV;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 10.10.3.

Article 10.10.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from viral haemorrhagic septicaemia

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.10.2. from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.10.3., or products described in point 1 of Article 10.10.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of VHSV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 10.10.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from viral haemorrhagic septicaemia

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 10.10.2. from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of VHSV.

This Article does not apply to *commodities* referred to in point 1 of Article 10.10.3.

Article 10.10.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from viral haemorrhagic septicaemia

- 1) *Competent Authorities* should not require any conditions related to VHS, regardless of the VHS status of the *exporting country, zone or compartment*, when authorising the importation or transit of fish fillets or steaks (chilled or frozen) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 10.10.2. from a country, zone or compartment not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.10.12.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from viral haemorrhagic septicaemia

- 1) When importing disinfected eggs of the species referred to in Article 10.10.2. for *aquaculture*, from a country, zone or compartment not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:
 - a) the VHS virus status of the water to be used during the *disinfection* of the eggs;
 - b) the prevalence of *infection* with VHS virus in broodstock (ovarian fluid and milt); and
 - c) the temperature and pH of the water to be used for *disinfection*.
- 2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should apply the following *risk* mitigation measures including:
 - a) the eggs should be disinfected prior to importing, in accordance with recommendations in Chapter 4.4. or those specified by the *Competent Authority* of the *importing country*; and
 - b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status.

The *Competent Authority* may wish to consider internal measures, such as renewed *disinfection* of the eggs upon arrival in the *importing country*.

- 3) When importing disinfected eggs of the species referred to in Article 10.10.2. for *aquaculture*, from a country, zone or compartment not declared free from VHS, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that the procedures described in point 2 of Article 10.10.12. have been fulfilled.

SECTION 11.
DISEASES OF MOLLUSCS

CHAPTER 11.1.
INFECTION WITH ABALONE HERPESVIRUS

Article 11.1.1.

For the purposes of the *Aquatic Code*, infection with abalone herpesvirus (AbHV) means *infection* with the herpesvirus known to cause *disease* in abalone.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.1.2.

Scope

The recommendations in this chapter apply to: *Haliotis diversicolor* (subspecies *aquatilis* and *supertexta*), *Haliotis laevegata*, *H. rubra* and hybrids of *H. laevegata* x *H. rubra*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.1.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with abalone herpesvirus

- 1) *Competent Authorities* should not require any conditions related to *infection* with abalone herpesvirus regardless of the *infection* with abalone herpesvirus status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animal products* from the species referred to in Article 11.1.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) heat sterilised hermetically sealed abalone products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
 - b) mechanically dried abalone products (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate AbHV).
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.1.2., other than those referred to in point 1 of Article 11.1.3., *Competent Authorities* should require the conditions prescribed in Articles 11.1.7. to 11.1.11. relevant to the *infection* with abalone herpesvirus status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 11.1.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with abalone herpesvirus, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 11.1.4.

Country free from infection with abalone herpesvirus

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with abalone herpesvirus if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with abalone herpesvirus (see Article 11.1.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with abalone herpesvirus if:

- 1) none of the *susceptible species* referred to in Article 11.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 11.1.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with abalone herpesvirus;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with abalone herpesvirus and subsequently lost its *disease* free status due to the detection of *infection* with abalone herpesvirus but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with abalone herpesvirus.

In the meantime, part or all of the non-affected area may be declared a free *zone* provided that such a part meets the conditions in point 3 of Article 11.1.5.

Article 11.1.5.

Zone or compartment free from infection with abalone herpesvirus

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with abalone herpesvirus if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with abalone herpesvirus may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 11.1.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 11.1.2. are present in the *zone* or *compartment* and the following conditions have been met:
- there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- basic biosecurity conditions* have been continuously met for at least the last two years; and
 - targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with abalone herpesvirus;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from *infection* with abalone herpesvirus and subsequently lost its *disease free* status due to the detection of *infection* with abalone herpesvirus in the *zone* but the following conditions have been met:
- on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with abalone herpesvirus.

Article 11.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with abalone herpesvirus following the provisions of points 1 or 2 of Articles 11.1.4. or 11.1.5. (as relevant) may maintain its status as free from *infection* with abalone herpesvirus provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with abalone herpesvirus following the provisions of point 3 of Articles 11.1.4. or 11.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with abalone herpesvirus provided that conditions that are conducive to clinical expression of *infection* with abalone herpesvirus, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with abalone herpesvirus, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 11.1.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with abalone herpesvirus

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* declared free from *infection* with abalone herpesvirus, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 11.1.4. or 11.1.5. (as applicable) and 11.1.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with abalone herpesvirus.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 11.1.3.

Article 11.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with abalone herpesvirus

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* not declared free from *infection* with abalone herpesvirus, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of AbHV.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for abalone herpesvirus, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with abalone herpesvirus and perform general examinations for pests and general health/disease status;
 - g) if *infection* with abalone herpesvirus is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as *infection* with abalone herpesvirus free or specific pathogen free (SPF) for *infection* with abalone herpesvirus;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 11.1.3.

Article 11.1.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with abalone herpesvirus

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* not declared free from *infection* with abalone herpesvirus, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 11.1.3., or products described in point 1 of Article 11.1.11., or other products authorised by the *Competent Authority*, and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of AbHV or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 11.1.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with abalone herpesvirus

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 11.1.2. from a country, *zone* or *compartment* not declared free from *infection* with abalone herpesvirus, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of AbHV.

This Article does not apply to *commodities* referred to in point 1 of Article 11.1.3.

Article 11.1.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with abalone herpesvirus

- 1) *Competent Authorities* should not require any conditions related to *infection* with abalone herpesvirus, regardless of the *infection* with abalone herpesvirus status of the *exporting country, zone* or *compartment*, when authorising the importation or transit of off the shell and eviscerated abalone meat (chilled or frozen) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 11.1.2. from a country, *zone* or *compartment* not declared free from *infection* with abalone herpesvirus, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 11.2.

INFECTION WITH *BONAMIA EXITIOSA*

Article 11.2.1.

For the purposes of the *Aquatic Code*, infection with *Bonamia exitiosa* means *infection* with *B. exitiosa*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.2.2.

Scope

The recommendations in this chapter apply to: Australian mud oyster (*Ostrea angasi*) and Chilean flat oyster (*O. chilensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.2.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *B. exitiosa*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *B. exitiosa*, regardless of the *infection* with *B. exitiosa* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 11.2.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) frozen oyster meat; and
 - b) frozen half-shell oysters.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.2.2., other than those referred to in point 1 of Article 11.2.3., *Competent Authorities* should require the conditions prescribed in Articles 11.2.7. to 11.2.11. relevant to the *infection* with *B. exitiosa* status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 11.2.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with *B. exitiosa*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 11.2.4.

Country free from infection with *B. exitiosa*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with *B. exitiosa* if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with *B. exitiosa* (see Article 11.2.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with *B. exitiosa* if:

- 1) none of the *susceptible species* referred to in Article 11.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 11.2.2. are present and the following conditions have been met:
- a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. exitiosa*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *B. exitiosa* and subsequently lost its *disease free* status due to the detection of *infection* with *B. exitiosa* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. exitiosa*.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 11.2.5.

Article 11.2.5.

Zone or compartment free from infection with *B. exitiosa*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with *B. exitiosa* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *B. exitiosa* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 11.2.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 11.2.2. are present in the *zone* or *compartment* and the following conditions have been met:
- a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with *B. exitiosa*;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from *infection* with *B. exitiosa* and subsequently lost its *disease free status* due to the detection of *infection* with *B. exitiosa* in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. exitiosa*.

Article 11.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *B. exitiosa* following the provisions of points 1 or 2 of Articles 11.2.4. or 11.2.5. (as relevant) may maintain its status as free from *infection* with *B. exitiosa* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *B. exitiosa* following the provisions of point 3 of Articles 11.2.4. or 11.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *B. exitiosa* provided that conditions that are conducive to clinical expression of *infection* with *B. exitiosa*, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *B. exitiosa*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 11.2.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *B. exitiosa*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 11.2.2. from a country, *zone* or *compartment* declared free from *infection* with *B. exitiosa*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 11.2.4. or 11.2.5. (as applicable) and 11.2.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with *B. exitiosa*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 11.2.3.

Article 11.2.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *B. exitiosa*

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 11.2.2. from a country, *zone* or *compartment* not declared free from *infection* with *B. exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation* measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

- b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *B. exitiosa*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
- a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *B. exitiosa*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with *B. exitiosa* and perform general examinations for pests and general health/disease status;
 - g) if *infection* with *B. exitiosa* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as *infection* with *B. exitiosa* free or specific pathogen free (SPF) for *infection* with *B. exitiosa*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 11.2.3.

Article 11.2.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *B. exitiosa*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 11.2.2. from a country, *zone or compartment* not declared free from *infection* with *B. exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 11.2.3., or products described in point 1 of Article 11.2.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *B. exitiosa* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 11.2.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *B. exitiosa*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 11.2.2. from a country, *zone or compartment* not declared free from *infection* with *B. exitiosa*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *B. exitiosa*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.2.3.

Article 11.2.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *B. exitiosa*

1) *Competent Authorities* should not require any conditions related to *infection* with *B. exitiosa*, regardless of the *infection* with *B. exitiosa* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:

- a) chilled oyster meat; and
- b) chilled half-shell oysters.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* listed above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 11.2.2. from a country, zone or compartment not declared free from *infection* with *B. exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 11.3.

INFECTION WITH *BONAMIA OSTREAE*

Article 11.3.1.

For the purposes of the *Aquatic Code*, infection with *Bonamia ostreae* means *infection* with *B. ostreae*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 11.3.2.

Scope

The recommendations in this chapter apply to: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean flat oyster (*O. puelchana*), Chilean flat oyster (*O. chilensis*), Asiatic oyster (*O. denselammellosa*) and Suminoe oyster (*Crassostrea ariakensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.3.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *B. ostreae*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *B. ostreae*, regardless of the *infection* with *B. ostreae* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 11.3.2. which are intended for any purpose and which comply with Article 5.4.1.:
 - a) frozen oyster meat;
 - b) frozen half-shell oysters.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.3.2., other than those referred to in point 1 of Article 11.3.3., *Competent Authorities* should require the conditions prescribed in Articles 11.3.7. to 11.3.11. relevant to the *infection* with *B. ostreae* status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 11.3.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with *B. ostreae*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 11.3.4.

Country free from infection with *B. ostreae*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with *B. ostreae* if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with *B. ostreae* (see Article 11.3.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with *B. ostreae* if:

- 1) none of the *susceptible species* referred to in Article 11.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 11.3.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. ostreae*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *B. ostreae* and subsequently lost its *disease* free status due to the detection of *infection* with *B. ostreae* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. ostreae*.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 11.3.5.

Article 11.3.5.

Zone or compartment free from infection with *B. ostreae*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with *B. ostreae* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *B. ostreae* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 11.3.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 2) any of the *susceptible species* referred to in Article 11.3.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last two years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last two years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with *B. ostreae*;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from *infection* with *B. ostreae* and subsequently lost its *disease free status* due to the detection of *infection* with *B. ostreae* in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *B. ostreae*.

Article 11.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *B. ostreae* following the provisions of points 1 or 2 of Articles 11.3.4. or 11.3.5. (as relevant) may maintain its status as free from *infection* with *B. ostreae* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *B. ostreae* following the provisions of point 3 of Articles 11.3.4. or 11.3.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *B. ostreae* provided that conditions that are conducive to clinical expression of *infection* with *B. ostreae*, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *B. ostreae*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 11.3.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *B. ostreae*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 11.3.2. from a country, *zone* or *compartment* declared free from *infection* with *B. ostreae*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 11.3.4. or 11.3.5. (as applicable) and 11.3.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with *B. ostreae*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 11.3.3.

Article 11.3.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *B. ostreae*

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 11.3.2. from a country, *zone* or *compartment* not declared free from *infection* with *B. ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation* measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

- b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *B. ostreae*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *B. ostreae*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with *B. ostreae* and perform general examinations for pests and general health/disease status;
 - g) if *infection* with *B. ostreae* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as *infection* with *B. ostreae* free or specific pathogen free (SPF) for *infection* with *B. ostreae*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 11.3.3.

Article 11.3.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *B. ostreae*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 11.3.2. from a country, *zone* or *compartment* not declared free from *infection* with *B. ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 11.3.3., or products described in point 1 of Article 11.3.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *B. ostreae* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 11.3.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *B. ostreae*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 11.3.2. from a country, *zone* or *compartment* not declared free from *infection* with *B. ostreae*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *B. ostreae*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.3.3.

Article 11.3.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *B. ostreae*

1) *Competent Authorities* should not require any conditions related to *infection* with *B. ostreae*, regardless of the *infection* with *B. ostreae* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:

- a) chilled oyster meat;
- b) chilled half-shell oysters.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* listed above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 11.3.2. from a country, zone or compartment not declared free from *infection* with *B. ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 11.4.

INFECTION WITH *MARTEILIA REFRINGENS*

Article 11.4.1.

For the purposes of the *Aquatic Code*, infection with *Marteilia refringens* means infection with *M. refringens*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.4.2.

Scope

The recommendations in this chapter apply to: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean oyster (*O. puelchana*), Chilean flat oyster (*O. chilensis*), blue mussel (*Mytilus edulis*) and Mediterranean mussel (*M. galloprovincialis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.4.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *M. refringens*

- 1) *Competent Authorities* should not require any conditions related to infection with *M. refringens*, regardless of the infection with *M. refringens* status of the *exporting country, zone or compartment*, when authorising the importation or transit of heat sterilised hermetically sealed mollusc products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time /temperature equivalent) from the species referred to in Article 11.4.2. which are intended for any purpose and which comply with Article 5.4.1.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.4.2., other than those referred to in point 1 of Article 11.4.3., *Competent Authorities* should require the conditions prescribed in Articles 11.4.7. to 11.4.11. relevant to the infection with *M. refringens* status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 11.4.2. but which could reasonably be expected to pose a *risk* of spread of infection with *M. refringens*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 11.4.4.

Country free from infection with *M. refringens*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from infection with *M. refringens* if all the areas covered by the shared water bodies are declared countries or *zones* free from infection with *M. refringens* (see Article 11.4.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from infection with *M. refringens* if:

- 1) none of the *susceptible species* referred to in Article 11.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 2) any of the *susceptible species* referred to in Article 11.4.2. are present and the following conditions have been met:
- a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last three years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two of the last three years without detection of *infection with M. refringens*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection with M. refringens* and subsequently lost its *disease free status* due to the detection of *infection with M. refringens* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two of the last three years without detection of *infection with M. refringens*.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 11.4.5.

Article 11.4.5.

Zone or compartment free from infection with *M. refringens*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection with M. refringens* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection with M. refringens* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 11.4.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 2) any of the *susceptible species* referred to in Article 11.4.2. are present in the *zone* or *compartment* and the following conditions have been met:
- a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- a) *basic biosecurity conditions* have been continuously met for at least the last three years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two of the last three years without detection of *infection with M. refringens*;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from *infection* with *M. refringens* and subsequently lost its *disease free* status due to the detection of *infection* with *M. refringens* in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two of the last three years without detection of *infection* with *M. refringens*.

Article 11.4.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *M. refringens* following the provisions of points 1 or 2 of Articles 11.4.4. or 11.4.5. (as relevant) may maintain its status as free from *infection* with *M. refringens* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *M. refringens* following the provisions of point 3 of Articles 11.4.4. or 11.4.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *M. refringens* provided that conditions that are conducive to clinical expression of *infection* with *M. refringens*, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *M. refringens*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 11.4.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *M. refringens*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 11.4.2. from a country, *zone* or *compartment* declared free from *infection* with *M. refringens*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 11.4.4. or 11.4.5. (as applicable) and 11.4.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with *M. refringens*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 11.4.3.

Article 11.4.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *M. refringens*

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 11.4.2. from a country, *zone* or *compartment* not declared free from *infection* with *M. refringens*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

- b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *M. refringens*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
- a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *M. refringens*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with *M. refringens* and perform general examinations for pests and general health/disease status;
 - g) if *infection* with *M. refringens* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as *infection* with *M. refringens* free or specific pathogen free (SPF) for *infection* with *M. refringens*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 11.4.3.

Article 11.4.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *M. refringens*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 11.4.2. from a country, *zone* or *compartment* not declared free from *infection* with *M. refringens*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 11.4.3., or products described in point 1 of Article 11.4.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *M. refringens* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 11.4.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *M. refringens*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 11.4.2. from a country, *zone* or *compartment* not declared free from *infection* with *M. refringens*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *M. refringens*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.4.3.

Article 11.4.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *M. refringens*

1) *Competent Authorities* should not require any conditions related to *infection* with *M. refringens*, regardless of the *infection* with *M. refringens* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:

- a) mollusc meat (chilled or frozen); and
- b) half-shell oysters (chilled or frozen).

Certain assumptions have been made in assessing the safety of the *aquatic animal products* listed above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 11.4.2. from a country, zone or compartment not declared free from *infection* with *M. refringens*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 11.5.

INFECTION WITH *PERKINSUS MARINUS*

Article 11.5.1.

For the purposes of the *Aquatic Code*, infection with *Perkinsus marinus* means infection with *P. marinus*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.5.2.

Scope

The recommendations in this chapter apply to: Eastern oyster (*Crassostrea virginica*), Pacific oyster (*C. gigas*), Suminoe oyster (*C. ariakensis*), soft shell clam (*Mya arenaria*), Baltic clam (*Macoma balthica*) and hard shell clam (*Mercenaria mercenaria*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.5.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *P. marinus*

- 1) *Competent Authorities* should not require any conditions related to infection with *P. marinus*, regardless of the infection with *P. marinus* status of the *exporting country, zone or compartment*, when authorising the importation or transit of heat sterilised hermetically sealed mollusc products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time /temperature equivalent) from the species referred to in Article 11.5.2. which are intended for any purpose and which comply with Article 5.4.1.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.5.2., other than those referred to in point 1 of Article 11.5.3., *Competent Authorities* should require the conditions prescribed in Articles 11.5.7. to 11.5.11. relevant to the infection with *P. marinus* status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 11.5.2. but which could reasonably be expected to pose a *risk* of spread of infection with *P. marinus*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 11.5.4.

Country free from infection with *P. marinus*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from infection with *P. marinus* if all the areas covered by the shared water bodies are declared countries or zones free from infection with *P. marinus* (see Article 11.5.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from infection with *P. marinus* if:

- 1) none of the *susceptible species* referred to in Article 11.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 2) any of the *susceptible species* referred to in Article 11.5.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last three years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *infection* with *P. marinus*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *P. marinus* and subsequently lost its *disease* free status due to the detection of *infection* with *P. marinus* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *infection* with *P. marinus*.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 11.5.5.

Article 11.5.5.

Zone or compartment free from infection with *P. marinus*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with *P. marinus* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *P. marinus* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 11.5.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 2) any of the *susceptible species* referred to in Article 11.5.2. are present in the *zone* or *compartment* and the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last three years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last three years without detection of *infection* with *P. marinus*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *P. marinus* and subsequently lost its *disease free* status due to the detection of *infection* with *P. marinus* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *infection* with *P. marinus*.

Article 11.5.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *P. marinus* following the provisions of points 1 or 2 of Articles 11.5.4. or 11.5.5. (as relevant) may maintain its status as free from *infection* with *P. marinus* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *P. marinus* following the provisions of point 3 of Articles 11.5.4. or 11.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *P. marinus* provided that conditions that are conducive to clinical expression of *infection* with *P. marinus*, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *P. marinus*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 11.5.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *P. marinus*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 11.5.2. from a country, *zone* or *compartment* declared free from *infection* with *P. marinus*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 11.5.4. or 11.5.5. (as applicable) and 11.5.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with *P. marinus*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 11.5.3.

Article 11.5.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *P. marinus*

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 11.5.2. from a country, *zone* or *compartment* not declared free from *infection* with *P. marinus*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk mitigation* measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

- b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *P. marinus*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *P. marinus*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with *P. marinus* and perform general examinations for pests and general health/disease status;
 - g) if *infection* with *P. marinus* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as free of *infection* with *P. marinus* or specific pathogen free (SPF) for *infection* with *P. marinus*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 11.5.3.

Article 11.5.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *P. marinus*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 11.5.2. from a country, *zone* or *compartment* not declared free from *infection* with *P. marinus*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 11.5.3., or products described in point 1 of Article 11.5.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *P. marinus* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 11.5.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *P. marinus*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 11.5.2. from a country, *zone* or *compartment* not declared free from *infection* with *P. marinus*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *P. marinus*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.5.3.

Article 11.5.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *P. marinus*

1) *Competent Authorities* should not require any conditions related to *infection* with *P. marinus*, regardless of the *infection* with *P. marinus* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:

- a) mollusc meat (chilled and frozen); and
- b) half-shell oysters (chilled and frozen).

Certain assumptions have been made in assessing the safety of the *aquatic animal products* listed above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 11.5.2. from a country, zone or compartment not declared free from *infection* with *P. marinus*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

Article 11.6.1.

For the purposes of the *Aquatic Code*, infection with *Perkinsus olseni* means *infection* with *P. olseni*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 11.6.2.

Scope

The recommendations in this chapter apply to: primarily venerid clams (*Austrovenus stutchburyi*, *Venerupis pullastra*, *V. aurea*, *Ruditapes decussatus* and *R. philippinarum*), abalone (*Haliotis rubra*, *H. laevigata*, *H. Cyclobates* and *H. scalaris*) and other species (*Anadara trapezia*, *Barbatia novaezelandiae*, *Macomona liliana*, *Paphies australis* and *Crassostrea ariakensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.6.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *P. olseni*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *P. olseni*, regardless of the *infection* with *P. olseni* status of the *exporting country, zone or compartment*, when authorising the importation or transit of heat sterilised hermetically sealed mollusc products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent) from the species referred to in Article 11.6.2. which are intended for any purpose and which comply with Article 5.4.1.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.6.2., other than those referred to in point 1 of Article 11.6.3., *Competent Authorities* should require the conditions prescribed in Articles 11.6.7. to 11.6.11. relevant to the *infection* with *P. olseni* status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 11.6.2. but which could reasonably be expected to pose a *risk* of spread of *infection* with *P. olseni*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 11.6.4.

Country free from infection with *P. olseni*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *infection* with *P. olseni* if all the areas covered by the shared water bodies are declared countries or *zones* free from *infection* with *P. olseni* free (see Article 11.6.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from *infection* with *P. olseni* if:

- 1) a country where the *susceptible species* referred to in Article 11.6.2. are present but there has been no observed occurrence of the *disease* for at least the last ten years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may make a *self-declaration of freedom* from *infection* with *P. olseni* when *basic biosecurity conditions* have been continuously met in the country for at least the last three years and *infection* with *P. olseni* is not known to be established in wild populations;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- basic biosecurity conditions* have been continuously met for at least the last three years; and
 - targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *infection* with *P. olseni*;

OR

- 3) it previously made a *self-declaration of freedom* from *infection* with *P. olseni* and subsequently lost its *disease free* status due to the detection of *infection* with *P. olseni* but the following conditions have been met:
- on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *infection* with *P. olseni*.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 2 of Article 11.6.5.

Article 11.6.5.

Zone or compartment free from infection with *P. olseni*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with *P. olseni* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *P. olseni* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- in a country of unknown status for *infection* with *P. olseni*, a *zone* or *compartment* where the *susceptible species* referred to in Article 11.6.2. are present but there has been no observed occurrence of the *disease* for at least the last ten years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may be declared free from *infection* with *P. olseni* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the last three years and *infection* with *P. olseni* is not known to be established in wild populations;

OR

- 2) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
- basic biosecurity conditions* have been continuously met for at least the last three years; and
 - targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last three years without detection of *infection* with *P. olseni*;

OR

- 3) it previously made a *self-declaration of freedom* for a *zone* from *infection* with *P. olseni* and subsequently lost its *disease free* status due to the detection of *infection* with *P. olseni* in the *zone* but the following conditions have been met:
- on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *infection* with *P. olseni*.

Article 11.6.6.

Maintenance of free status

A country, zone or compartment that is declared free from infection with *P. olseni* following the provisions of point 1 of Articles 11.6.4. or 11.6.5. (as relevant) may maintain its status as free from infection with *P. olseni* provided that basic biosecurity conditions are continuously maintained.

A country, zone or compartment that is declared free from infection with *P. olseni* following the provisions of point 2 of Articles 11.6.4. or 11.6.5. (as relevant) may discontinue targeted surveillance and maintain its status as free from infection with *P. olseni* provided that conditions that are conducive to clinical expression of infection with *P. olseni*, as described in the corresponding chapter of the *Aquatic Manual*, exist and basic biosecurity conditions are continuously maintained.

However, for declared free zones or compartments in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *P. olseni*, targeted surveillance needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of infection.

Article 11.6.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *P. olseni*

When importing aquatic animals and aquatic animal products of species referred to in Article 11.6.2. from a country, zone or compartment declared free from infection with *P. olseni*, the Competent Authority of the importing country should require that the consignment be accompanied by an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country certifying that, on the basis of the procedures described in Articles 11.6.4. or 11.6.5. (as applicable) and 11.6.6., the place of production of the aquatic animals and aquatic animal products is a country, zone or compartment declared free from infection with *P. olseni*.

The certificate should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to commodities referred to in point 1 of Article 11.6.3.

Article 11.6.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *P. olseni*

- 1) When importing, for aquaculture, live aquatic animals of species referred to in Article 11.6.2. from a country, zone or compartment not declared free from infection with *P. olseni*, the Competent Authority of the importing country should assess the risk and, if justified, apply the following risk mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *P. olseni*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *P. olseni*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in quarantine;

- f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with *P. olseni* and perform general examinations for pests and general health/disease status;
 - g) if *infection* with *P. marinus* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as *infection* with *P. olseni* free or specific pathogen free (SPF) for *infection* with *P. olseni*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone or compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 11.6.3.

Article 11.6.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *P. olseni*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 11.6.2. from a country, *zone or compartment* not declared free from *infection* with *P. olseni*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 11.6.3., or products described in point 1 of Article 11.6.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *P. olseni* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 11.6.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *P. olseni*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 11.6.2. from a country, *zone or compartment* not declared free from *infection* with *P. olseni*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *P. olseni*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.6.3.

Article 11.6.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *P. olseni*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *P. olseni*, regardless of the *infection* with *P. olseni* status of the *exporting country, zone or compartment*, when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and which comply with Article 5.4.2.:
 - a) mollusc meat (chilled and frozen); and

b) half-shell molluscs (chilled and frozen).

Certain assumptions have been made in assessing the safety of the *aquatic animal products* listed above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 11.6.2. from a country, *zone* or *compartment* not declared free from *infection* with *P. olseni*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.
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CHAPTER 11.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Article 11.7.1.

For the purposes of the *Aquatic Code*, infection with *Xenohaliotis californiensis* means infection with *X. californiensis*.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 11.7.2.

Scope

The recommendations in this chapter apply to: black abalone (*Haliotis cracherodii*), white abalone (*H. sorenseni*), red abalone (*H. rufescens*), pink abalone (*H. corrugata*), green abalone (*H. tuberculata* and *H. fulgens*), flat abalone (*H. wallalensis*) and Japanese abalone (*H. discus-hannai*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.7.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from infection with *X. californiensis*

- 1) *Competent Authorities* should not require any conditions related to infection with *X. californiensis*, regardless of the infection with *X. californiensis* status of the *exporting country, zone or compartment*, when authorising the importation or transit of heat sterilised hermetically sealed abalone products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent) from the species referred to in Article 11.7.2. which are intended for any purpose and which comply with Article 5.4.1.
- 2) When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.7.2., other than those referred to in point 1 of Article 11.7.3., *Competent Authorities* should require the conditions prescribed in Articles 11.7.7. to 11.7.11. relevant to the infection with *X. californiensis* status of the *exporting country, zone or compartment*.
- 3) When considering the importation or transit of *aquatic animals* and *aquatic animal products* of a species not covered in Article 11.7.2. but which could reasonably be expected to pose a *risk* of spread of infection with *X. californiensis*, the *Competent Authority* should conduct a *risk analysis* in accordance with the recommendations in Chapter 2.1. The *Competent Authority* of the *exporting country* should be informed of the outcome of this assessment.

Article 11.7.4.

Country free from infection with *X. californiensis*

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from infection with *X. californiensis* if all the areas covered by the shared water bodies are declared countries or *zones* free from infection with *X. californiensis* (see Article 11.7.5.).

As described in Article 1.4.6., a country may make a *self-declaration of freedom* from infection with *X. californiensis* if:

- 1) none of the *susceptible species* referred to in Article 11.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 2) any of the *susceptible species* referred to in Article 11.7.2. are present and the following conditions have been met:
 - a) there has been no observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last three years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *X. californiensis*;

OR

- 4) it previously made a *self-declaration of freedom* from *infection* with *X. californiensis* and subsequently lost its *disease free status* due to the detection of *infection* with *X. californiensis* but the following conditions have been met:
 - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *X. californiensis*.

In the meantime, part or all of the non-affected area may be declared a *free zone* provided that such a part meets the conditions in point 3 of Article 11.7.5.

Article 11.7.5.

Zone or compartment free from infection with *X. californiensis*

If a *zone* or *compartment* extends over more than one country, it can only be declared a *zone* or *compartment* free from *infection* with *X. californiensis* if all the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.6., a *zone* or *compartment* within the *territory* of one or more countries not declared free from *infection* with *X. californiensis* may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if:

- 1) none of the *susceptible species* referred to in Article 11.7.2. are present in the *zone* or *compartment* and *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 2) any of the *susceptible species* referred to in Article 11.7.2. are present in the *zone* or *compartment* but the following conditions have been met:
 - a) there has not been any observed occurrence of the *disease* for at least the last ten years despite conditions that are conducive to its clinical expression (as described in the corresponding chapter of the *Aquatic Manual*); and
 - b) *basic biosecurity conditions* have been continuously met for at least the last three years;

OR

- 3) the disease status prior to *targeted surveillance* is unknown but the following conditions have been met:
 - a) *basic biosecurity conditions* have been continuously met for at least the last three years; and
 - b) *targeted surveillance*, as described in Chapter 1.4., has been in place, in the *zone* or *compartment*, for at least the last two years without detection of *infection* with *X. californiensis*;

OR

- 4) it previously made a *self-declaration of freedom* for a *zone* from *infection* with *X. californiensis* and subsequently lost its *disease free* status due to the detection of *infection* with *X. californiensis* in the *zone* but the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
 - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (as described in the *Aquatic Manual*) have been completed; and
 - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of the *disease*; and
 - d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *infection* with *X. californiensis*.

Article 11.7.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *infection* with *X. californiensis* following the provisions of points 1 or 2 of Articles 11.7.4. or 11.7.5. (as relevant) may maintain its status as free from *infection* with *X. californiensis* provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *infection* with *X. californiensis* following the provisions of point 3 of Articles 11.7.4. or 11.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as free from *infection* with *X. californiensis* provided that conditions that are conducive to clinical expression of *infection* with *X. californiensis*, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of *infection* with *X. californiensis*, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

Article 11.7.7.

Importation of aquatic animals and aquatic animal products from a country, zone or compartment declared free from infection with *X. californiensis*

When importing *aquatic animals* and *aquatic animal products* of species referred to in Article 11.7.2. from a country, *zone* or *compartment* declared free from *infection* with *X. californiensis*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 11.7.4. or 11.7.5. (as applicable) and 11.7.6., the place of production of the *aquatic animals* and *aquatic animal products* is a country, *zone* or *compartment* declared free from *infection* with *X. californiensis*.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This Article does not apply to *commodities* referred to in point 1 of Article 11.7.3.

Article 11.7.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *X. californiensis*

- 1) When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 11.7.2. from a country, *zone* or *compartment* not declared free from *infection* with *X. californiensis*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

- b) the treatment of water used in transport and of all effluent and waste materials in a manner that ensures inactivation of *X. californiensis*.
- 2) If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
- 3) For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/publications/our-publications/Pages/Miscellaneous.aspx>) may be summarised to the following points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health and disease history;
 - c) take and test samples for *X. californiensis*, pests and general health/disease status;
 - d) import of a founder (F-0) population and quarantine in a secure facility;
 - e) produce F-1 generation from the F-0 stock in *quarantine*;
 - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *infection* with *X. californiensis* and perform general examinations for pests and general health/disease status;
 - g) if *infection* with *X. californiensis* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as *infection* with *X. californiensis* free or specific pathogen free (SPF) for *infection* with *X. californiensis*;
 - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
- 4) With respect to point 3 e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

This Article does not apply to *aquatic animals* referred to in point 1 of Article 11.7.3.

Article 11.7.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *X. californiensis*

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 11.7.2. from a country, *zone* or *compartment* not declared free from *infection* with *X. californiensis*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1) the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 11.7.3., or products described in point 1 of Article 11.7.11., or other products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *X. californiensis* or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

Article 11.7.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from infection with *X. californiensis*

When importing, for use in animal *feed* or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 11.7.2. from a country, *zone* or *compartment* not declared free from *infection* with *X. californiensis*, the *Competent Authority* of the *importing country* should require that:

- 1) the consignment is delivered directly to, and held in, *quarantine* facilities for slaughter and processing into products authorised by the *Competent Authority*; and
- 2) water used in transport and all effluent and waste materials from the processing are treated in a manner that ensures inactivation of *X. californiensis*.

This Article does not apply to *commodities* referred to in point 1 of Article 11.7.3.

Article 11.7.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from infection with *X. californiensis*

- 1) *Competent Authorities* should not require any conditions related to *infection* with *X. californiensis*, regardless of the *infection* with *X. californiensis* status of the *exporting country, zone or compartment*, when authorising the importation or transit of off the shell, eviscerated abalones (chilled or frozen) which have been prepared and packaged for retail trade and which comply with Article 5.4.2.

Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

For these *commodities* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *commodity* being used for any purpose other than for human consumption.

- 2) When importing *aquatic animals* or *aquatic animal products*, other than those referred to in point 1 above, of species referred to in Article 11.7.2. from a country, *zone or compartment* not declared free from *infection* with *X. californiensis*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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