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26th edition

Aquatic Animal Health Code

World Organisation for Animal Health

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FOREWORD

The Aquatic Animal Health Code (the Aquatic Code) provides standards for the improvement of aquatic animal health and farmed fish welfare worldwide. These standards should be used by Members to set up measures for the prevention, early detection, reporting and control of pathogenic agents in aquatic animals (amphibians, crustaceans, fish and molluscs). Implementation of the recommendations in the Aquatic Code ensures the safety of international trade in aquatic animals and aquatic animal products, while avoiding unjustified sanitary barriers.

The World Organisation for Animal Health (WOAH, founded as OIE) has developed and published international standards since 1968. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) recognises the role of the Organisation (under its foundational name "Office International des Epizooties") as the international standard setting organisation for animal health and zoonoses.

The development of new and revised standards for the Aquatic Code is under the responsibility of the Aquatic Animal Health Standards Commission (the Aquatic Animals Commission), which comprises six elected members. The Aquatic Animals Commission draws upon the expertise of internationally renowned experts to contribute to standards development to ensure that the standards are based on the latest scientific information. Comments from Members and partner International Organisations are sought through the twice-yearly circulation of new or revised texts. The Aquatic Animals Commission collaborates with other Specialist Commissions, as relevant.

The Aquatic Code is published annually in English, French and Spanish and may be viewed and downloaded from the World Organisation for Animal Health website (www.woah.org).

This edition includes new and amended texts in the following sections and chapters, that were adopted by the World Assembly of Delegates of the World Organisation for Animal Health at the 91st General Session in May 2024:

- *Usage of glossary definitions: 'Aquatic Animal Health Services', 'Competent Authority', and 'Veterinary Authority'*
- *Usage of glossary definition: 'aquatic animal products'*
- *Article 1.1.5. of Chapter 1.1. 'Notification of disease and provision of epidemiological information'*
- *Article 1.3.1. of Chapter 1.3. 'Diseases listed by WOAH'*
- *Article 8.1.3. of Chapter 8.1 'Infection with Batrachochytrium dendrobatidis'*
- *Article 8.2.3. of Chapter 8.2 'Infection with Batrachochytrium salmandrivorans'*
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- *Article 11.1.3. of Chapter 11.1. 'Infection with abalone herpesvirus'*
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- *Article 11.6.3. of Chapter 11.6. 'Infection with Perkinsus olseni'*
- *Article 11.7.3. of Chapter 11.7. 'Infection with Xenohaliotis californiensis'*
- *Model Articles X.X.5. and X.X.6. for disease-specific chapters*
- *Article 9.3.2. of Chapter 9.3. 'Infection with decapod iridescent virus 1'*
- *Article 10.6.2. of Chapter 10.6. 'Infection with infectious haematopoietic necrosis virus'*
- *Article 10.11.2. of Chapter 10.11. 'Infection with tilapia lake virus'*
- *Articles 11.5.1. and 11.5.2. of Chapter 11.5. 'Infection with Perkinsus marinus'.*

Details of the amendments made in this edition can be found in the 91st General Session report and the Aquatic Animals Commission reports, available on the World Organisation for Animal Health website (www.woah.org).

I wish to thank the members of the Aquatic Animals Commission, Delegates, international experts and other Specialist Commissions for their expert advice. Thanks also to WOAH staff who contributed to the work that has resulted in the publication of this 26th edition of the Aquatic Code.

Dr Monique Eloit
Director General
World Organisation for Animal Health

Members of the WOAH Aquatic Animals Commission, 2023-2024:
President: Dr Ingo Ernst
Vice-President: Dr Alicia Gallardo Lagno
Vice-President: Dr Fiona Geoghegan
Members: Dr Kevin Christison, Dr Hong Liu and Prof Espen Rimstad.

July 2024

USER'S GUIDE

A. Introduction

1) The WOAH *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) establishes 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 WOAH Member Countries on how to use the *Aquatic Code*.

2) Competent Authorities should use the standards in the *Aquatic Code* to develop measures for prevention including biosecurity at aquaculture establishments, early detection, reporting, control or eradication 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) The standards in the *Aquatic Code* are based on the most recent scientific and technical information and are adopted by the World Assembly of Delegates. 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 aquatic animal products 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 year that a chapter was first adopted and the year of last revision are noted at the end of each chapter.

6) The *Aquatic Code* is available on the WOAH website at: http://www.woah.org.

B. *Aquatic Code* content

1) Key terms and expressions used in more than one chapter in the *Aquatic Code* are defined in the Glossary, where common dictionary definitions are not deemed to be adequate. 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 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 WOAH, procedures for notification to WOAH, and criteria for listing species as susceptible to infection with a specific pathogenic agent.

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 WOAH standards. The importing country should also use these standards to justify import measures which are more stringent than existing WOAH 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 Aquatic Animal Health Services and the Competent Authorities of Member Countries to meet their objectives of improving aquatic animal health and the 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 biosecurity for aquaculture establishments, zoning, compartmentalisation, disinfection, contingency planning, fallowing, handling, disposal and treatment 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 diseases listed by WOAH 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 Organic Statutes of the Office International des Epizooties. Listed diseases, as prescribed in Chapter 1.1., are compulsorily notifiable. Member Countries are encouraged to also provide information to WOAH 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 WOAH.

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

2) Diagnostic tests

Methods for diagnosis of listed diseases are provided in the WOAH *Manual of Diagnostic Tests for Aquatic Animals* (hereafter referred to as the *Aquatic Manual*). Experts responsible for laboratory testing should be fully conversant with the methods in the *Aquatic Manual*.

3) Freedom from a disease

Article 1.4.6. provides general principles for declaring a country, zone or compartment free from infection with a pathogenic agent. This article applies when there is no disease-specific chapter.

4) 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.

5) Determining the susceptibility of species to listed diseases

Chapter 1.5. provides criteria for determining which species are listed as susceptible in Article X.X.2. of each disease-specific chapter in the *Aquatic Code*. This is important in the aquaculture context, given the large number of existing and new aquaculture species.

This is work in progress and the list of susceptible species in some chapters is yet to be assessed against the criteria in Chapter 1.5.

6) Trade requirements

Aquatic animal health measures related to international trade should be based on WOAH 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 WOAH standards, as described in Chapter 2.1. Members of the World Trade Organization should refer to the Agreement on the Application of Sanitary and Phytosanitary Measures.

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 WOAH informal procedure for dispute mediation.

Disease-specific chapters in the *Aquatic Code* include articles listing the aquatic animal products 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 aquatic animal products.

7) Safety of aquatic animal products for trade

Chapter 5.4. describes the criteria used to assess the safety of aquatic animal products. The aquatic animal products that have been assessed and found to meet these criteria are listed in each disease-specific chapter. Article 5.4.1. describes criteria to assess the safety of aquatic animal products for any purpose. Article 5.4.2. describes criteria to assess the safety of aquatic animal products for the purposes of retail trade for human consumption.

Article X.X.3. lists aquatic animal products that may be imported for any purpose regardless of the disease status of the exporting country, zone or compartment for the disease in question. The inclusion of an aquatic animal product in Article X.X.3. is based on evidence that demonstrates the absence of the pathogenic agent in that product or the inactivation of the pathogenic agent by physical, chemical or biological means.

Article X.X.14. and Article 10.4.16. list aquatic animal products that may be imported for retail trade for human consumption regardless of the disease status of the exporting country, zone or compartment for the disease in question. The assessment for inclusion of aquatic animal products in these articles is based on the form and presentation of the product, the expected volume of aquatic animal waste generated by the consumer and the likely presence of viable pathogenic agent in the aquatic animal waste.

8) International aquatic animal 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 products. This includes the relevant Competent Authority's ethical approach to the provision of international health certificates and the Veterinary Authority's 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 animals and aquatic animal products 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 aquatic animal products 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 country, zone or compartment of origin. 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. 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.

9) 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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

GLOSSARY

For the purposes 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 combination of governmental and non-governmental individuals and organisations that perform activities to implement the standards of the *Aquatic Code*.

AQUATIC ANIMAL HEALTH STATUS

means the status of a country, *zone* or *compartment* with respect to a *disease* in accordance with the criteria listed in the relevant disease-specific chapter or Chapter 1.4. of the *Aquatic Code*.

AQUATIC ANIMAL PRODUCTS

means non-viable *aquatic animals*, parts of *aquatic animals*, or manufactured goods containing any material derived from *aquatic animals* that are intended for sale or trade.

AQUATIC ANIMAL WASTE

means entire carcasses of *aquatic animals*, parts of *aquatic animals*, or associated liquids which are intended for disposal.

AQUATIC ANIMALS

means all viable life stages (including *eggs* and *gametes*) of fish, molluscs, crustaceans and amphibians originating from *aquaculture establishments* or from the wild.

AQUATIC CODE

means the WOAH *Aquatic Animal Health Code*.

AQUATIC MANUAL

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

BASIC BIOSECURITY CONDITIONS

means a minimum set of conditions, as described in Article 1.4.6., required to ensure *biosecurity* for a specific *disease*, in a country, *zone* or *compartment*.

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 *pathogenic agents*;

e) endocrine tissues from fish or used in fish.

BIOSECURITY

means a set of management and physical measures designed to mitigate the *risk* of introduction of *pathogenic agents* into, or spread within, or release from, *aquatic animal* populations.

BIOSECURITY PLAN

means a document that identifies potential pathways for the introduction of *pathogenic agents* into, or spread within, or release from, a *zone*, *compartment* or *aquaculture establishment* and describes the measures applied to mitigate the identified *risk*, in accordance with the recommendations in the *Aquatic Code*.

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 must be clearly documented by the *Competent Authority(ies)*.

COMPETENT AUTHORITY

means a Governmental Authority of a Member Country having the responsibility in the whole or part of the territory for the implementation of certain standards of the *Aquatic Code*.

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 *pathogenic 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 a system, as described in Article 1.4.7., which ensures the rapid recognition of signs that are suspicious of a *listed disease*, or an*emerging disease*, 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 an investigation by the *Aquatic Animal Health Services* with minimal delay.

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.

FALLOWING

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 *vectors* of a *disease* of concern, decisions on *fallowing* 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 (WOAH), located at:

12, rue de Prony, 75017 Paris, FRANCE
Telephone: 33-(0)1 44 15 18 88
Fax: 33-(0)1 42 67 09 87
Electronic mail: woah@woah.org
WWW: http://www.woah.org

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 *Veterinary Authority* informs the *Headquarters*,

b) the *Headquarters* inform the *Veterinary Authority* 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*.

PASSIVE SURVEILLANCE

means *aquatic animal* health surveillance typically based on observations of clinical or behavioural signs of *disease*, or an assessment of mortality or production data, which are generated by an *early detection system* or from other information which is available to the *Competent Authority*.

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 WOAH of its claimed status and WOAH may publish the claim but publication does not imply WOAH 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 species of *aquatic animals* that have been demonstrated as susceptible to *infection* with a specific *pathogenic agent*, in accordance with Chapter 1.5.

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.

VECTOR

means any living organism that has been demonstrated to transmit a *pathogenic agent* to *susceptible species*. *Susceptible species* are not considered as *vectors* for a specific *pathogenic agent*.

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 having the primary responsibility in the whole territory for coordinating the implementation of the standards of the *Aquatic Code* by *Competent Authorities*.

VETERINARY STATUTORY BODY

means an autonomous authority regulating *veterinarians* and veterinary paraprofessionals.

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 an area in one or more countries containing an *aquatic animal* population with a specific *aquatic animal health status* with respect to a *disease*, in which *surveillance* and control measures and *basic biosecurity conditions* are applied. The *zone* should be defined by the *Competent Authority*.

NB: MOST RECENT UPDATE ADOPTED IN 2024.

SECTION 1.

NOTIFICATION, DISEASES LISTED BY WOAH 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 Organic Statutes of the Office international des Epizooties, Member Countries shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its *territory* or *territories*.

All *notifications* and all information sent by WOAH to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to WOAH by the *Veterinary 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 WOAH, whatever information is necessary to minimise the spread of important *diseases* of *aquatic animals* and their *pathogenic agents* and to assist in achieving better worldwide 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) For the purposes of this chapter an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given *disease* that is the subject of a *notification*. An event is specific to a pathogen and strain, when appropriate, and includes all related *outbreaks* reported from the time of the immediate *notification* through to the final report. Reports of an event include *susceptible species*, number and geographical distribution of affected *aquatic animals* and *epidemiological units*.

4) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the WOAH *disease* reporting format.

5) 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.

6) 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 *quarantine* measures and restrictions applied to 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 *Veterinary Authority* shall, under the responsibility of the Delegate, send to the *Headquarters*:

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) recurrence 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;

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. For each event notified, a final report 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.

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

1) a *notification* through WAHIS or by fax or email, when an *emerging disease* event has occurred in a country, a *zone* or a *compartment*;

2) periodic reports subsequent to a *notification* of an *emerging disease* should continue:

   a) for the time necessary to have reasonable certainty that:

      i) the *disease* has been eradicated; or

      ii) the situation has become stable;

   OR

   b) until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the WOAH list as described in Chapter 1.2.;

3) a final report once requirements in point 2 a) or b) are met.

Article 1.1.5.

1) Although Member Countries are only required to notify *listed diseases* and *emerging diseases*, they are encouraged to provide WOAH with other important *aquatic animal* health information.

2) The *Headquarters* shall communicate by email or through the interface of WAHIS to *Competent Authorities* all *notifications* received as provided in Articles 1.1.2. to 1.1.4. and other relevant information.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 1.2.

CRITERIA FOR LISTING AQUATIC ANIMAL DISEASES

Article 1.2.1.

Introduction

This chapter describes the criteria for the inclusion of *diseases* in Chapter 1.3.

The objective of listing *diseases* is to support Member Countries by providing information needed to take appropriate action to prevent the transboundary spread of important *diseases* of *aquatic animals*. This is achieved by transparent, timely and consistent *notification*.

Each *listed disease* usually has a corresponding chapter that assists Member Countries in the harmonisation of *disease* detection, prevention and control, and provides standards for safe *international trade* in *aquatic animals* and *aquatic animal products*.

The requirements for *notification* are detailed in Chapter 1.1.

Principles and methods of validation of diagnostic tests are described in Chapter 1.1.2. of the *Aquatic Manual*.

Article 1.2.2.

The criteria for the inclusion of a *disease* in the WOAH list are as follows:

1) International spread of the *pathogenic agent* (via *aquatic animals*, *aquatic animal products*, *vectors* or fomites) is likely.

AND

2) At least one country may demonstrate country or *zone* freedom from the *disease* in susceptible *aquatic animals*, based on provisions of Chapter 1.4.

AND

3) A precise *case definition* is available and a reliable means of detection and *diagnosis* exists.

AND

4)

a) Natural transmission to humans has been proven, and human infection is associated with severe consequences.

OR

b) The *disease* has been shown to affect the health of cultured *aquatic animals* at the level of a country or a *zone* resulting in significant consequences e.g. production losses, morbidity or mortality at a *zone* or country level.

OR

c) The *disease* has been shown to, or scientific evidence indicates that it would affect the health of wild resulting in significant consequences e.g. morbidity or mortality at a population level, reduced productivity or ecological impacts.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 1.3.

DISEASES LISTED BY WOAH

The *diseases* in this chapter have been assessed in accordance with Chapter 1.2. and constitute the WOAH list of *aquatic animal diseases*.

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 diseases*:

– Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)
– Infection with epizootic haematopoietic necrosis virus
– Infection with *Gyrodactylus salaris*
– Infection with HPR-deleted or HPR0 infectious salmon anaemia virus
– Infection with infectious haematopoietic necrosis virus
– Infection with koi herpesvirus
– Infection with *Megalocytivirus pagrus 1*
– Infection with salmonid alphavirus
– Infection with spring viraemia of carp virus
– Infection with tilapia lake virus
– Infection with viral haemorrhagic septicaemia virus.

Article 1.3.2.

The following *diseases* of molluscs are *listed diseases*:

– 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 diseases*:

– Acute hepatopancreatic necrosis disease
– Infection with *Aphanomyces astaci* (crayfish plague)
– Infection with decapod iridescent virus 1
– Infection with *Hepatobacter penaei* (necrotising hepatopancreatitis)
– Infection with infectious hypodermal and haematopoietic necrosis virus
– Infection with infectious myonecrosis virus
– Infection with *Macrobrachium rosenbergii* nodavirus (white tail disease)
– Infection with Taura syndrome virus
– Infection with white spot syndrome virus
– Infection with yellow head virus genotype 1.

Article 1.3.4.

The following *diseases* of amphibians are *listed diseases*:

– Infection with *Batrachochytrium dendrobatidis*
– Infection with *Batrachochytrium salamandrivorans*
– Infection with *Ranavirus* species.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 1.4.

AQUATIC ANIMAL DISEASE SURVEILLANCE

Article 1.4.1.

Purpose

This chapter provides guidance on the *surveillance* approaches to be used by a *Competent Authority* to make and maintain a *self-declaration of freedom from disease* or to confirm the occurrence of a *listed disease* or an *emerging disease*.

Article 1.4.2.

Introduction and scope

This chapter supports a *Competent Authority* to meet the requirements for *self-declaration of freedom from disease* at the level of a country, *zone* or *compartment*, and for maintenance of freedom, that are presented in each disease-specific chapter. It also provides a *Competent Authority* with guidance to meet the requirements of *notification* of a *listed disease* or an *emerging disease* in accordance with Chapter 1.1.

This chapter is not intended to provide detailed technical guidance on *surveillance* design or analysis. *Competent Authorities* are encouraged to consult published literature and seek appropriate expertise to design and analyse *surveillance* programmes that meet the requirements of the *Aquatic Code*.

1) The general requirements of a *surveillance* system necessary to support a *self-declaration of freedom from disease* are specified in Articles 1.4.5. to 1.4.8.
2) The criteria that have been used to set the periods specified in each disease-specific chapter for *basic biosecurity conditions* to be in place, or for *targeted surveillance* that should be undertaken, prior to claiming freedom, are included in Articles 1.4.9. and 1.4.10.
3) The requirements for each of the four pathways for claiming freedom, and for maintaining freedom, are introduced in Article 1.4.3. and described in detail in Articles 1.4.11. to 1.4.15.
4) Guidance on the design of surveys to demonstrate freedom from *disease*, and for combining multiple sources of *surveillance* information are provided in Articles 1.4.16. and Article 1.4.17., respectively.
5) Article 1.4.18. provides guidance on diagnostic confirmation of *listed diseases* or an *emerging disease*.

Competent Authorities should refer to the relevant disease-specific chapter of the *Aquatic Manual* for recommendations on sample collection and appropriate diagnostic methods for *surveillance* and *diagnosis* of *listed diseases*. The relevant disease-specific chapter of the *Aquatic Manual* should also be consulted for the necessary information on epidemiology and diagnostic performance of assays required for *surveillance* programme design.

Article 1.4.3.

Pathways for demonstrating freedom from disease

Competent Authorities may use one of four pathways to make a *self-declaration of freedom from disease*. Each pathway outlines the *aquatic animal* health circumstances and requirements that should be met for a self-declaration to be made. Any one of these four pathways may be utilised; however, a *Competent Authority* should provide evidence that all relevant requirements to demonstrate *disease* freedom have been met as described in this chapter and the relevant disease-specific chapter of the *Aquatic Code* including when water bodies are shared with other countries or are under the control of different *Competent Authorities*. The four pathways are:

1. Absence of susceptible species

   This pathway may be utilised if, as described in Article 1.4.11., it can be demonstrated that no *susceptible species* are present at the country or *zone* level.

2. Historical freedom

This pathway may be utilised if, as described in Article 1.4.12., there is evidence of historical absence of a *disease* at the country or *zone* level, that is supported primarily by *passive surveillance* information generated by a country's *early detection system*. *Targeted surveillance* data may also be used in this pathway, where appropriate.

3. Targeted surveillance

This pathway may be utilised at the country, *zone* or *compartment* level. The pathway primarily uses *targeted surveillance* data, but other sources of evidence may be utilised as described in Article 1.4.13. *Passive surveillance* information may also be used in this pathway, where appropriate.

4. Returning to freedom

This pathway may be utilised, as described in Article 1.4.14., in circumstances where a self-declaration had been made, but free status was subsequently lost due to detection of the *disease* for a country, *zone* or *compartment*.

Table 1.1. A summary of the four pathways for *self-declaration of freedom from disease*, including the types of primary and secondary *surveillance* information, and the applicable level of application for either a country, *zone* or *compartment*.

Pathway	Primary surveillance evidence to claim disease freedom	Secondary evidence to claim freedom (if required)	Applicable level of application
1. Absence of *susceptible species*	Surveys, historical data, import records, environmental information	None	Country, *zone*
2. Historical freedom	*Passive surveillance*	*Targeted surveillance* (in populations where *passive surveillance* is not appropriate)	Country, *zone*
3. *Targeted surveillance*	*Targeted surveillance*	*Passive surveillance* (in appropriate populations)	Country, *zone*, *compartment*
4. Returning to freedom	*Targeted surveillance*	*Passive surveillance* (in appropriate populations)	Country, *zone*, *compartment*

Article 1.4.4.

Publication by WOAH of a self-declaration of freedom from disease by a Member Country

A Member Country may make a *self-declaration of freedom from disease* in a country, *zone* or *compartment*. The Member Country should inform WOAH of the claimed status for a country, *zone* or *compartment* and WOAH may publish the self-declaration.

A Member Country requesting the publication of a self-declaration should follow the Standard Operating Procedure (available on the WOAH website) for submission and provide documented information on its compliance with the relevant chapters of the *Aquatic Code*. This information should include, but is not limited to the following:

1) the scope of the declaration, i.e. the specific *disease*, the level of freedom (country, *zone* or *compartment*) and the pathway utilised to claim or return to *disease* freedom;
2) information to verify that *basic biosecurity conditions* and the requirements of *surveillance* systems have been met;
3) details of the *surveillance* design and assumptions;
4) the *surveillance* analysis and results;
5) the measures implemented to maintain freedom.

The *self-declaration of freedom* will be published only after all the information provided has been received and administrative and technical screening has been performed by WOAH, with a satisfactory outcome. Publication does not however, imply endorsement of the claim of freedom by WOAH and does not reflect the official opinion of WOAH. Responsibility for the accuracy of the information contained in a self-declaration lies entirely with the WOAH Delegate of the Member Country concerned.

An *outbreak* in a Member Country, a *zone* or a *compartment* having a self-declared free status results in the loss of the self-declared free status. The notification of an *outbreak* in a country, *zone* or *compartment* for which a *self-declaration of freedom* has been made, will result in an update of the WOAH website concerning the original declaration. A

Member Country wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this chapter.

Article 1.4.5.

Biosecurity and surveillance system requirements

The following *biosecurity* and *surveillance* system requirements should be met for any *self-declaration of freedom from disease* in the given country, *zone* or *compartment*:

1) the quality of *Aquatic Animal Health Services* can be substantiated to meet the requirements of Chapter 3.1.;
2) *basic biosecurity conditions* (which include an *early detection system*) as described in Article 1.4.6. are in place;
3) there has been no vaccination of susceptible *aquatic animals* for the specific *disease* from the implementation of the *basic biosecurity conditions* prior to self-declaration;
4) the *Aquatic Animal Health Services* have sufficient capacity and expertise to investigate and report *disease* events to a *Competent Authority*;
5) a *Competent Authority* has access to appropriate diagnostic capability (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed diseases* and *emerging diseases* in accordance with Article 1.4.18.

Article 1.4.6.

Basic biosecurity conditions

Basic biosecurity conditions include requirements for preventing the introduction and spread of a specific *disease* and for detection of the *disease* should it occur. The requirements for *basic biosecurity conditions* include:

1) an *early detection system* (as described in Article 1.4.7.);
2) measures to prevent the introduction of the *pathogenic agent* into a country, *zone* or *compartment*, or the spread within or from *infected zones* and *protection zones*, in accordance with the relevant disease-specific chapter.

In making a self-declaration of freedom from a specific *disease* for a country, *zone* or *compartment*, a *Competent Authority* should describe how all of the requirements for *basic biosecurity conditions* relevant to its declaration, are continuously met.

Article 1.4.7.

Early detection system

The *early detection system* of a *Competent Authority* is important to generate evidence for claims of *disease* freedom and to provide assurance that a change in *disease* status would be rapidly discovered.

A *self-declaration of freedom from disease* needs to document that the *early detection system* fulfils each of the requirements below:

1) observers (e.g. the personnel of *aquaculture establishments*, processors, transportation services) have broad awareness of the characteristic signs of *listed diseases* and *emerging diseases*;
2) *veterinarians* and *aquatic animal health professionals* are trained in recognising and reporting suspicion of *listed disease* and *emerging disease* occurrence;
3) the *Aquatic Animal Health Services* have capacity to undertake rapid and effective *disease* investigation based on a national chain of command led by a *Competent Authority*;
4) the *Aquatic Animal Health Services* have access to sufficient diagnostic capability (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed diseases* and the capacity and expertise to investigate *emerging diseases* as described in Article 1.4.18.;
5) *veterinarians*, *aquatic animal health professionals* and others with an occupational role with *aquatic animals* have a legal obligation to report suspicion of the occurrence of *listed diseases* or *emerging diseases* to a *Competent Authority*.

The sensitivity of an *early detection system* is the likelihood that the *disease* will be detected if present. Of fundamental importance is *disease* reporting by farmers, *aquatic animal health professionals*, *veterinarians* and others to initiate the

necessary steps of *passive surveillance*. Specifically, a *Competent Authority* should be able to demonstrate that efforts have been made to make relevant observers (e.g. farmers and fishers) aware of signs of *listed diseases* and *emerging diseases*, and secondly the obligation of farmers, *aquatic animal health professionals*, *veterinarians* and others with an occupational role with *aquatic animals* to report suspicion. The underpinning legal instruments should be cited.

The capacity of the *Aquatic Animal Health Services* to respond to suspicion of a *listed disease* can be evidenced by response plans, and a descriptive chain of command that will result in an official declaration that the *pathogenic agent* has been detected. Standard operating procedures for diagnostic assays for *listed diseases* and accreditation to internationally recognised laboratory standards can demonstrate the capacity of the *Aquatic Animal Health Services* to detect *listed diseases*. In addition, the effective functioning of the *early detection system* is best illustrated through examples of investigations in response to reported suspicion of *disease*. The sensitivity of an *early detection system* (i.e. the likelihood of *pathogenic agent* detection following introduction) can be quantified, for example, by use of a scenario tree model; however, in most circumstances a qualitative assessment will be sufficient.

Article 1.4.8.

Requirements for passive surveillance

In addition to the characteristics of an *early detection system* described in Article 1.4.7., the conditions described in this article should be met for *passive surveillance* information to be utilised for a *self-declaration of freedom from disease*.

1) The conditions, which apply to each defined *study population* of *susceptible species* of a specific *disease*, are that:

    a) conditions (biotic and abiotic) are conducive to clinical expression of the *infection*, such that if the *pathogenic agent* were present within the population of *susceptible species*, it would produce signs of the *disease* at least seasonally;

    b) observation of signs of the *disease*, which may include increased mortality, would lead to investigation and, where appropriate, reporting to a *Competent Authority*;

    c) populations of susceptible farmed *aquatic animals* should be under sufficient observation, such that, if signs of the *disease* were to occur, they would be observed;

    d) for populations of susceptible wild *aquatic animals*, they should:

        i) be under sufficient observation, such that if signs of the *disease* were to occur, they would be observed and reported, or

        ii) be epidemiologically linked to farmed populations, such that if the *disease* were to occur in wild *aquatic animal* populations it would be observed and reported in adjacent farmed populations.

2) *Passive surveillance* depends primarily on observers (e.g. farmers, *aquatic animal health professionals*, *veterinarians* and others) recognizing signs of *disease* that are suspicious of a *listed disease* or unexplained increased mortality and reporting them to a *Competent Authority*. For wild populations, the requirements of points 1a), b) and d) may not be met under most circumstances and, therefore, *passive surveillance* will be insufficiently sensitive. If a *Competent Authority* utilises *passive surveillance* information for defined populations of wild *aquatic animals*, it should demonstrate that the conditions of this article have been met, and that the *early detection system* will result in detection of the *disease* should it occur.

3) Awareness of signs of *disease* and the necessary level of observation is best demonstrated through examples of reporting by farmers, *aquatic animal health professionals*, *veterinarians* and others to a *Competent Authority*. In addition to reporting, information for *passive surveillance* may originate from inspections at processing plants, routine visits by government officials and surveys (e.g. fisheries and aquatic fauna surveys), submissions to laboratories, *aquaculture establishment* records (e.g. mortality, medicine use, etc.).

4) Evidence from published literature will generally be sufficient to demonstrate the environmental conditions in which *infection* of *susceptible species* will result in clinical signs. This information should be supplemented with data on the environmental conditions for the *target populations*.

5) *Passive surveillance* only contributes to the *early detection system* if observations and investigations that lead to suspicion of *listed diseases* or *emerging diseases* are rapidly reported, to allow a *Competent Authority* to undertake their own investigation.

Article 1.4.9.

Required periods for basic biosecurity conditions

1) Prior to a Member Country making a *self-declaration of freedom from disease*, *basic biosecurity conditions* should be in place for a sufficient duration, so that, by the end of the period, should the *disease* have been introduced before the *basic biosecurity conditions* began:
   a) the specific *pathogenic agent* would not remain present in the environment (see pathway 1 – absence of *susceptible species*); or
   b) the *disease* would manifest clinically and be detected by the country's *early detection system*(see pathway 2 – historical freedom); or
   c) by the time *targeted surveillance* commenced (see pathway 3 – *Targeted surveillance*), *infection* levels would have reached the minimum *prevalence* estimate (i.e. the design *prevalence*) used in the survey design to calculate the sample sizes (e.g. number of *aquaculture establishments* and *aquatic animals* needed to demonstrate freedom).
2) Each disease-specific chapter of the *Aquatic Code* includes minimum periods that *basic biosecurity conditions* should be in place prior to a *self-declaration of freedom*. These periods reference a default minimum period or a longer period if determined necessary based on the factors described below:
   a) For pathway 1, the default minimum period of *basic biosecurity conditions* required prior to a self-declaration, for all *listed diseases*, is six months. It is expected that this period will be sufficient for most *diseases* to ensure that no viable *pathogenic agent* introduced via *aquatic animal commodities* has remained present in the environment, and the *early detection system* was well established and demonstrated to be functioning. The required period that *basic biosecurity conditions* should be in place prior to making a self-declaration, using this pathway, is determined for each *listed disease* based on its epidemiology (e.g. agent stability in the environment, presence of resistant life stages, *vectors*), and a period longer than the default minimum may be specified in the relevant disease-specific chapter of the *Aquatic Code*.
   b) For pathway 2, the default minimum period of *basic biosecurity conditions* required prior to a self-declaration, for all *listed diseases*, is ten years. This period is the minimum required to achieve 95% likelihood of freedom if the annual likelihood of detection is approximately 30%. However, if the average annual likelihood of detection is considered to be less than 30% (following consideration of the factors below), the minimum period required for *basic biosecurity conditions* defined in the relevant disease-specific chapter of the *Aquatic Code* will be set to a period longer than ten years, as appropriate. An evaluation of the following factors will determine whether a period longer than ten years is recommended in the disease-specific chapters:
      i) the maximum duration of the production cycle for the *susceptible species*;
      ii) the life stages at which *aquatic animals* are susceptible;
      iii) the variation in predilection to clinical *disease* among *susceptible species*;
      iv) the expected severity and duration of clinical signs in the *susceptible species*;
      v) environmental conditions that influence levels of *infection* and clinical expression, including seasonality of the *disease* (i.e. periods of the year when *prevalence* and intensity of *infection* are highest and most conducive to detection);
      vi) factors specific to the *pathogenic agent* (e.g. production of spores);
      vii) production systems and management practices that would affect observation of clinical signs if they were to occur;
      viii) any other relevant factors that may influence presentation of clinical signs and observation of the *disease* should it be present.
   c) For pathway 3, the default minimum period of *basic biosecurity conditions* required prior to commencement of *targeted surveillance* will be one year. It is expected that this period will be sufficient under most circumstances for a *disease* to reach a *prevalence* sufficiently high to be detected by a survey designed in accordance with the recommendations of this chapter. However, the epidemiology of a *disease* and nature of production systems may limit the increase in *prevalence* and intensity of *infection* in the *susceptible species* following introduction of the *disease*. In these instances, the minimum period required for *basic biosecurity conditions* defined in the relevant disease-specific chapter of the *Aquatic Code* will be set to a period longer than one year, as appropriate. An evaluation of the following factors will determine whether a period longer than one year is required:
      i) the maximum duration of the production cycle for the *susceptible species*;
      ii) the life stages at which *aquatic animals* are susceptible;
      iii) seasonality of the *disease* (periods of the year when *prevalence* and intensity of *infection* is highest and most conducive to detection);
      iv) production systems and management practices that would affect occurrence of *infection*;

v) any other relevant factors that may influence the expected rate of increase in *prevalence* and intensity of *infection* in *susceptible species* following introduction of the *disease*.

d) Pathway 4 is only applicable following the loss of *disease* freedom due to a *disease outbreak*. This circumstance implies a failure of *basic biosecurity conditions* to prevent the introduction of the *disease*. The pathway of *disease* introduction should be investigated and *basic biosecurity conditions* should be reviewed and modified as necessary to reduce the likelihood of *disease* introduction by the same or similar routes. Mitigation measures should be implemented following eradication of the *disease*, and prior to commencement of any *targeted surveillance* that will be utilised as evidence for a subsequent self-declaration.

Article 1.4.10.

Required periods for targeted surveillance

Prior to a *Competent Authority* making a *self-declaration of freedom from disease* utilising pathway 3 or pathway 4, *targeted surveillance* should be conducted for a defined period, as described in the relevant disease-specific chapter of the *Aquatic Code*. The period of *targeted surveillance* is determined for each disease-specific chapter of the *Aquatic Code*, based on the factors described below:

1) the maximum duration of the production cycle for the *susceptible species*;

2) the life stages at which *aquatic animals* are susceptible;

3) seasonality of the *disease* (periods of the year when *prevalence* and intensity of *infection* is highest and most conducive to detection);

4) production systems and management practices that would affect the seasonal occurrence of *infection*.

For a country or *zone*, the minimum default period for which *targeted surveillance* should occur prior to a *self-declaration of freedom* is two years. During the period of *targeted surveillance*, surveys should occur during defined time periods when conditions are optimal for detection of the *pathogenic agent* (e.g. seasons, temperatures, and life stages). All populations of *susceptible species* in the country or *zone* should be considered in the design of each survey (i.e. included in the sampling frame). Populations with higher likelihood of *infection* can be preferentially sampled. Article 3.1. of the relevant disease-specific chapter of the *Aquatic Manual* should be used to inform sampling. There should be a gap of at least three months between surveys and, if there are breaks in production, the surveys should also ideally span two production cycles.

For a country or *zone* to regain freedom in accordance with pathway 4, the required period of *targeted surveillance* specified in the disease-specific chapter of the *Aquatic Code* will be consistent with the original self-declaration of freedom.

For *compartments*, the minimum default period that *targeted surveillance* should occur prior to a *self-declaration of freedom from disease* is one year. This shorter period for a *compartment* reflects the more clearly defined populations, the *biosecurity* required to maintain its population's health status and a likely narrower variation in environmental variables. However, a different period (more than one year) may be stipulated in the disease-specific chapter of the *Aquatic Code* if warranted by the epidemiology of the *disease* and the criteria proposed above. For example, different requirements may be appropriate where *susceptible species* have a three-year production cycle, versus one that has a six-month production cycle; particularly if the *disease* is likely to occur at a very low *prevalence* until near the end of the production cycle.

For *compartments* to regain freedom in accordance with pathway 4, the required period of *targeted surveillance* specified in the disease-specific chapter of the *Aquatic Code* may be less than the original declaration of freedom (dependent on the nature of the specific *disease* and as specified in the relevant disease-specific chapter). However, at least one survey in the *compartment* is required to demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective.

Article 1.4.11.

Pathway 1 – Absence of susceptible species

Unless otherwise specified in the relevant disease-specific chapter of the *Aquatic Code*, a self-declaration of freedom from a specific *disease* may be made for a country or *zone* without applying *targeted surveillance* if there are no *susceptible species* (as listed in Article X.X.2. of the relevant disease-specific chapter of the *Aquatic Code*) present in that country or *zone*.

Basic biosecurity conditions should be in place for a period of time prior to a *self-declaration of freedom from disease*.

This pathway relies on confidence that *susceptible species* are in fact absent from a country or *zone*. To be confident that *susceptible species* are absent there should be:

1) sound knowledge of the range of *susceptible species* of a *pathogenic agent*; and

2) sufficient knowledge, of the local *aquatic animal* fauna (including wild populations) demonstrated by the following forms of evidence:

    a) reports which provide evidence regarding the absence of the *susceptible species* in the country or *zone* from structured surveys (e.g. of fisheries and aquatic fauna surveys, historical fisheries data);

    b) documentation from the relevant *Competent Authority* showing that those *susceptible species* have not been imported into the country or *zone*;

    c) provision of documentation which sets out scientific evidence indicating that the likelihood of the presence of *susceptible species* in the country or *zone* is negligible (e.g. data on physiological requirements, oceanographic information, biodiversity databases).

This pathway cannot be used for *diseases* where there is uncertainty regarding the full range of *susceptible species* (e.g. *diseases* with a broad host range), or where the *pathogenic agent* may not be obligate (e.g. able to survive indefinitely outside the host). In these cases, the pathway will be absent from the relevant disease-specific chapter of the *Aquatic Code*, and alternative pathways to demonstrate freedom should be utilised.

The pathway is intended primarily to be used by a *Competent Authority* wishing to establish freedom ahead of farming a new species.

Article 1.4.12.

Pathway 2 – Historical freedom

Unless otherwise specified in the relevant disease-specific chapter of the *Aquatic Code*, a *self-declaration of freedom from disease* may be made for a country or *zone* on the basis of historical freedom. The primary evidence for historical freedom is *passive surveillance* information generated by a country's *early detection system*. For this pathway to be utilised, the following conditions should be met:

1) the country or *zone* has *basic biosecurity conditions* in place, including an *early detection system*, that is sufficiently sensitive to detect the *disease* should it occur, and the requirements for *basic biosecurity conditions* of Article 1.4.6., *early detection system* of Article 1.4.7. and *passive surveillance* of Article 1.4.8. are met;

2) the *disease* has not been reported in the country or *zone* (including in wild *aquatic animal* populations) for the minimum period specified in the relevant disease-specific chapter of the *Aquatic Code*.

Requirements for passive surveillance

A *Competent Authority* making a *self-declaration of freedom from disease* on the basis of historical freedom will need to provide an explanation of how the criteria (i.e. for *basic biosecurity conditions*) presented for this pathway have been met. Specifically, a *Competent Authority* needs to provide evidence that its *early detection system* meets the conditions described in Article 1.4.7. and the requirements for *passive surveillance* in Article 1.4.8. The *early detection system* needs to represent all the *susceptible species* populations in the country or *zone*. If a *Competent Authority* cannot demonstrate that the required characteristics are fulfilled, due to a country's circumstances (e.g. nature of the *early detection system*, environmental conditions, nature of the *aquaculture*), this pathway is not considered valid. Instead, an alternative pathway that utilises *targeted surveillance* data will be required, or the *passive surveillance* information will need to be supplemented with *targeted surveillance* data (see below).

Need for targeted surveillance

If the requirements for *passive surveillance* specified in points 1 and 2 above would not be met for some defined populations of *susceptible species* (e.g. for wild populations), *targeted surveillance* may be used to provide additional evidence of freedom for those populations. Pathway 2 should only be utilised as the basis of a *self-declaration of freedom from disease*, if it is based primarily on *passive surveillance* information to demonstrate historical freedom; alternatively, pathway 3, as described in Article 1.4.13., should be used.

Article 1.4.13.

Pathway 3 – Targeted surveillance

As specified in the relevant disease-specific chapter of the *Aquatic Code*, a *self-declaration of freedom from disease* may be made for a country, a *zone* or a *compartment* where the primary evidence for freedom is *targeted surveillance* data. For this pathway to be utilised, the following conditions should be met:

1) prior to the commencement of *targeted surveillance*, *basic biosecurity conditions* have been in place for a default minimum period as specified in the relevant disease-specific chapter of the *Aquatic Code*;

2) the *disease* has not been reported in the country, *zone* or *compartment*, despite *targeted surveillance* that has been conducted for a period as specified in the relevant disease-specific chapter of the *Aquatic Code*, and in accordance with the requirements below.

Requirements for targeted surveillance

For many *diseases*, there will be significant temporal variability in the *prevalence* and intensity of *infection* (and therefore likelihood of detection by *targeted surveillance*). For example, the likelihood of detection may be greatest for a particular life stage, or during periods of the year when *pathogenic agent* replication and transmission are at their highest.

Environmental variability from one year to another may also result in differences in *prevalence* and intensity between years that could affect likelihood of detection. Surveys should therefore be designed to account for such variability and sample populations in a manner to maximise the likelihood of detecting a *disease* should it occur. This may require targeting temporal windows such that sampling can only take place during limited periods within a single year. Based on an assessment of potential pathways of introduction of the *diseases*, high risk regions or *aquaculture establishments* should be identified and preferentially included in the *surveillance* programmes. For example, establishments near ports or processing facilities may have higher likelihood of exposure to introduced *pathogenic agents*.

To maximise the likelihood of *pathogenic agent* detection, surveys should select species and life stages most likely to be infected and take place at times of the year when temperature and season offer the best opportunity for detection. At least two surveys per year (for at least two consecutive years – the default minimum period) need to be conducted three or more months apart to declare freedom unless disease-specific evidence supports an alternative strategy. In situations where seasonal conditions do not permit a gap of at least three months between surveys, the maximum possible time gap should be allowed to elapse between one survey and the next.

Over the period of *targeted surveillance*, the combined number of *aquaculture establishments* and *aquatic animals* sampled should be sufficient to generate at least 95% confidence that the *pathogenic agent* would be detected if present at or above the design *prevalence* in the country, *zone* or *compartment*. Design *prevalence* at the animal and higher levels of aggregation (i.e. pond, *aquaculture establishment*, village, etc.) should be set to a maximum of 2% (a higher design *prevalence* can only be used if justified by epidemiological evidence as described in Article 1.4.16.). Surveys should be designed in accordance with the recommendations provided in Article 1.4.16.

Other sources of data

This pathway to *disease* freedom should be based primarily on the results of *targeted surveillance*. However, the submission may also include an analysis of the *passive surveillance* information to provide supplemental evidence. This evidence may be used for defined populations of *susceptible species* where *passive surveillance* is demonstrated to be sufficiently sensitive (as described in Article 1.4.8.).

Article 1.4.14.

Pathway 4 – Returning to freedom

As specified in the relevant disease-specific chapter of the *Aquatic Code*, a *self-declaration of freedom from disease* may be made for a country, a *zone* or a *compartment* for which a self-declaration had previously been made, but subsequently lost due to an *outbreak* of the *disease*.

For a country or a *zone*, the default minimum period of *surveillance* to regain freedom is consistent with the requirements for pathway 3. However, a self-declaration of freedom can be made sooner if the relevant *Competent Authority* can demonstrate that the approach would provide an appropriate standard of evidence for the circumstances of the *outbreak* and the *disease*.

Compartments are able to return to freedom relatively rapidly; however, a minimum period of time is required as specified in each disease-specific chapter of the *Aquatic Code* to demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective.

For a country, *zone* or *compartment*, a self-declaration utilising this pathway should provide information on the process employed to review and update *basic biosecurity conditions*. This information should also address the outcomes of the review and any relevant *sanitary measures* implemented to strengthen *basic biosecurity conditions*.

1. Infected zone and protection zone

Infected zones and *protection zones* should be established through exposure contact tracing from known infected *aquaculture establishments* (e.g. by following movements of *aquatic animals* or equipment to and from infected establishments) to identify all known infected establishments. Once contact tracing is complete and no new cases are being reported or detected through tracing, the boundaries of *infected zones* and *protection zones* can be finalised. The geographic extent of an *infected zone* should be based on the spatial distributions of infected and non-infected establishments within a region (e.g. river, estuary or bay). The *zone* should be defined to encompass geographically clustered infected populations.

The geographic extent of a *protection zone* needs to provide a very high level of confidence that measures implemented within the *zone* will prevent spread from the *zone* and should be based on the epidemiology of the transmissible *pathogenic agent*, the potential for exposure of neighbouring *aquaculture establishments*, the type of aquaculture production systems (e.g. open or closed systems), the influence of wild populations, and the local hydrology. In the marine environment, local hydrology (including tidal excursion), the distribution of suitable habitats for *susceptible species* and the movement of wild *susceptible species* or *vectors* should be considered. In the freshwater environment, the boundaries of the *protection zone* should be informed by the distance downstream that viable *pathogenic agent* is likely to spread on currents. If susceptible wild populations or *vectors* are present, their migratory patterns and ranges should be used.

Once *infected zones* and *protection zones* have been established, and no new cases have been detected for a period equal to or greater than the incubation period of the *pathogenic agent* (but no shorter than one month), the region outside of the *infected zones* and *protection zones* can be declared a *disease free zone*. Re-establishing *disease* freedom in the *infected zones* and *protection zones* requires *targeted surveillance*.

2. Requirements for targeted surveillance in a country or zone

Once all infected populations have been depopulated and affected *aquaculture establishments* have been disinfected, as described in Chapter 4.4., and synchronously fallowed as described in Chapter 4.7., for a period determined by the biophysical properties of the *pathogenic agent* (i.e. survival in the environment), a *surveillance* programme within the *protection zones* and *infected zones* should commence. The programme should include both farmed and wild populations of *susceptible species* in the *protection zones* and *infected zones*. A *risk*-based approach to the design of the survey is recommended (as described in Article 1.4.6.). The following *aquaculture establishments* or populations should be preferentially selected for sampling:

a) establishments which have been restocked following depopulation;

b) establishments and wild populations at greatest *risk* of exposure to *infection* during the *outbreak*, i.e. in close hydrographical proximity to infected establishments or with other epidemiological contacts such as sharing equipment or movements of *aquatic animals*;

c) wild populations of *susceptible species* downstream or in the immediate vicinity of previously infected establishments.

It is recommended that at least two negative surveys are conducted prior to reclaiming freedom. The second survey should start at least three months after completion of the first survey. Surveys should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. If there are breaks in production, the surveys should also ideally span two production cycles. The number of *aquaculture establishments* and the samples taken per establishment in each survey should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected if present above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence). If *disease* is detected in wild populations of *susceptible species* and eradication is not possible, the country or *zone* remains infected.

3. Requirements for targeted surveillance in a compartment

Once the infected populations have been depopulated and affected *aquaculture establishments* disinfected, as described in Chapter 4.4. and fallowed as described in Chapter 4.7., for a period determined by the biophysical properties of the *pathogenic agent* (i.e. survival in the environment), the *compartment* can be restocked. A single survey is required following restocking to demonstrate that eradication has been successful. The survey should be undertaken at least sixth months, or at the maximum length of time allowed by the production cycle of species, after the *aquaculture establishment* has been restocked to ensure that the reviewed *basic biosecurity conditions* are effective. The survey should take place during optimum seasons, temperatures, and priority life stages to optimise

pathogenic agent detection. The number of holding *units* (e.g. ponds, tanks) and the animals per holding *unit* sampled should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

Article 1.4.15.

Maintenance of disease free status

A country, *zone* or *compartment* that is declared free may maintain its free status provided that the *biosecurity* and *surveillance* requirements described in Article 1.4.5. are continuously maintained and the following requirements are met, as relevant:

1) For a country or *zone* with shared water bodies extending across the *territory* of other countries, free status can only be maintained if the requirements to maintain freedom are in place across all epidemiologically linked shared water bodies.

2) A country, *zone* or *compartment* declared free may maintain its free status without *targeted surveillance* provided that the requirements for *passive surveillance* in Article 1.4.8. are met for the entire country, *zone* or *compartment*, and in the case of:

   a) a declared free *zone*, the *zone* occurs within the *territory* of a country declared free;

   b) a declared free *compartment*, the *compartment* occurs within the *territory* of a country declared free.

3) If the conditions of point 2 are not met, ongoing *targeted surveillance* for the *pathogenic agent*, as described in Article 1.4.16., is required at a level determined by a *Competent Authority*, to generate an annual 95% confidence of detection, taking into account the likelihood of *infection*.

4) *Competent Authorities* should ensure prompt investigation of any health events or other information that may raise suspicion of the occurrence of a *listed disease* from which a country, *zone* or *compartment* has been declared free. The investigation should be undertaken in accordance with Article 1.4.18. and the requirements of Chapters 1.1. and 5.1. should be met at all times.

Article 1.4.16.

Design of surveys to demonstrate freedom from disease

Surveys to demonstrate freedom from a specified *disease* (i.e. *targeted surveillance*) are required for pathway 3 as described in Article 1.4.13. to achieve a *disease* free status, and to regain a *disease* free status following detection of the *pathogenic agent* as described in Article 1.4.14. and to maintain *disease* freedom. Surveys may be required to supplement *passive surveillance* information generated by the *early detection system* required for pathway 2 as described in Article 1.4.12. In addition, where conditions are not conducive to clinical expression of *disease*, and, therefore, the *early detection system* cannot provide evidence for the maintenance of freedom, ongoing *targeted surveillance* is required.

It is not possible to provide absolute certainty of the absence of *disease*. Surveys can demonstrate freedom from *disease* by generating evidence that a *disease* is not present in a population at or above a predetermined *prevalence* (the design *prevalence*) and to an acceptable level of confidence. Apparent *disease* at any level in the *target population* automatically invalidates any freedom from *disease* claim, unless, on the basis of further testing, positive test results are accepted as false positives. A survey to demonstrate freedom from *disease* should meet the following requirements set out in this article:

1. Population

   The population of *epidemiological units* should be clearly defined. *Aquaculture establishments* and holding *units* (e.g. ponds, tanks) within establishments are the most commonly used *epidemiological unit* in surveys to demonstrate *disease* freedom. It is, therefore, important that *Competent Authorities* should keep registries of *aquaculture establishments*, which include geographic location and species held.

   The *target population* consists of all individuals within the selected population of *susceptible species* to the *disease* in a country, *zone* or *compartment*, to which the *surveillance* results apply. *Disease* introduction may be more likely

to occur in some components of the *target population* than others. In these cases, it is advisable to focus *surveillance* efforts on this part of the population.

The design of the survey will depend on the size and structure of the population being studied. If the population can be considered to be homogenous with regards to likelihood of exposure, a single-stage survey can be used.

Farmed *aquatic animals* are not individually identified and usually kept in holding *units* (e.g. ponds, tanks) which can lead to clusters of *infection* within *aquaculture establishments*. Similarly, wild *aquatic animal* populations are not evenly distributed within a *zone*. For these reasons, multi-stage sampling is recommended. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. *aquaculture establishments* or villages) are selected. At the second stage, animals are selected for testing from each of the first-stage sampling groups.

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

2. Dossier of evidence

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.

3. Statistical methodology

The analysis and interpretation 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 diagnostic *sensitivity* and *specificity* of the test or test system;

c) the design *prevalence* (or *prevalences* where a multi-stage design is used).

Analysis of data for evidence of freedom from *disease* involves estimating the probability (alpha) that the evidence observed (i.e. negative results for *disease* detection from *surveillance*) could have been produced assuming that *infection* is present in the population at or above the minimum specified *prevalence* (the design *prevalence*). The confidence in (or, equivalently, the *sensitivity* of) the survey 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 (that the survey would detect *infection* if *infection* were present at or above the specified level) should be equal to or greater than 95%.

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

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 similar populations, and epidemiology of the *disease*.

The values for design *prevalence* used in calculations should be based on the epidemiology of the *disease*. Justification for the selection of design *prevalence* values should be provided, and should be based on the following recommendations:

a) At the individual animal level (e.g. *prevalence* of infected animals in a pond, tank or net pen, or cages), the design *prevalence* is based on the epidemiology 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. A suitable design *prevalence* value at the animal level may be:

   i) between 1% and 5% for *infections* that are present in a small part of the population, e.g. are transmitted slowly or have been recently introduced, etc.;

   ii) over 5% for highly transmissible and persistent *infections*;

   iii) 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*.

b) At higher levels (e.g. net pen or cage, pond, *aquaculture establishments*, village, etc.) the design *prevalence* should be based on empirical evidence and reflect the expected behaviour of the *infection*. A higher establishment-level design *prevalence* can be used for *diseases* which spread rapidly between pens or cages, and establishments. *Diseases* which are transient or less contagious require lower design *prevalences*:

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

4. Risk-based sampling

Risk-based sampling is an approach to identify and sample populations that have the greatest likelihood of *infection*. It can be applied to the design of surveys to demonstrate freedom from *disease* for a country, *zone* or *compartment*. A key advantage of *risk*-based sampling is that it can improve the efficiency of *surveillance* to demonstrate freedom from *disease* compared to random sampling approaches.

Risk-based sampling requires the identification of *risk* factors that are applied to *bias* sample collection to populations of *aquatic animals* considered most likely to be infected if the specific *disease* had been introduced and had established. Where *risk*-based sampling is used for demonstration of freedom, the *risk* factors that underpin survey design, and the evidence or assumptions for their selection, should be documented. Where existing *risk assessments* are available, these may be utilised to identify *risk* factors associated with *disease* introduction, exposure and establishment. The identification of appropriate *risk* factors may include consideration of:

a) the possible pathways of *disease* introduction (e.g. through *aquatic animals*, *aquatic animal products*, *feed*, fomites, *vectors* and water);

b) proximity of susceptible populations to sources of *disease* exposure (e.g. to *aquatic animal* processing facilities, or ports);

c) environmental or husbandry conditions that are permissive for *disease* establishment (e.g. temperature, salinity, production system type, habitat type, exposure to recent stressors);

d) conditions that are conducive for development of clinical *disease*; including the species or life stages that are most susceptible to clinical *disease*;

e) evidence of morbidity or mortality.

5. Test characteristics

All *surveillance* involves performing one or more tests for evidence of the presence of current or past *infection*, ranging from laboratory assays to farmer observations. The performance level of a test is described in terms of its diagnostic *sensitivity* and *specificity*. Imperfect *sensitivity* 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 diagnostic *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. Samples that test positive should be confirmed or refuted using a second highly specific test. Where more than one test is used (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. Information on test characteristics provided in the relevant disease-specific chapter of the *Aquatic Manual* should be used unless more appropriate information is available. The estimate of test *sensitivity* when the test was used in apparently healthy *aquatic animals* should be used. Samples should not be pooled before testing, unless approved in the relevant disease-specific chapter of the *Aquatic Manual*. If 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.

6. Sample size

In surveys conducted to demonstrate the absence or presence of an *infection*, 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:

a) the *sensitivity* and *specificity* of the diagnostic test,

b) the design *prevalence* (or *prevalences* where a multi-stage design is used),

c) 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):

a) the size of the population (but it is acceptable to assume that the population is infinitely large),

b) the desired power of the survey.

Software for the calculation of sample sizes at varying parameter values are available. Table 1.2. 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 *infection* at a design *prevalence* of 2%, provided that all efforts are made to ensure that all presumed false positives are indeed false (i.e. by use of a second highly specific assay). This means that there is a 95% confidence that the *prevalence* is 2% or lower, which

reflects the fact that false negative results can occur. Incorrectly concluding that a population is free can be reduced by increasing the sample size and using more than one assay but cannot be completely eliminated.

In the case in which the values of *sensitivity* and *specificity* are not known (e.g. no information is available in the relevant disease-specific chapter of 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.

7. Multi-stage structured survey design

In general, a survey to demonstrate freedom at *zone* or country level should use a multi-stage design. The first sampling level is often *aquaculture establishments* (or villages) or populations of wild *susceptible species*, and the second stage may be ponds or individual animals within the establishment (or village) or defined stocks within a wild population. At each level, design levels need to be set and sample sizes calculated.

8. 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.

Table 1.2. Sample sizes for different design *prevalences* and test characteristics.

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

Design prevalence (%)	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false positive if the population is free
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

Article 1.4.17.

Combining multiple sources of information

Pathway 1 to achieving *disease* freedom (absence of *susceptible species*) relies on a range of data sources. Pathway 2 to achieving *disease* freedom (historical freedom) will primarily use evidence from *passive surveillance*, which may come from multiple sources (as described in Article 1.4.8.) and may be supplemented with *targeted surveillance* if necessary (as described in Article 1.4.12.). *Passive surveillance* information can also be used to provide additional support for *disease* freedom, based on *targeted surveillance* (i.e. pathway 3). Estimates of the confidence in each data source may be combined to provide an overall level of confidence of freedom from *disease* for the combined data sources. The methodology used to combine the estimates from multiple data sources:

1) should be scientifically valid and fully documented, including references to published material; and

2) should, where possible, take into account any lack of statistical independence between different data sources.

If combining evidence from different sources including *passive surveillance* and *targeted surveillance*, a *Competent Authority* may choose to use various approaches, such as a scenario tree modelling approach.

Article 1.4.18.

Diagnostic confirmation of a listed disease or an emerging disease

A *Competent Authority* is required to provide *disease notifications* as described in Chapter 1.1.

The relevant disease-specific chapter of the *Aquatic Manual* provides recommendations for the appropriate diagnostic methods for presumptive and confirmatory diagnostic purposes. The assays recommended for these purposes are presented in Table 4.1 of the relevant disease-specific chapter of the *Aquatic Manual*.

The recommended standards of diagnostic evidence to confirm *infection* in either apparently healthy or clinically diseased animals are provided in Section 6 of the relevant disease-specific chapter of the *Aquatic Manual*. These case definitions for suspect and confirmed cases have been developed to support decision making in relation to trade and for confirmation of *disease* status at the level of a country, *zone* or *compartment*. A *Competent Authority* may choose to apply a lower standard of evidence for *disease* confirmation within its *territory* for known endemic *diseases*.

If standards of evidence are not met to confirm a suspect case of *disease* in accordance with the case definitions in Section 6 of the relevant disease-specific chapter of the *Aquatic Manual*, ongoing investigation is required until sufficient evidence is obtained to either:

1) exclude the presence of a *listed disease* or an *emerging disease*; or

2) to confirm the presence of a *listed disease* or an *emerging disease*.

If a Member Country does not have access to a laboratory with the capability to undertake the necessary diagnostic tests and which meets the requirements of Chapter 1.1.1. of the *Aquatic Manual* it should seek advice from the relevant WOAH Reference Laboratory.

In all circumstances, Member Countries should comply with the requirements described in Chapter 1.1. to provide transparent and timely *notifications* to allow Member Countries to take appropriate action to prevent the transboundary spread of important *diseases* of *aquatic animals*.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2022.

CHAPTER 1.5.

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

Article 1.5.1.

Purpose

In each disease-specific chapter, Article X.X.2. lists the *aquatic animal* species that have been found to be susceptible to *infection* with the relevant *pathogenic agent*. The recommendations of each disease-specific chapter apply only to the species listed in Article X.X.2.

The purpose of this chapter is to provide criteria for determining which species are listed as susceptible in Article X.X.2. of each disease-specific chapter in the *Aquatic Code*.

Article 1.5.2.

Scope

Species of *aquatic animals* are considered susceptible to *infection* with a *pathogenic agent* when the presence of a multiplying or developing *pathogenic agent* has been demonstrated by the occurrence of natural *cases* or by experimental exposure that mimics natural transmission pathways. Susceptibility includes clinical or non-clinical *infection*.

The decision to list an individual species as susceptible in a disease-specific chapter should be based on a finding that the evidence is definite in accordance with Article 1.5.3.A taxonomic ranking higher than species is listed when the criteria in Article 1.5.9.are met.

Possible susceptibility of a species is also important information and, in accordance with Article 1.5.8., these species are included in Section 2.2.2. *Species with incomplete evidence for susceptibility* 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 procedures: includes injection, exposure to unnaturally high loads of *pathogenic agent*, 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. injection, infective 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 *pathogenic agent*.

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 4 (diagnostic methods) of the relevant disease-specific 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 *pathogenic agent* 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, after application of Article 1.5.7., if there is incomplete evidence to demonstrate susceptibility of a species but partial information is available, these species will be included in Section 2.2.2. *Species with incomplete evidence for susceptibility* of the relevant disease-specific chapter in the *Aquatic Manual*.

If there is incomplete evidence to demonstrate susceptibility of a species, the *Competent Authority* should, prior to the implementation of any import health measures for the species, undertake a *risk assessment* for the *pathogenic agent* under consideration, in accordance with the recommendations in Chapter 2.1.

Article 1.5.9.

Listing susceptible species at a taxonomic ranking of Genus or higher

Some *pathogenic agents* have low host species specificity and can infect numerous species across multiple taxa. These *pathogenic agents* are eligible for assessment using this article if they have at least one *susceptible species* in each of three or more taxa at the ranking of Family. The outcome of applying this article may be that *susceptible species* are listed in Article X.X.2. of each disease-specific chapter at a ranking of Genus or higher.

1) For *pathogenic agents* that have a low host species specificity, a decision to conclude susceptibility of species at a taxonomic ranking of Genus or higher should only be made where:
   a) after application of Article 1.5.7., more than one species within the taxonomic ranking has been found to be susceptible;

   AND

   b) no species within the taxonomic ranking has been found to be non-susceptible to *infection*;

   AND

   c) the taxonomic ranking is at the lowest level supported by evidence of points a) and b).
2) Evidence of non-susceptibility of a species to *infection* includes:
   a) absence of *infection* in a species exposed to the *pathogenic agent* in natural settings where the *pathogenic agent* is known to be present and has caused *infection* in co-located *susceptible species*;

   OR

   b) absence of *infection* in a species exposed to the *pathogenic agent* through appropriately designed experimental procedures.

NB: FIRST ADOPTED IN 2014; MOST RECENT UPDATE ADOPTED IN 2019.

SECTION 2.

RISK ANALYSIS

CHAPTER 2.1.

IMPORT RISK ANALYSIS

Article 2.1.1.

Introduction

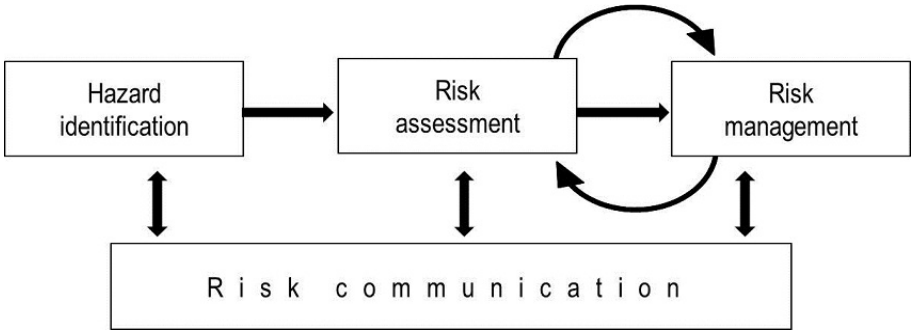
The importation of *aquatic animals* and *aquatic animal products* involves a degree of *disease risk* to the *importing country*. This *risk* may be represented by one or several *diseases* or *infections*.

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 analysis*, *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 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)
   - *aquatic animal 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 WOAH 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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2016.

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 WOAH 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.

Competent Authorities 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

The relevant *Competent Authority* should undertake to reply to requests from the *Competent Authority* of other Member Countries, 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 the *Competent Authority*.

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 WOAH 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 WOAH experts under the auspices of WOAH

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

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

Under these procedures, the Director General of WOAH 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 WOAH *Performance of Aquatic Animal Health Services* (*PVS Tool*: Aquatic).

The expert(s) produce(s) a report in consultation with the *Aquatic Animal Health Services* of the Member Country.

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

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2024.

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 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, albiet 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.

NB: FIRST ADOPTED IN 2012; MOST RECENT UPDATE ADOPTED IN 2024.

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.1.

BIOSECURITY FOR AQUACULTURE ESTABLISHMENTS

Article 4.1.1.

Purpose

To provide recommendations on the development and implementation of *biosecurity* measures primarily to mitigate the *risk* of the introduction of specific *pathogenic agents* into *aquaculture establishments*, and if *pathogenic agents* are introduced, to mitigate the *risk* of further spread within, or release from, the *aquaculture establishment*.

Article 4.1.2.

Scope

Biosecurity principles are relevant to the application of the standards in the *Aquatic Code* at the level of a country, *zone*, *compartment* or *aquaculture establishment*. This chapter describes recommendations on *biosecurity* to be applied to *aquaculture establishments*, including semi-open, semi-closed and closed systems. The chapter describes general principles of *biosecurity* planning, categories of *aquaculture* production systems, area management, mitigation measures for transmission pathways, the application of *risk analysis* and approaches for *biosecurity plan* development.

For further guidance on *disease* prevention and control refer to other chapters of Section 4.

Article 4.1.3.

Introduction

Biosecurity at the level of an *aquaculture establishment* is integral to effective *biosecurity* at the level of a country, *zone* or *compartment* and thus the optimal health status and welfare of *aquatic animal* populations. This chapter describes *biosecurity* principles designed to mitigate the *risks* associated with the introduction of *pathogenic agents* into, the spread within, or the release from *aquaculture establishments*.

Given the unique challenges posed by varied *aquaculture* production systems and the vast diversity of farmed *aquatic animal* species, the development of *biosecurity plans* for *aquaculture establishments* requires the assessment of *disease risks* posed by specific *pathogenic agents* and their potential transmission pathways. A *biosecurity plan* describes management and physical measures to mitigate the identified *risks* according to the circumstances of the *aquaculture establishment*. *Aquaculture establishment* personnel, service providers and *aquatic animal health professionals* or *veterinarians* should be engaged in developing and implementing the *biosecurity plan* to ensure it is practical and effective.

The outcome achieved through the implementation of *biosecurity* at *aquaculture establishments* is improved health and welfare of *aquatic animals* throughout the production cycle. The benefits may include improved market access, increased productivity (through improved survival, growth rates and *feed* conversion), and a reduction in the use of

veterinary medicinal products (including *antimicrobial agents*), thus leading to a reduction in production costs and the rate of emergence of antimicrobial resistance.

Article 4.1.4.

General principles

Biosecurity is a set of management and physical measures which, when used together, cumulatively reduce the *risk* of *infection* in *aquatic animal* populations within an *aquaculture establishment*. Planning and implementation of *biosecurity* within an *aquaculture establishment* requires identification of *risks* and cost-effective measures to achieve the identified *biosecurity* objectives of the plan. The measures required will vary among *aquaculture establishments*, depending on factors such as likelihood of exposure to *pathogenic agents*, the species of farmed *aquatic animal*, the category of *aquaculture* production system, husbandry practices, environmental conditions and geographical location. Different approaches may be used to achieve an identified *biosecurity* objective; however, the general principles for developing and implementing a *biosecurity plan* are consistent and are described below:

1) Potential pathways for *pathogenic agents* to be transmitted into, spread within and released from the *aquaculture establishment* must be identified, as described in Article 4.1.7., giving consideration to the category of *aquaculture* production system and design of the *aquaculture establishment*.

2) *Risk analysis* should be undertaken to identify and evaluate *disease* threats and ensure that the plan addresses *risks* appropriately and efficiently. The *risk analysis* may range from a simple to a complex analysis depending on the objectives of the *biosecurity plan*, the circumstances of the *aquaculture establishment* and the *disease risks*, as described in Article 4.1.8.

3) *Biosecurity* measures to address identified *disease risks* should be evaluated on the basis of their potential effectiveness, initial and ongoing costs (e.g. building works, maintenance), and management requirements, as described in Article 4.1.8.

4) Management practices should be integrated into the *aquaculture establishment*'s operating procedures and relevant training provided to personnel, as described in Article 4.1.9.

5) Appropriate records and documentation are essential to demonstrate effective implementation of the *biosecurity plan*. Examples are described in Article 4.1.9.

6) A schedule for routine reviews and audits of the *biosecurity plan* should be described. Triggers for *ad hoc* review must be determined (e.g. *outbreaks* of *disease*, and changes to infrastructure, production techniques, or *risk* profiles). Third party audits may be required where recognition of the *biosecurity* measures is required by customers, or regulators, or for market access, as described in Article 4.1.9.

Article 4.1.5.

Categories of aquaculture production systems

Four different categories of *aquaculture* production systems are defined based on the capacity to treat water entering and exiting the system, and the level of control over *aquatic animals* and *vectors*. These factors need to be considered in *biosecurity* planning.

Open systems

In an open *aquaculture* production system it is not possible to have control of the water, environmental conditions, animals or *vectors*. These production systems may include stock enhancement of wild populations with *aquatic animals* originating from *aquaculture establishments* or from the wild. As these systems cannot be considered '*aquaculture establishments*', they are not considered further in this chapter. However, movements of *aquatic animals* between *aquaculture establishments* and open systems should be assessed to determine the need for *disease* mitigation measures.

Semi-open systems

In a semi-open *aquaculture* production system, it is not possible to have control over the water entering or exiting the system, or over the environmental conditions. Some *aquatic animals* and *vectors* may also enter and exit the system. Examples of semi-open *aquaculture* production systems are net pens or cages for finfish and suspended baskets or rope systems for molluscs in natural water bodies.

Semi-closed systems

In a semi-closed *aquaculture* production system, there is some control over the water entering and exiting the system and over the environmental conditions. *Aquatic animals* and *vectors* can be prevented from entering and exiting the system; however, there is limited control to prevent the entry or exit of *pathogenic agents*. Examples of semi-closed *aquaculture* production systems are ponds, raceways, floating enclosures, and flow through tanks.

Closed systems

In a closed *aquaculture* production system, there is sufficient control over water entering and exiting the system to exclude *aquatic animals*, *vectors* and *pathogenic agents*. Environmental conditions can also be controlled. Examples of closed *aquaculture* systems include recirculating *aquaculture* production systems, production systems with a safe water supply free from *pathogenic agents* or *aquatic animals* (e.g. ground water), or those with high levels of treatment (and redundancy) of water entering and exiting the system.

Article 4.1.6.

Area management

It may not be possible to control the transmission of *pathogenic agents* among semi-open or semi-closed *aquaculture establishments* that are in close proximity within shared water bodies. In these circumstances, a consistent set of *biosecurity* measures should be applied by all of the *aquaculture establishments* considered to be epidemiologically linked. Area management agreements can formalise the coordination of common *biosecurity* measures among all of the epidemiologically linked *aquaculture establishments*.

Article 4.1.7.

Transmission pathways and mitigation measures

Pathogenic agents can move into, spread within, and be released from *aquaculture establishments* via various transmission pathways. The identification of all potential transmission pathways is essential for the development of an effective *biosecurity plan*. Pathways that are likely to result in transmission of specific *pathogenic agents* should be prioritised for mitigation.

The *risks* associated with the introduction into, spread within, and release of *pathogenic agents* from the *aquaculture establishment* need to be considered for each of the following transmission pathways.

1. Aquatic animals

   Movement of *aquatic animals* into, within and from *aquaculture establishments*, either intentionally or unintentionally, may pose a high likelihood of transmitting *pathogenic agents*. This is particularly the case when clinically and sub-clinically infected *aquatic animals*, or *aquatic animals* with unknown health status are moved into a susceptible population.

   Aquatic animals intentionally introduced into, or moved within, an *aquaculture establishment* may include broodstock, larvae, juvenile stock for on-growing, and genetic material such as *eggs* and milt. Both horizontal and vertical transmission mechanisms of *pathogenic agents* should be considered for *aquatic animals*. The *risk* of

transmitting *pathogenic agents* via *aquatic animals* should be managed giving consideration to the following mitigation measures:

a) Only introduce into the *aquaculture establishment aquatic animals* with a known health status, which is of equal or higher status than the existing animals in the establishment.

b) If *aquatic animals* of unknown *disease* status are introduced, they should be placed into *quarantine*.

c) Where appropriate, quarantined *aquatic animals* to mitigate *disease risks* (for example, treatment for external parasites).

d) Ensure biosecure transport of *aquatic animals* that avoids exposure to and release of *pathogenic agents*.

e) Only move *aquatic animals* between different populations within the establishment following consideration of the *disease risks* and with a view to maintaining the highest possible health status of the *aquatic animal* population.

f) Where possible, isolate *aquatic animal* populations that display clinical signs of *disease* from other populations until the cause is known and the situation is resolved.

g) Remove moribund or dead *aquatic animals* from production units as soon as possible and dispose of them in a biosecure manner in accordance with Chapter 4.8.

h) Report unexplained or unusual mortalities, or suspicion of a notifiable *disease* or an *emerging disease* in *aquatic animals* to the *Competent Authority* in accordance with local requirements. Investigation and *diagnosis* of the cause of mortality should be undertaken by *aquatic animal health professionals* or *veterinarians*.

i) If possible, completely remove *aquatic animals* from all or parts of the *aquaculture establishment* at intervals, for instance between *aquatic animal* generations or production cycles, followed by cleaning, *disinfection* and drying of production installations. Sites should be fallowed for a period sufficient to interrupt *infection* cycles and reduce or eliminate pathogen challenge to restocked *aquatic animals*. *Fallowing* should be coordinated for *aquaculture establishments* that are epidemiologically linked through shared water bodies.

j) Consider physical measures to minimise the likelihood of escape of farmed *aquatic animals* or the entry of wild *aquatic animals* into the *aquaculture establishment*. The likelihood of entry or escape of *aquatic animals* will be higher for semi-open than for closed or semi-closed systems.

2. Aquatic animal products and aquatic animal waste

Aquatic animal products may also be brought into, moved within or moved out of *aquaculture establishments*; for example, *aquatic animal products* derived from *aquatic animals* harvested at other sites. *Aquatic animal waste* may be generated when *aquatic animals* have died or been killed for *disease* control purposes, or when they have been killed and processed for human consumption or other purposes.

Movement of *aquatic animal products* and *aquatic animal waste* into, within or from *aquaculture establishments* may pose a *risk* of *pathogenic agent* transmission. This is particularly the case when a susceptible population is exposed to *aquatic animal products* and *aquatic animal waste* derived from clinically or sub-clinically infected *aquatic animals*. Movement of *aquatic animal waste* into *aquaculture establishments* should be avoided. *Aquatic animal waste* should be stored, transported, disposed of and treated as described in Chapter 4.8.

For intentional movements of *aquatic animal products* and *aquatic animal waste*, the likelihood of presence of *pathogenic agents* in the *aquatic animals* from which *aquatic animal products* and *aquatic animal waste* are derived should be evaluated giving consideration to the species, source, and health status.

The *risk* of transmitting *pathogenic agents* via *aquatic animal products* and *aquatic animal waste* should be assessed and managed giving consideration to the following mitigation measures:

a) Determine the potential *disease risk* of *aquatic animal products* and *aquatic animal waste* to *aquatic animals* in the establishment and the environment;

b) Manage *aquatic animal products* and *aquatic animal waste* in areas within the *aquaculture establishment* that are isolated from *aquatic animal* populations to minimise identified *disease* transmission *risks*;

c) Ensure procedures are implemented for appropriate collection, treatment (inactivating *pathogenic agents*), transport, storage or disposal of *aquatic animal products* and *aquatic animal waste* to minimise identified *disease* transmission *risks*.

3. Water

Water may present a *risk* of the introduction of *pathogenic agents* into, spread within, and release from *aquaculture establishments*. The source of the water, and how it may provide an epidemiological link between the *aquaculture establishment* and other farmed or wild populations or processing plants, should be identified and considered. Exposure to transport water and ballast water should be considered.

The *risk* of the *aquaculture establishment* being exposed to water containing *pathogenic agents* may be influenced by the category of *aquaculture* production system, the likelihood being higher for semi-open than for semi-closed and closed systems. Any water that is flowing from *aquatic animals* with lower or unknown health status presents a potential *risk* of transmitting *pathogenic agents* to *aquatic animals* of a higher health status.

The *risk* of transmitting *pathogenic agents* via water should be assessed, and managed giving consideration to the following mitigation measures:

a) Where possible, choose a water source that is entirely free of susceptible *aquatic animal* populations and *pathogenic agents* of concern. Such water sources may include saline or fresh groundwater, de-chlorinated municipal water, and artificial seawater. These water sources may be particularly suitable for *aquatic animals* with high health status, such as broodstock.

b) Provide an appropriate level of screening, filtration or *disinfection* (in accordance with Chapter 4.4.) of water from sources that are likely to contain *susceptible species* and which may present a *risk* of *pathogenic agent* transmission (e.g. oceans, streams or lakes). The type and level of treatment required will depend on the identified *risks*.

c) Provide an appropriate level of filtration and *disinfection* (in accordance with Chapter 4.4.) of effluent water (and associated filtered waste) from *aquaculture establishments* (or associated slaughterhouses or processing facilities) where it may present a *risk* of *pathogenic agent* transmission to wild *aquatic animals* or other *aquaculture establishments* with *susceptible species*. The type and level of treatment required will depend on the identified *risks*.

d) Ensure the position of water intakes and outlets for semi-closed and closed *aquaculture establishments*, and the location of semi-open *aquaculture establishments*, minimises contamination from other farmed or wild populations or processing plants, taking into account factors such as distance and water currents.

e) The likelihood of ingress of contaminated water either through flooding from external sources or from defective infrastructure (e.g. leaking pipes, blocked drains, bund wall failure) should be assessed and appropriate management or infrastructure measures applied.

f) Assess the *risk* and establish procedures to treat and dispose of waste water resulting from the transport of *aquatic animals*.

4. Feed

Feed can be an important pathway for transmission of *pathogenic agents* to *aquatic animals*. *Feed* manufactured from infected *aquatic animals* may contain *pathogenic agents*, or become contaminated during harvest, transport, storage or processing. Poor hygiene may contribute to contamination during manufacture, transport, storage and use of *feed*.

In closed or semi-closed production systems there can be a high level of control of *aquatic animal feed*. However, in semi-open production systems, *aquatic animals* may obtain food from their environment (e.g. filter-feeding molluscs or predation of wild fish by farmed fish in net pens or cages). The *risk* of *disease* transmission from *feed* to the environment also needs to be managed.

The *risk* of transmitting *pathogenic agents* via *aquatic animal feed* should be assessed, and managed by mitigation measures as described in Chapter 4.9., for example using *feed* and *feed ingredients* that:

a) have undergone sufficient processing to inactivate *pathogenic agents* of concern;

b) are from sources that are declared free from the *pathogenic agents* of concern or have been confirmed (e.g. by testing) that *pathogenic agents* are not present in the *feed* or *feed ingredients*;

c) have been processed, manufactured, stored, transported and delivered during feeding to *aquatic animals* in a manner to prevent contamination by *pathogenic agents*.

5. Fomites

Equipment, *vehicles*, packaging material, clothing, footwear, sediments, infrastructure and other fomites can mechanically transfer *pathogenic agents* into, within and from an *aquaculture establishment*.

The likelihood of transferring *pathogenic agents* will depend on the stability of the *pathogenic agent* in the environment, the presence and nature of organic matter on the fomite surface, as well as the type of surface and its capacity to hold water. The likelihood of transferring *pathogenic agents* may be higher for fomites which are difficult to clean and disinfect. Sharing equipment between *aquaculture establishments*, or between different production units within an *aquaculture establishment*, or between *aquaculture establishments* and processing facilities, may result in the spread of *pathogenic agents*. The *risk* of transmitting *pathogenic agents* via fomites should be assessed and managed giving consideration to the following mitigation measures:

a) Assess the *disease risk* associated with any fomites moved into, within or from the *aquaculture establishment*.

b) Ensure procedures and infrastructure are in place to clean and disinfect fomites, including at designated delivery and loading areas, prior to entry into the *aquaculture establishment*. Recommendations for the cleaning and *disinfection* of fomites are described in Chapter 4.4.

c) Dedicate items that are difficult to disinfect, or those with a high likelihood of contamination, to a specific *aquaculture establishment* or to areas within an establishment instead of moving them after *disinfection*.

d) Apply the mitigation measures described at points a) to c) above to the movement of fomites between production units within an *aquaculture establishment* with the measures determined based on an evaluation of the *risk* of *disease* transmission.

6. Vectors

Vectors can transmit *pathogenic agents* to susceptible *aquatic animals* in *aquaculture establishments*. They may include *aquatic animals* entering via the water supply, predators, wild birds, scavengers, and pest animals such as rodents. *Vectors* can also transmit *pathogenic agents* within and from an *aquaculture establishment*.

The likelihood of transmitting *pathogenic agents* via *vectors* varies with the type of *vector*, the nature of the *pathogenic agent*, the category of *aquaculture* production system, and the level of *biosecurity*.

The *risk* of transmitting *pathogenic agents* via *vectors* should be assessed and managed giving consideration to the following mitigation measures:

a) Physical mitigation measures to prevent the access of *vectors* to *aquaculture establishments* may include:

   i) filtering or screening of water entering and exiting semi-closed and closed *aquaculture* production systems to prevent entry of wild *aquatic animals*;

   ii) surrounding land-based *aquaculture* production systems by a fence or a wall to prevent entry of animals and people, with a gate for controlled access for authorized personnel and visitors;

   iii) surrounding floating *aquaculture* production systems by barriers on the establishment perimeter to prevent contact with or entry of wild *aquatic animals* and other animals;

   iv) covering outdoor or unenclosed *aquaculture* production systems with nets to prevent access by birds.

b) Pest control.

7. Personnel and visitors

a) Access of personnel and visitors to *aquaculture establishments* should be controlled by creating a defined border between the outer *risk* area and the inner biosecure area comprising facilities for:

   i) completion of a register, which should include visitors' names, contact information, and details of exposure to *aquatic animals* or *pathogenic agents* over a preceding period, including visits to other *aquaculture establishments* or other facilities;

   ii) changing of clothes and shoes, or use of disposable coverings (e.g. hoods, coats, gloves, shoe coverings);

   iii) *disinfection* of hands, and the use of foot baths.

b) All visitors should be briefed and supervised to ensure compliance with the *biosecurity plan*.

c) Clear signage should be displayed to promote awareness and compliance with *biosecurity plan* measures by personnel, visitors and the public.

Article 4.1.8.

Risk analysis

Risk analysis is an accepted approach for evaluating *biosecurity* threats and is used to support the development of mitigation measures. A formal *risk analysis* has four components: *hazard* identification, *risk assessment*, *risk management* and *risk communication*. This article elaborates the principles described in Chapter 2.1. and applies them to guide the development of *biosecurity plans* for *aquaculture establishments*.

A *biosecurity plan* may not necessarily require a comprehensive *risk analysis* to evaluate *disease risks* linked to transmission pathways. The chosen approach may depend on the objectives of the *biosecurity plan*, the level of *biosecurity* that is appropriate for the specific production requirements of the *aquaculture establishment*, the complexity of the threats to be addressed, and the availability of information and resources. Depending on these circumstances, a partial analysis may be appropriate, and can build on previous experiences to identify the *hazards* associated with relevant transmission pathways.

The three formal steps of the *risk analysis* process to underpin a *biosecurity plan* are:

Step 1 – Hazard identification

Hazard identification determines which *pathogenic agents* should be the subject of the *risk assessment*. A *hazard* may include a specific *pathogenic agent* or be defined in more general terms as a group of *pathogenic agents*. This step includes identifying and collecting relevant information on the *pathogenic agents* that have potential to cause *diseases* in *aquatic animal* populations within an *aquaculture establishment*. This process must consider the *aquatic animal health status* of the establishment and, for semi-open and semi-closed *aquaculture* production systems, the *aquatic animal health status* of the epidemiologically linked environments. Known and *emerging diseases* which could negatively impact the farmed population should be identified, regardless of whether they are present in the *aquaculture establishment*.

To complete the next steps of the *risk assessment*, information on the identified *hazards* is required and includes: i) the frequency of occurrence, ii) the biophysical characteristics, iii) the likelihood of detection if present and iv) the possible transmission pathways (described in Article 4.1.7.). Many of the *hazards* will share the same pathways.

Step 2 – Risk assessment

A *risk assessment* can be initiated once it has been identified that a *hazard* exists, and the required information listed under step 1 has been gathered. The aim of the *risk assessment* is to establish a *risk* estimate, which is the product of the likelihood and consequences of entry of a *pathogenic agent* into, spread within or release from the *aquaculture establishment*.

A *risk assessment* can be quantitative or qualitative. Both methods require the same conceptual pathway which identifies the necessary steps for *hazard* introduction, establishment and spread to be constructed. In a qualitative assessment, introduction and establishment are estimated using descriptors of likelihood. A quantitative assessment requires data on which to estimate likelihood. In most circumstances, the likelihood of *disease* transmission and associated consequences will be assessed qualitatively but within a formal *risk assessment* framework. Examples of descriptors for qualitative estimates of likelihood and consequence are given in Tables 1 and 2. Table 3 illustrates how estimates of likelihood and consequence can be combined in a matrix to give an estimate of *risk*. Table 4 provides an interpretation of *risk* estimates.

Table 1. Qualitative descriptors of likelihood

Estimate	Descriptor
Remote	Very unlikely, but not impossible.
Unlikely	May occur, but only in rare circumstances.
Possible	Clear evidence to suggest this is possible in this situation.
Likely	It is likely, but not certain, to occur.
Certain	It is certain to occur.

Table 2. Qualitative descriptors of consequences

Estimate	Descriptor of consequences at level of the aquaculture establishment
Insignificant	Impact not detectable or minimal. No trade impacts.
Minor	Limited decreased production affecting only a small number of units or short-term, and/or very limited and transitory disruption to trade.
Moderate	Decreased production (e.g. sustained increased mortality or decreased growth rate) and/or some short-term to medium-term disruption to trade, resulting in financial loss.
Major	Considerable, decreased production, and/or some medium-term to long-term disruption to trade, resulting in significant financial loss.
Catastrophic	Complete production loss, possibly barriers to resumption of production, and/or complete loss of trade, resulting in extreme financial loss.

Table 3. Matrix for estimating risk

Likelihood estimate	Consequence rating					
		insignificant	minor	moderate	major	catastrophic
	remote	negligible	low	low	low	medium
	unlikely	low	low	medium	medium	high
	possible	low	medium	medium	high	high
	likely	low	medium	high	high	extreme
	certain	low	high	high	extreme	extreme

Risk assessments inform which *hazards* need to be addressed, which critical control points on the transmission pathway should be targeted for management, and the measures that are most likely to be effective in reducing *risk*.

Table 4. Interpretation of risk estimates

Risk estimate*	Descriptor
Negligible	Acceptable level of *risk*. No action required.
Low	Acceptable level of *risk*. On-going monitoring may be required.
Medium	Unacceptable level of *risk*. Review and strengthen the *risk* mitigation measures.
High	Unacceptable level of *risk*. Identify and implement additional *risk* mitigation measures.
Extreme	Unacceptable level of *risk*. Take immediate action to mitigate the *risk*.

* Likelihood and consequence estimates are combined using the *risk* matrix (Table 3) to produce the *risk* estimate.

Step 3 - Risk management

Risk management is used to determine the appropriate management response for the assessed level of *risk* as described in Table 4. The *risk assessment* process identifies the steps within transmission pathways necessary for a *risk* to be realised and thus allows the most effective mitigation measures to be determined. Many of the *hazards* will share the same pathways and therefore mitigation measures may be effective against more than one *hazard*. Information on *hazards* and their pathways of introduction (step 1) should be combined with an assessment of *risk* associated with each pathway (step 2) to identify the most appropriate and cost-effective *risk* mitigation measures.

Article 4.1.7.describes some possible mitigation measures relevant to different transmission pathways. The most appropriate mitigation measures for a specific *aquaculture establishment* will depend on the effectiveness and reliability of the mitigation measure, the category of *aquaculture* production system and cost.

After the implementation of the *biosecurity plan*, *hazards* should be regularly reassessed, and measures adjusted according to any changed *risk* estimates.

Article 4.1.9.

Biosecurity plan development

The purpose of a *biosecurity plan* is primarily to reduce the *risk* of introducing *pathogenic agents* into an *aquaculture establishment*, and if *pathogenic agents* are introduced, to reduce the *risk* of further spread within or release from the *aquaculture establishment*. The plan will document identified transmission pathways and the outputs of any *risk analysis* performed (*hazards*, *risk* estimate and mitigation measures), and information relevant to ongoing implementation, monitoring and review of the plan.

1. Development of a biosecurity plan

The process of developing a *biosecurity plan* will vary depending on its objectives, the level of *biosecurity* appropriate to the specific production system requirements, the complexity of the *disease risks* to be addressed, and availability of information and resources. Consideration and documentation of the following issues are recommended:

a) objectives, scope and regulatory requirements for the *biosecurity plan*;

b) information about the *aquaculture establishment* including an up-to-date plan of the layout of buildings and production units (including *epidemiological units*, if any, and structures and processes to maintain separation), loading/unloading, unpacking, processing, *feed* storage, *aquatic animal waste* storage, reception areas, access points and maps showing major movements of *aquatic animals*, *aquatic animal products* and *aquatic animal waste*, water, *feed* and fomites;

c) the potential pathways for entry of *pathogenic agents* into, spread within or release from the *aquaculture establishment* (refer to Article 4.1.7.above);

d) a *risk analysis*, including identification of the major *disease hazards* to the *aquaculture establishment* (refer to Article 4.1.8.above);

e) the mitigation measures that have been determined to address *risks*;

f) emergency procedures in the event of a *biosecurity* failure. These may include reporting requirements, and emergency measures to eradicate *pathogenic agents* such as *aquatic animal* depopulation and disposal, and site *disinfection*, in accordance with Chapters 4.4. and 7.4.;

g) internal and external communication procedures, roles and responsibilities of *aquaculture establishment* personnel and essential contact information, e.g. for personnel, *aquatic animal health professionals* or *veterinarians* and the *Competent Authority*;

h) monitoring and audit schedule;

i) performance evaluation;

j) standard operating procedures required to support implementation of the mitigation measures described by the *biosecurity plan*, emergency procedures and the training requirements of establishment personnel.

2. Key components of a biosecurity plan

a) Standard operating procedures (SOPs)

SOPs describe routine management processes that must be performed to support the effectiveness of the *biosecurity plan*. Each SOP should clearly describe its objectives, personnel responsibilities, the procedure (including record keeping), precautions and a review date.

b) Training of personnel

Personnel should be trained in the application of the SOPs including completion of forms, checklists and other records associated with each procedure, as well as routine communication requirements.

The *biosecurity plan* should include a training programme to ensure that all personnel are capable of playing their role in the implementation of *biosecurity* at the *aquaculture establishment*.

c) Documentation and record keeping

The *biosecurity plan* describes the documentation necessary to provide evidence of compliance with the plan. The level of detail required in the documentation depends on the outcomes of the transmission pathway assessment.

Examples of documentation required include: *aquaculture establishment* layout, movements of *aquatic animals*, origin and destination and health status of the *aquatic animals* introduced to the *aquaculture establishment*, *quarantine* measures, records of visitors to the establishment, escapees, stocking densities, feeding and growth rates, records of personnel training, treatments/vaccination, water quality, cleaning and *disinfection* events, morbidity and mortality (including removal and disposal of mortalities), *surveillance* and laboratory records.

d) Emergency procedures

Procedures should be developed and, when necessary, implemented to minimise the impact of emergencies, *disease* events, or unexplained mortality in *aquatic animals*. These procedures should include clearly defined thresholds that help to identify an emergency incident and activate response protocols, including reporting requirements.

e) Health monitoring

Health monitoring as part of the *biosecurity plan* involves monitoring of the health status of *aquatic animals* in *aquaculture establishments*. Monitoring should be performed at a production unit and establishment level. Activities may include *disease surveillance*, routine monitoring of stock for important health and production parameters (e.g. by personnel, an *aquatic animal health professional* or a *veterinarian*), recording of clinical signs of *disease*, morbidity and mortality, laboratory test results and analysis of these data (e.g. calculation of rates of morbidity and mortality).

f) Routine review and auditing

The *biosecurity plan* should describe a systematic auditing schedule to verify implementation and compliance with the requirements of the *biosecurity plan*. Routine revision of the *biosecurity plan* is necessary to ensure that it continues to effectively address *biosecurity risks*.

The *biosecurity plan* should also be reviewed at least annually or in response to changes to the *aquaculture establishment* operations, changes in facility design, changes in husbandry approaches, identification of a new *disease risk*, or the occurrence of a *biosecurity* incident. *Biosecurity* incidents, and actions taken to remedy them, should be documented to enable re-assessments of SOPs.

NB: FIRST ADOPTED IN 2021.

CHAPTER 4.2.

ZONING AND COMPARTMENTALISATION

Article 4.2.1.

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 4.2.2.

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 4.2.3.

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 *Competent Authority* 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 *Competent Authority* 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 among the relevant enterprise/industry, the *Competent Authority* and the *Aquatic Animal Health Services*, and their respective responsibilities, including the procedures for oversight of the operation of the *compartment* by the *Competent Authority*.

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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 4.3.

APPLICATION OF COMPARTMENTALISATION

Article 4.3.1.

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 4.2. with the objective to facilitate trade in *aquatic animals* and *aquatic animal products* 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 4.3.2.

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 4.3.3.

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 or *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 4.3.4.

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 4.3.5.

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 4.3.6.

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 a WOAH Reference Laboratory.

Article 4.3.7.

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 4.3.4., 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 4.3.8.

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*.

NB: FIRST ADOPTED IN 2010; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 4.4.

DISINFECTION OF AQUACULTURE ESTABLISHMENTS AND EQUIPMENT

Article 4.4.1.

Purpose

To provide recommendations on planning and implementation of *disinfection* procedures to prevent the introduction, establishment or spread of *pathogenic agents*.

Article 4.4.2.

Scope

This chapter describes recommendations for *disinfection* of *aquaculture establishments* and equipment during routine biosecurity activities and for emergency response. Guidance is provided on general principles, planning and implementation of *disinfection* activities.

For specific methods of pathogen inactivation refer to the disease-specific chapters in the *Aquatic Manual*.

Article 4.4.3.

Introduction

Disinfection is employed as a *disease* management tool in *aquaculture establishments* as part of a *biosecurity plan*. *Disinfection* is used to prevent entry or exit of target *pathogenic agents* to or from an *aquaculture establishment* or *compartment*, as well as the spread of *pathogenic agents* within *aquaculture establishments*. *Disinfection* may be used during emergency *disease* response to support the maintenance of *disease* control *zones* and for *disease* eradication (stamping-out procedures) from affected *aquaculture establishments*. The specific objective of *disinfection* will determine the strategy used and how it is applied.

When possible, the spread of *pathogenic agents* should be prevented by avoiding transmission pathways rather than attempting to manage them through *disinfection*. For example, difficult to disinfect items (e.g. gloves, dive and harvest equipment, ropes and nets) should be dedicated to a specific site rather than moved between production units or *aquaculture establishments* after *disinfection*.

Article 4.4.4.

General principles

Disinfection is a structured process that uses physical and chemical procedures to remove organic material and destroy or inactivate *pathogenic agents*. The process should include planning and implementation stages that take into account potential options, efficacy and *risks*.

The *disinfection* process may vary depending on whether the overall objective is *disease* prevention, control or eradication. Procedures addressing eradication will generally involve destocking of all *aquatic animals* as well as *disinfection* of *aquaculture establishments* and equipment, whereas *disease* control aims at limiting the spread of

disease between or within *aquaculture establishments*. Although different approaches may be used to achieve the identified objective, the general principles described below should be applied in all cases.

1) The *disinfection* process should include the following phases:

   a) Cleaning and washing

      Cleaning and washing of surfaces and equipment is necessary to remove solid waste, organic matter (including biofouling) and chemical residues as these may reduce the efficacy of *disinfectants*. The use of detergent is also important to break down biofilms. The detergent used should be compatible with the *disinfectant* and the surface being treated. After cleaning, any excess water should be drained and before the application of *disinfectants* all surfaces and equipment should be inspected to ensure there is no remaining organic material.

      Where treatment of water is required, the presence of suspended solids may also reduce the efficacy of some *disinfectants*. Removal of suspended solids through various processes such as filtration, sedimentation, coagulation or flocculation should be performed.

      Biofilms, often referred to as slime, are a thin film of microorganisms and extracellular polymeric substances that adhere to surfaces. Biofilms physically protect embedded microorganisms against *disinfectants*. In order to achieve effective *disinfection*, biofilms should be removed during the cleaning and washing stage prior to the application of *disinfectants*.

      All waste produced should be disposed of in a biosecure manner because it may contain viable *pathogenic agents* that have the potential to spread *infection* if not controlled.

   b) Application of disinfectants

      This phase involves the application of chemical compounds or physical processes that are appropriate to inactivate the *pathogenic agent*.

      The application of *disinfectants* should take into account the type of material requiring *disinfection* and how *disinfectants* should be applied. Hard non-permeable materials (e.g. polished metal surfaces, plastics and painted concrete) can be cleaned thoroughly and allow contact with the *disinfectant* because there is little opportunity for infective material to lodge in crevices. *Disinfection* efficacy will decrease if the surface is corroded, pitted or paint is flaking, therefore proper maintenance of surfaces and equipment is essential. For permeable surfaces and materials (e.g. woven material, nets and soil), a higher *disinfectant* concentration and a longer contact time is required because the surface area is greater, chemicals cannot penetrate easily and residual organic matter may be present.

      The choice of the application method should ensure all surfaces come into contact with the agent for the required period of time. The application of *disinfectants* should be undertaken methodically (e.g. using a grid pattern) to ensure that complete coverage and adequate contact times are achieved. Each phase should start from the highest point and proceed downwards, commencing from the least contaminated areas. However for some equipment, rinsing of surfaces with the *disinfectant* may be sufficient. When *disinfectants* are applied to vertical surfaces, care should be taken to ensure that the required contact time is maintained before the *disinfectant* drains away. Vertical surfaces may need retreatment or require the addition of compatible foaming agents to prolong adherence to surfaces.

      For pipes and biofilters, complete filling with the *disinfectant* solution should be done to ensure contact with all surfaces. Difficult to access and complex areas may require fumigation or use of misting equipment.

   c) Removal or inactivation of the disinfectant

      Removal or inactivation of chemical residues is important to avoid toxicity to *aquatic animals*, corrosion of equipment and environmental impacts. Processes that may be employed for the removal or inactivation of chemical residues may include: rinsing of surfaces, dilution to acceptable levels, treatment to inactivate chemical agents or, time to allow deactivation or dissipation of the active compound. These processes may be used in isolation or in combination.

2) *Disinfectants* should be used in accordance with relevant legislation. *Disinfectants* may present *risks* to the health of people, *aquatic animals* and the environment. Chemical *disinfectants* should be stored, used and disposed of in accordance with regulations and manufacturer's instructions.

3) *Disinfection* should be monitored to ensure appropriate dose of *disinfectant* and *disinfection* efficacy. Depending on the application process and the *pathogenic agent* of concern, this may be done in different ways. Examples include measurement of the active agent (e.g. residual chlorine levels), indirect measurement of the active agent by an indicator process (e.g. monitoring oxygen reduction potential), and measuring efficacy using indicator bacteria (e.g. heterotrophic bacteria plate counts).

   In facilities that have undergone destocking and *disinfection*, the use of a sentinel population prior to restocking may be considered. The sentinel population should be susceptible to the pathogen of concern and exposed to conditions that would be conducive to the expression of clinical *disease* should viable pathogen remain.

4) *Aquaculture establishments* should keep records of the *disinfection* processes applied. The records should be sufficient to allow evaluation of the *disinfection* plan.

Article 4.4.5.

Planning

A *disinfection* plan should be developed that incorporates an assessment of the transmission pathways, the type of material to be disinfected, the *pathogenic agents* to be inactivated, the health and safety precautions and control measures required, and the environment in which the process is to be undertaken. The *disinfection* plan should include a mechanism for determining efficacy. The *disinfection* plan should be regularly reviewed to ensure the *disinfection* process remains effective and efficient. Any changes to the disinfection plan should also be documented.

The planning process should assess the critical control points where *disinfection* will be most effective. *Disinfection* priorities should be developed by considering potential pathways for spread of *pathogenic agents* and the relative likelihood of contamination. For effective *disinfection* of facilities containing *vectors*+ (e.g. ponds) the *vectors* should be excluded, removed or destroyed as part of the *disinfection* process.

An inventory of all items requiring *disinfection* should be developed when practical. An assessment should be made of the materials used in construction, their surface porosity and resistance to chemical damage, and accessibility for *disinfection*. Then, the appropriate *disinfection* method should be decided for each item.

The level of cleaning required prior to *disinfection* should be assessed for each type of equipment. If heavy soiling with solids and particulate matter is present, specific attention should be given to the cleaning process and the resources required. The physical or chemical cleaning process should be compatible with the *disinfectant* chosen.

Personnel, equipment and materials to be disinfected should be assessed taking into account the type and number of items to be treated and how waste material will be managed.

The ability to control water flow and water volumes should be considered at the planning stage and will depend on the enterprise type (recirculation, flow-through and open systems). Water may be disinfected using a variety of methods as described in Article 4.4.11.

Article 4.4.6.

Disinfection in an emergency response

Disinfection is an essential part of any emergency response to support *disease* control activities such as *quarantine* of affected *aquaculture establishments* and stamping-out procedures. The conditions associated with an emergency response require different approaches for *disinfection* to those used in routine biosecurity. These conditions include a high level of *disease risk* (due to the significance of the *disease*), high pathogen loading, potential high volumes of infected *aquatic animals* and *aquatic animal waste*, large areas requiring *disinfection* and large volumes of contaminated water. Planning should consider these circumstances, incorporate an evaluation of *risks* and include methods for monitoring efficacy.

In an emergency response it may be preferable to avoid transmission pathways rather than relying on *disinfection*. Equipment should not be moved from an infected *aquaculture establishment* unless effective *disinfection* has been achieved. In some circumstances, equipment or material that is difficult to disinfect or has a high likelihood of contamination may need to be disposed of in a biosecure manner rather than be disinfected.

Article 4.4.7.

Types of disinfectants

Types of *disinfectants* commonly used in *aquaculture* include the following:

1. Oxidising agents

   The majority of oxidising agents are relatively fast acting and are effective *disinfectants* for a large range of micro-organisms. These compounds are inactivated by organic matter and therefore should be used following an effective cleaning stage. Organic matter consumes oxidising agents and the initial concentration (loading dose) may drop rapidly, making effective dosing levels (residual dose) difficult to predict. Therefore, residual dose levels

should always be monitored to ensure that they remain above the minimum effective concentration for the required time period.

Oxidising agents may be toxic to *aquatic animals* and therefore should be removed or inactivated.

Common oxidising agents include chlorine compounds, chloramine-T, iodophores, peroxygen compounds, chlorine dioxide and ozone.

2. pH modifiers (alkalis and acids)

Modification of pH can be achieved through the use of either alkaline or acidic compounds. Advantages of using pH modifiers include the ease of determining their concentrations and that they are not inactivated by organic matter. Also, they can be used in areas where the application of other effective *disinfectants* is not possible, such as in pipes or on biofilter surfaces.

3. Aldehydes

Aldehydes act by denaturing protein. Two aldehyde compounds that may be used during decontamination of *aquaculture establishments* are formaldehyde and glutaraldehyde. They are highly effective against a wide range of organisms but require long exposure times. Aldehydes maintain their activity in the presence of organic matter and are only mildly corrosive. Glutaraldehyde is used in the liquid form as a cold sterilant, particularly for heat-sensitive equipment. Formaldehyde may be used as a mist or a gas for fumigation.

4. Biguanides

Of the many biguanides available, chlorhexidine is the most commonly used. However they are not effective in hard or alkaline water and are less effective against many *pathogenic agents* compared to other groups of *disinfectants*. These compounds are comparatively non-corrosive and relatively safe, thus they are commonly used in the *disinfection* of skin surfaces and delicate equipment.

5. Quaternary ammonium compounds (QACs)

The biocidal efficacy of QACs is variable and selective. They are effective against some vegetative bacteria and some fungi, but not all viruses. QACs are most active against gram-positive bacteria; action against gram-negative bacteria is slow, with some strains showing resistance. These compounds are not effective against spores. The advantages of QACs are that they are noncorrosive and have wetting properties that enhance contact with surfaces. QACs may be toxic to *aquatic animals* and should be removed from surfaces following *disinfection* procedures.

6. Ultraviolet (UV) irradiation

UV irradiation is a viable option for the treatment of water entering or leaving *aquaculture establishments* where there is some control of water flows in recirculation or flow-through systems. UV irradiation should be used following effective filtration because suspended solids reduce UV transmission and the effectiveness of this method.

7. Heat treatment

Susceptibility of *pathogenic agents* to heat treatment varies significantly. Under most conditions, moist heat is more effective than dry heat.

8. Desiccation

Desiccation may be an effective *disinfectant* for susceptible *pathogenic agents* and may be used in circumstances where other *disinfection* methods are impractical or as an ancillary method to other *disinfection* methods.

Desiccation can be considered to be a *disinfection* method if complete drying of the item is achieved because the absence of water will kill many *pathogenic agents*. However, moisture content may be difficult to monitor in some circumstances. The effectiveness will vary depending on environmental conditions such as temperature and humidity.

9. Combined disinfection methods

Combined *disinfection* methods should be considered wherever they are synergistic and provide a higher assurance of effective *pathogenic agent* inactivation. Some examples include:

a) direct sunlight and desiccation as a combined *disinfection* method provides three potential *disinfection* actions, i.e. UV irradiation, heating and desiccation. It has no operational cost and may be used subsequent to other methods;

b) ozone and UV irradiation are often combined in series as they provide back-up systems and different modes of action. UV irradiation also has the advantage of removing ozone residues from treated water.

Antagonistic effects may occur when chemical agents or detergents are combined.

Article 4.4.8.

Selection of a disinfectant

The *disinfectant* should be selected considering the following:

– efficacy against the *pathogenic agents*;
– effective concentration and exposure time;
– ability to measure efficacy;
– nature of the items to be disinfected and the potential for them to be damaged;
– compatibility with the available water type (e.g. fresh water, hard water or seawater);
– availability of the *disinfectant* and equipment;
– ease of application;
– the ability to remove organic matter;
– cost;
– impacts of residues on *aquatic animals* and the environment; and
– user safety.

Article 4.4.9.

Types of aquaculture establishments and equipment

Aquaculture establishments and equipment differ widely in their characteristics. This section presents some considerations for effective *disinfection* of different types of *aquaculture establishments* and equipment.

1. Ponds

Ponds are generally large and may be earthen based or be fitted with plastic liners. These characteristics together with the large volumes of water make cleaning prior to decontamination difficult and high organic loads may affect many chemical *disinfectants*. Ponds should be drained of water and have as much organic matter as possible removed prior to *disinfection*. All water and organic matter should be disinfected or disposed of in a biosecure manner. Earthen ponds should be dried thoroughly and lime compounds applied to raise pH and aid the inactivation of *pathogenic agents*. Scraping, ploughing or tilling of the base of unlined ponds will also aid in incorporation of liming compounds and drying.

2. Tanks

Tank construction material (e.g. fibreglass, concrete or plastic) will determine the type of *disinfection* method used. Bare concrete tanks are susceptible to corrosion by acids and potential damage by high pressure sprayers. They are also porous and therefore require longer application of chemicals to ensure *disinfection*. Plastic, painted and fibreglass tanks are more easily disinfected because they have smooth, non-porous surfaces that facilitate thorough cleaning and are resistant to most chemicals.

Tanks should be drained of water and have as much organic matter as possible removed prior to *disinfection*. Water and organic matter should be disinfected or disposed of in a biosecure manner. Tank equipment should be removed for separate cleaning and *disinfection*, and all organic waste and debris removed. Tank surfaces should be washed using high-pressure sprayers or mechanical scrubbing with detergent to remove fouling such as algae and biofilms. Heated water may be used to enhance the cleaning process. Before application of *disinfectants* any excess cleaning water should be drained and disinfected or disposed of in a biosecure manner.

When *disinfectants* are applied to vertical surfaces, care should be taken to ensure that adequate contact time is maintained before the *disinfectant* is drained. Following *disinfection*, tanks should be rinsed to remove all residues and allowed to dry completely.

3. Pipes

Disinfection of pipes may be difficult due to lack of access. Pipe construction material should be taken into consideration when selecting the *disinfection* method.

Pipes can be cleaned through the use of alkaline or acid solutions, or foam projectile pipe cleaning systems. For cleaning to be effective, biofilms must be removed followed by flushing of the resulting particulate matter and thorough rinsing.

Once pipes are cleaned, chemical *disinfectants* or circulation of heated water can be used. All steps require pipes to be fully filled so that internal surfaces are treated.

4. Cage nets and other fibrous materials

Nets used in cage culture are often large, difficult to handle, have significant levels of biofouling and are usually made from fibrous materials that trap organic matter and moisture. Nets should be dedicated to a single *aquaculture establishment* or area because they have a high likelihood of contamination and may be difficult to disinfect.

Once the net has been removed from the water, it should be transferred directly to the net washing site. Nets should be thoroughly cleaned prior to *disinfection* to remove organic matter and aid in the penetration of chemical *disinfectants*. Cleaning of nets is best achieved by first removing gross biofouling and then washing with a detergent solution. Water and organic matter should be disposed of in a biosecure manner.

Following cleaning, nets may be disinfected by complete immersion in chemical *disinfectants* or heated water. Treatment duration should be sufficient to allow penetration into net material. Treatment may have a detrimental impact upon the strength of nets. This must be considered when deciding upon the treatment method to be applied to ensure net integrity is not compromised. Following *disinfection*, nets should be dried before storage. If rolled nets are not completely dry they will retain moisture which may enhance survival of the *pathogenic agent*.

Other fibrous materials such as wood, ropes and dip nets have characteristics similar to cage nets and they require special consideration. Wherever possible, it is recommended that equipment is site specific if it includes fibrous material.

5. Vehicles

The likelihood of *vehicle* contamination will be determined by their use, e.g. transportation of mortalities, live *aquatic animals*, harvested *aquatic animals*. All potentially contaminated internal and external surfaces should be disinfected. Special consideration should be given to areas likely to be contaminated such as the internal surface of *containers*, pipes, transportation water and waste. The application of corrosive *disinfectants* to *vehicles* should be avoided or if used, corrosive residues removed following *disinfection* by thorough rinsing. Oxidative compounds such as chlorines are the most commonly used *disinfectants* for *vehicles*.

All boats should undergo routine *disinfection* to ensure that they do not transfer *pathogenic agents*. The level of contamination of boats will be determined by their use. Boats used to harvest or to remove dead *aquatic animals* from *aquaculture* sites should be considered as highly likely to be contaminated. Organic material should be regularly removed from decks and work areas.

As part of the *disinfection* planning process, an assessment should be made to identify areas likely to be contaminated such as in and around machinery, holding tanks, bilges and pipes. All loose equipment should be removed, cleaned and disinfected separately from *disinfection* of the boat. Additional procedures should be developed for well-boats because of their potential to transfer *pathogenic agents* through the discharge of contaminated water. Contaminated effluent water should be disinfected prior to discharge (refer to Article 4.4.11.).

Where possible, boats should be placed on land or dry-docked, for *disinfection* in order to limit waste water entering the aquatic environment and to allow access to hull and niche areas. Biofouling organisms, that may act as *vectors*, and fomites should be removed.

Where boats cannot be removed to land or dry-docked, a *disinfection* method should be chosen that minimises the discharge of toxic chemicals into the aquatic environment. Divers should inspect and clean hulls. Where appropriate, mechanical methods such as high-pressure sprayers or steam cleaners should be considered as an alternative to chemical *disinfection* for cleaning above and below the water-line. Fumigation may also be considered for large areas if they can be adequately sealed.

6. Buildings

Aquaculture establishments include buildings for culture, harvesting and processing of *aquatic animals*, and other buildings associated with storage of *feed* and equipment.

The approach to *disinfection* may vary depending on the structure of the building and degree of contact with contaminated material and equipment.

Buildings should be designed to allow effective cleaning and thorough application of *disinfectants* to all internal surfaces. Some buildings will contain complex piping, machinery and tank systems that may be difficult to disinfect. Wherever possible, buildings should be cleared of debris and emptied of equipment, prior to *disinfection*.

Misting or foaming agents are options for *disinfection* of complex areas and vertical surfaces. Fumigation can be considered for large or difficult to access areas if buildings can be adequately sealed.

7. Containers

Containers range from simple plastic bins used to transport harvested *aquatic animal products* or dead *aquatic animals* through to complex tank systems used for the transport of live *aquatic animals*.

Containers are generally manufactured using smooth non-porous material (e.g. plastic, stainless steel) which can be easily disinfected. They should be considered high *risk* items because they are in close contact with *aquatic animals* or their *products* (e.g. blood, diseased *aquatic animals*). In addition the need to move them between locations makes them potential fomites for the spread of *pathogenic agents*. In the case of transport of live *aquatic animals*, *containers* may also have pipes and pumping systems and confined spaces that should also be disinfected.

All water should be drained from the *container* and any *aquatic animals*, faecal matter and other organic material removed by flushing with clean water and disposed of in a biosecure manner. All pipes and associated pumps should also be inspected and flushed. *Containers* should then be washed using appropriate chemical detergents combined with high-pressure water cleaners or mechanical scrubbing.

All internal and external surfaces of *containers* should be treated using an appropriate *disinfection* method. They should then be rinsed and inspected to ensure there are no organic residues and stored in a manner that allows them to drain and dry quickly.

8. Biofilters

Biofilters associated with closed or semi-closed production systems are an important control point for *disease*. Biofilters are designed to maintain a colony of beneficial bacteria to enhance water quality. The conditions that support these bacteria may also enhance survival of some *pathogenic agents* should they be present. It is normally not possible to disinfect biofilters without also destroying beneficial bacteria. Therefore potential water quality issues should be taken into account when planning strategies for *disinfection* of biofilters.

When disinfecting biofilters and their substrates, the system should be drained, organic residues removed and surfaces cleaned. *Disinfection* of biofilter systems can be undertaken by modifying water pH levels (using either acid or alkaline solutions). Where this is undertaken, the pH levels must be sufficient to inactivate the *pathogenic agent*, but should not be corrosive to pumps and equipment within the biofilter system. Alternatively, the biofilter can be completely dismantled, including removal of biofilter substrate, and the components cleaned and *disinfectants* applied separately. In the case of emergency *disease* response, the latter procedure is recommended. The biofilter substrate should be replaced if it cannot be effectively disinfected. Biofilter systems should be thoroughly rinsed before re-stocking.

9. Husbandry and harvesting equipment

Aquaculture establishments will normally have a range of husbandry and harvesting equipment that come into close contact with *aquatic animals* and have potential to act as fomites. Examples include graders, automatic vaccinators and fish pumps.

The general principles described in Article 4.4.4. should be applied to *disinfection* of husbandry and harvesting equipment. Each item should be examined to identify areas that come into close contact with *aquatic animals* and where organic material accumulates. If required, equipment should be dismantled to allow adequate cleaning and application of *disinfectants*.

Article 4.4.10.

Personal equipment

Disinfection of personal equipment should consider the likelihood and degree of contamination associated with previous use. Where possible, personal equipment should be site specific to avoid the need for regular *disinfection*.

Equipment should be chosen which is non-absorbent and easy to clean. All staff entering a production area should use protective clothing that is clean and uncontaminated. On entry and exit of production areas boots should be cleaned and disinfected. When footbaths are used they should incorporate a cleaning procedure to remove accumulations of organic material and mud, be sufficiently deep to cover boots, use a *disinfectant* solution that is not inactivated by organic matter and be regularly refreshed with a new solution.

Some types of personal equipment such as dive equipment may require special attention because they are difficult to disinfect, may be moved from site to site and are often prone to chemical corrosion. Frequent rinsing of equipment will assist in reducing build-up of organic matter and make *disinfection* more efficient. Equipment should be allowed to dry thoroughly to ensure that moist microenvironments that may harbour *pathogenic agents* are minimised.

Article 4.4.11.

Disinfection of water

Aquaculture establishments may need to disinfect intake and effluent water to eliminate *pathogenic agents*. The most appropriate *disinfection* method will differ depending on the *disinfection* objective and the characteristics of the water to be disinfected.

Exclusion of *aquatic animals* and removal of suspended solids from the water to be treated are essential prior to the application of *disinfectants*. Pathogens are known to adhere to organic and inorganic matter and removal of suspended solids can significantly reduce loading of *pathogenic agents* in water. Removal of suspended solids can be achieved by filtration or settlement of suspended material. The most suitable filtration system will depend on the initial quality of water, volumes to be filtered, capital and operating costs and reliability.

Physical (e.g. UV irradiation) and chemical (e.g. ozone, chlorine and chlorine dioxide) *disinfectants* are commonly used to disinfect water. Suspended solids should be removed prior to the application of these *disinfectants* because organic matter may inhibit oxidative *disinfection* processes and suspended solids inhibit UV transmittance, reducing the efficacy of UV irradiation. A combination of methods may be beneficial where they are synergistic or where a level of redundancy is required.

It is essential to monitor the efficacy of water *disinfection*. This can be achieved by direct testing for *pathogenic agents* of concern, indirect monitoring of indicator organisms or monitoring of residual levels of *disinfectants*.

Management of chemical residues is important to avoid toxic effects on *aquatic animals*. For example, residuals formed between ozone and seawater such as bromide compounds are toxic to early life stages of *aquatic animals* and may be removed using charcoal filtration. Residual chlorine should be removed from water by chemical deactivation or off gassing.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 4.5.

RECOMMENDATIONS FOR SURFACE DISINFECTION OF SALMONID EGGS

Article 4.5.1.

Introduction

The practice of disinfecting salmonid *eggs* at hatcheries is an essential part of ensuring that *pathogenic agents* are not transferred between incubators and between facilities and forms a part of routine hatchery hygiene protocols. The *disinfection* process is also important for *international trade* in salmonid *eggs* between countries, *zones* or *compartments* 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, povidine-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 4.5.2.

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) rinse in pathogen-free 0.9% to 1.1.% saline (30-60 seconds) to remove organic matter; then

2) immerse in an iodophore solution containing 100 ppm available iodine for a minimum of 10 minutes. The iodophore concentration should be monitored to ensure effective levels are maintained. The ratio of *eggs* to iodophore solution should be a maximum of 1:4; then

3) rinse again in pathogen-free 0.9% to 1.1.% saline for 30-60 seconds; then

4) hold in pathogen-free water.

All rinsing and *disinfection* solutions should be prepared using pathogen free water. Iodophore solutions may be buffered using sodium bicarbonate ($NaHCO_3$) if the pH is low.

NB: FIRST ADOPTED IN 2015; MOST RECENT UPDATE ADOPTED IN 2017.

CHAPTER 4.6.

CONTINGENCY PLANNING

Article 4.6.1.

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 4.6.2.

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 4.6.3.

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 4.6.4.

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 4.6.5.

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 a WOAH 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 4.6.6.

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 4.6.7.

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.

NB: FIRST ADOPTED IN 2000.

CHAPTER 4.7.

FALLOWING IN AQUACULTURE

Article 4.7.1.

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 4.7.2.

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 4.7.3.

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 *vectors* 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 4.7.4.

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 4.4. 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 4.7.5.

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.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2016.

CHAPTER 4.8.

HANDLING, DISPOSAL AND TREATMENT OF AQUATIC ANIMAL WASTE

Article 4.8.1.

Introduction

The objective of this chapter is to provide guidance on storage, transport, disposal and treatment of *aquatic animal waste* 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 4.8.2.

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 4.8.3.

Definitions

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 4.8.4.

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 4.8.5.

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 *aquatic animal 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 or contaminated 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 4.4.

Article 4.8.6.

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 4.8.7.

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 *aquatic animal 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 waste* 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 4.8.8.

Methods of disposal for low risk waste

Low risk waste can be disposed of using all methods described in Article 4.8.7. 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 4.8.7.

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 4.8.9.

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 4.8.7. and 4.8.8.).

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

NB: FIRST ADOPTED IN 2010.

CHAPTER 4.9.

CONTROL OF PATHOGENIC AGENTS IN AQUATIC ANIMAL FEED

Article 4.9.1.

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 4.9.2.

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 4.9.3.

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 4.9.4.

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 4.9.5.

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 4.9.6.

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*.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2015.

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 WOAH 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 WOAH standards. *Importing countries* should align their requirements with the recommendations in the relevant standards of WOAH. If there are no such recommendations or if the country chooses a level of protection requiring measures more stringent than the standards of WOAH, 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 WOAH 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* appears in *aquatic animals* 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. The *Competent Authority* of the *importing country* should be informed of the result of the investigation because further action may be required if the source of the *infection* did not originate in the *exporting country*.

3) In case of suspicion, on reasonable grounds, that an *international aquatic animal health certificate* may be fraudulent, the *Competent Authorities* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country 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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2017.

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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2015.

CHAPTER 5.3.

WOAH 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 WOAH

The *Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS Agreement) specifically encourages the Members of the World Trade Organization (WTO) to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to implement *sanitary measures* more stringent than those in international standards, if these are deemed necessary to protect *aquatic animal* or human health and are scientifically justified by a *risk analysis*. In such circumstances, Members should adopt a consistent approach to *risk management*.

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

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

Article 5.3.2.

Introduction to the determination of the equivalence of sanitary measures

The importation of *aquatic animals* and *aquatic animal products* involves a degree of *risk* to *aquatic animal* and human health in an *importing country*. The estimation of that *risk* and the choice of the appropriate *risk management* options are made difficult by differences among the *aquatic animal* health management systems and *aquatic animal* production and processing systems in Member Countries. However, significantly different systems and measures may achieve equivalent *aquatic animal* and human health protection for the purposes of *international trade*.

The recommendations in this chapter are intended to assist Member Countries to determine whether *sanitary measures* arising from different systems achieve the same level of *aquatic animal* and human health protection. Principles are provided that may be utilised in a determination of equivalence, and outline a step-wise process for trading partners to follow. These provisions are applicable whether equivalence applies to specific measures, specific *commodities* or on a systems-wide basis.

Article 5.3.3.

General considerations on the determination of the equivalence of sanitary measures

Before trade in *aquatic animals* or their *products* occurs, an *importing country* should be assured that *aquatic animal* and human health in its *territory* will be appropriately protected. In most cases, the *risk management* measures adopted will rely in part on judgements made about the *aquatic animal* health management and *aquatic animal* production systems in the *exporting country* and the effectiveness of *sanitary measures* applied 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 in infrastructure, policies or operating procedures, laboratory systems, approaches to control of *diseases*, border security and internal movement controls.

If trading partners agree that the measures applied achieve the same level of health protection, these measures are considered equivalent. Benefits of applying equivalence may include:

1) minimising costs associated with *international trade* by allowing *sanitary measures* to be tailored 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 testing.

The *Aquatic Code* recognises equivalence by recommending alternative *sanitary measures* for many *diseases*. Equivalence may be achieved, 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 determination of equivalence, Member Countries should base their *sanitary measures* on the WOAH standards and guidelines.

Member Countries should use *risk analysis* to establish the basis for a determination of equivalence.

Article 5.3.4.

Prerequisite considerations for the determination of equivalence

1. Application of risk assessment

Risk assessment provides a structured basis for judging equivalence among different *sanitary measures* as it allows a comparison of the effect of a measure on a particular step in the importation pathway with the effect of a proposed alternative measure.

A determination of equivalence should compare the effectiveness of the *sanitary measures* against the particular *risk* or group of *risks* against which they are designed to protect.

2. Categorisation of sanitary measures

Proposals for equivalence may consider a single component (e.g. an isolation or sampling procedure, a test or treatment requirement, a certification procedure) or multiple components (e.g. a production system for a *commodity*) of a *sanitary measure*, or a combination of *sanitary measures*. *Sanitary measures* may be applied consecutively or concurrently.

Sanitary measures are described in each disease-specific chapter of the *Aquatic Code* to manage the *risk* posed by that *disease*.

For the purposes of determining 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 the *Competent Authority*);
b) programme design and 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. ELISA) and procedures (e.g. pre-export inspection).

Sanitary measures proposed for a determination of equivalence may fall into one or more of these categories, which are not mutually exclusive.

In some cases, such as a method for inactivation of *pathogenic agents*, a comparison of specific technical requirements may suffice. In many instances, however, assessment of whether the same level of protection will be achieved may only be determined through an evaluation of all relevant components of an *exporting country*'s *aquatic animal* health management systems and *aquatic animal* production systems.

Article 5.3.5.

Principles for determination of equivalence

Determination 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 in relation to human and animal life and health in its *territory*; this 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 *risk*;
3) an *importing country* should recognise that *sanitary measures* different from the ones it has proposed may be capable of achieving the same level of protection; in particular, it should consider the existence of *free zones* or *free compartments*, and of safe *aquatic animal products*;
4) the *importing country* should, upon request, consult with the *exporting country* with the aim of facilitating a determination of equivalence;
5) any *sanitary measure* or combination of *sanitary measures* can be proposed for determination 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, to minimise administrative burden, and to facilitate resolution of claims;
7) the *exporting country* should be able to demonstrate objectively how the alternative *sanitary measures* 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 determination 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 *importing country* should take into account any arrangements it has with other *exporting countries* on similar issues;
12) the *importing country* may also take into account any knowledge of the *exporting country*'s arrangements with other *importing countries*;
13) the *exporting country* should, upon request, provide the *importing country* access to information on the procedures or systems that are the subject of the equivalence determination;
14) the *importing country* should be the sole judge of equivalence, but should provide to the *exporting country* a full explanation for its judgement;
15) to facilitate a determination of equivalence, Member Countries should base their *sanitary measures* on relevant WOAH standards and guidelines, where these exist. However, they may choose to implement more stringent *sanitary measures* if these are scientifically justified by a *risk analysis*;
16) to allow the determination 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 that may bear on the determination of equivalence; and
17) appropriate technical assistance from an *importing country*, following a request by an *exporting country*, may facilitate the successful completion of a determination of equivalence.

Article 5.3.6.

Sequence of steps to be taken in determination of equivalence

There is no single sequence of steps that should be followed in all determinations of equivalence. The steps that trading partners choose will generally depend on the circumstances and their trading experience. Nevertheless, the interactive sequence of steps described below may be useful for assessing any *sanitary measures* irrespective of their categorisation as infrastructure, programme design and implementation or specific technical requirement components of an *aquatic animal* health management system or *aquatic animal* 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 for which it wishes to propose an alternative 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 *risk*;
2) the *importing country* explains the reason for the measure in terms that would facilitate comparison with an alternative *sanitary measure* and consistent with the principles set out in these provisions;
3) the *exporting country* demonstrates the case for equivalence of an alternative *sanitary measure* in a form that facilitates evaluation by an *importing country*;

4) the *exporting country* responds to any technical concerns raised by the *importing country* by providing relevant further information;

5) determination of equivalence by the *importing country* should take into account as appropriate:
   a) the impact of biological variability and uncertainty;
   b) the expected effect of the alternative *sanitary measure*;
   c) WOAH standards and guidelines;
   d) the results of a *risk assessment*;
6) the *importing country* notifies the *exporting country* of its judgement and its reasons within a reasonable period of time. The judgement:
   a) recognises the equivalence of the *exporting country*'s alternative *sanitary measure*; or
   b) requests further information; or
   c) rejects the case for equivalence of the alternative *sanitary measure*;
7) an attempt should be made to resolve any differences of opinion over judgement of a case by using an agreed mechanism such as the WOAH informal procedure for dispute mediation (Article 5.3.8.);
8) depending on the category of measures involved, the *importing country* and the *exporting country* may informally acknowledge the equivalence or enter into a formal agreement of equivalence giving effect to the judgement.

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

Article 5.3.7.

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

The terms 'zone' and 'zoning' in the *Aquatic Code* have the same meaning as 'region', 'area' and 'regionalisation' in the SPS Agreement of the WTO.

The requirements for establishing a *zone* or a *compartment* declared free of a *disease* are described in Chapter 4.2. and in each disease-specific and should be considered by trading partners when establishing *sanitary measures* for trade. The requirements include:

1. For zoning
   a) The *exporting country* identifies a geographical area within its *territory*, which, based on *surveillance*, it considers to contain an *aquatic animal subpopulation* with a distinct health status with respect to a specific *disease*.
   b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures applied to distinguish such an area epidemiologically from other parts of its *territory*, in accordance with the recommendations in the *Aquatic Code*.
   c) Upon request, the *exporting country* provides to the *importing country*:
      i) an explanation of why the area, as described in points a) and b) above, can be treated as an epidemiologically separate *zone* for *international trade* purposes;
      ii) access to information on the procedures or systems that establish the *zone*.
   d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *aquatic animals* or *aquatic animal products*, taking into account:
      i) an evaluation of the *exporting country*'s *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* concerned; and
      iv) other relevant WOAH standards or guidelines.

e) The *importing country* notifies the *exporting country* of its judgement and its 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 such as the WOAH 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 an 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, and other premises operating under common management practices and *biosecurity plan*. The *compartment* contains an identifiable *aquatic animal subpopulation* with a distinct health status with respect to a specific *disease*. 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 the *disease* in question.

c) The *exporting country* describes the *compartment*, in accordance with Chapters 4.2. and 4.3.

d) Upon request, the *exporting country* provides to the *importing country*:
   i) an explanation of why such a *subpopulation*, as described in points a) and b) above, can be treated as an epidemiologically separate *compartment* for *international trade* purposes; and
   ii) access to information on the procedures or systems that establish the *compartment*.

e) The *importing country* determines whether it accepts such a *subpopulation* as a *compartment* for the importation of *aquatic animals* or *aquatic animal products*, taking into account:
   i) an evaluation of the *exporting country*'s *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 WOAH standards or guidelines.

f) The *importing country* notifies the *exporting country* of its judgement and its 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 such as the WOAH 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 an agreement recognising the *compartment*.

Article 5.3.8.

The WOAH informal procedure for dispute mediation

WOAH maintains a voluntary in-house mechanism for assisting Member Countries to resolve differences. In-house procedures that will apply are that:

1) Both parties agree to give WOAH a mandate to assist them in resolving their differences.

2) If considered appropriate, the Director General of WOAH 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 WOAH.

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 submit a confidential report to the Director General of WOAH, who then transmits it to both parties.

NB: FIRST ADOPTED IN 2013; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 5.4.

CRITERIA TO ASSESS THE SAFETY OF AQUATIC ANIMAL COMMODITIES

Preamble: 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 animal products imported or transited for any purpose regardless of the disease X status of the exporting country, zone or compartment

Point 1 of Article X.X.3. of all disease-specific chapters (Sections 8-11) lists *aquatic animal products* that can be imported or transited for any purpose regardless of the *disease* X status of the *exporting country*, *zone* or *compartment*. The criteria for inclusion of *aquatic animal products* in point 1 of Article X.X.3. are based on the absence of the *pathogenic agent* in the *aquatic animal product* or inactivation of the *pathogenic agent* by treatment or processing.

The assessment of the safety of the *aquatic animal product* 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 prior to importation (i) is done by using 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 and transport of the *aquatic animal product* do not jeopardise the safety of the traded *aquatic animal product*.

Criteria

For an *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 product*:

   a) There is strong evidence that the *pathogenic agent* is not present in the tissues from which the *aquatic animal product* is derived.

   AND

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

OR

2) Even if the *pathogenic agent* is present in, or contaminates the tissues from which the *aquatic animal product* is derived, the treatment or processing methods to produce the *aquatic animal product* inactivate the *pathogenic agent* such as:

   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 animal products imported or transited for retail trade for human consumption regardless of the disease X status of the exporting country, zone or compartment

Point 1 of Article X.X.14. and Article 10.4.16. lists *aquatic animal products* for retail trade for human consumption. The criteria for inclusion of *aquatic animal products* in point 1 of Article X.X.14. and Article 10.4.16. include consideration of the form and presentation of the product, the expected volume of *aquatic animal waste* generated by the consumer and the likely presence of viable *pathogenic agent* in the *aquatic animal waste*.

For the purposes of this criterion retail means the selling or provision of the *aquatic animal product* directly to the consumer with the intended purpose of human consumption. The retail pathway may also include wholesale distribution of the *aquatic animal 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 animal products* are used for human consumption only; (ii) *aquatic animal 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 *aquatic animal 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 animal product* prior to importation do not jeopardise the safety of the *aquatic animal products*.

Criteria

For *aquatic animal products* to be considered safe for *international trade* under the provisions of point 1 of Article X.X.14. and Article 10.4.16., it should comply with the following criteria:

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

EITHER

2) it includes an amount of raw *aquatic animal waste* generated by the consumer that is unlikely to result in the introduction and establishment of the *pathogenic agent*;

OR

3) the *pathogenic agent* is not normally found in the *aquatic animal waste* generated by the consumer.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2018.

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 WOAH 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*.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2010.

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 WOAH (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*.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2004.

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.

NB: FIRST ADOPTED IN 1995.

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 WOAH *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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 1997.

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 *aquatic animal products* 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*.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

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 dispatch;

   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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2010.

CHAPTER 5.11.

MODEL HEALTH CERTIFICATES FOR INTERNATIONAL TRADE IN LIVE AQUATIC ANIMALS AND AQUATIC ANIMAL PRODUCTS

Article 5.11.1.

Notes for guidance on the health certificates for international trade in live aquatic animals and aquatic animal products

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 aquatic animal products: 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 aquatic animal product (single or multiple), whether processed, semi-processed or raw, that is intended to be fed to aquatic animals.
	Further processing: applies to aquatic animal products 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 aquatic animal products: 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:

<table>
<tr><td rowspan="8">Part I: Details of dispatched consignment</td><td rowspan="2">I.1. Consignor:
Name:
Address:</td><td>I.2. Certificate reference number:</td></tr>
<tr><td>I.3. Competent Authority:</td></tr>
<tr><td colspan="2">I.4. Consignee:
Name:
Address:</td></tr>
<tr><td>I.5. Country of origin:
ISO Code*:</td><td>I.6. Zone or compartment of origin**:</td></tr>
<tr><td>I.7. Country of destination:
ISO Code*:</td><td>I.8. Zone or compartment of destination**:</td></tr>
<tr><td colspan="2">I.9. Place of origin:
Name:
Address:</td></tr>
<tr><td>I.10. Place of shipment:</td><td>I.11. Date of departure:</td></tr>
<tr><td rowspan="11"></td><td rowspan="2">I.12. Means of transport:

Aeroplane □ Ship □ Railway wagon □

Road vehicle □ Other □

Identification:</td><td>I.13. Expected border post:</td></tr>
<tr><td>I.14. CITES permit No(s)**:</td></tr>
<tr><td rowspan="2">I.15. Description of commodity:</td><td>I.16. Commodity code (ISO code):</td></tr>
<tr><td>I.17. Total quantity:</td></tr>
<tr><td>I.18.</td><td>I.19. Total number of packages:</td></tr>
<tr><td>I.20. Identification of container/seal number:</td><td>I.21. Type of packaging:</td></tr>
<tr><td colspan="2">I.22. Commodities intended for use as:

Breeding □ Grow out □

Slaughter □ Restocking □

Ornamental □ Competition/exhibition □

Other □ If other, specify.</td></tr>
<tr><td colspan="2">I.23. For import or admission:

Definitive import □ Re-entry □ Temporary admission □</td></tr>
<tr><td colspan="2">I.24. Identification of commodities:

Amphibian □ Crustacean □

Fish □ Mollusc □</td></tr>
<tr><td>Wild stock □</td><td>Cultured stock □</td></tr>
<tr><td>Species (scientific name):

Identification system*:

Sex*:</td><td>Age*:

Batch number*:</td></tr>
</table>

* Optional. ** If referenced in Part II.

COUNTRY:

Part II: Zoosanitary information		II.a. Certificate reference number:
	The undersigned Certifying Official certifies that the animal(s)/gametes described above satisfy(ies) the following requirements:	
	Certifying Official:	
	Name and address (in capital letters):	Official position:
	Date:	Signature:
	Stamp:	

Article 5.11.3.

Model health certificate for international trade in aquatic animal products

COUNTRY:

<table>
<tr><td rowspan="10">Part I: Details of dispatched consignment</td><td rowspan="2">I.1. Consignor:
Name:
Address:</td><td>I.2. Certificate reference number:</td></tr>
<tr><td>I.3. Competent Authority:</td></tr>
<tr><td colspan="2">I.4. Consignee:
Name:
Address:</td></tr>
<tr><td>I.5. Country of origin:
ISO Code*:</td><td>I.6. Zone or compartment of origin**:</td></tr>
<tr><td>I.7. Country of destination:
ISO Code*:</td><td>I.8. Zone or compartment of destination**:</td></tr>
<tr><td colspan="2">I.9. Place of origin:
Name:
Address:</td></tr>
<tr><td>I.10. Place of shipment:</td><td>I.11. Date of departure:</td></tr>
<tr><td rowspan="2">I.12. Means of transport:

Aeroplane □ Ship □ Railway wagon □

Road vehicle □ Other □

Identification:</td><td>I.13. Expected border post:</td></tr>
<tr><td>I.14. CITES permit No(s)**:</td></tr>
<tr><td rowspan="2">I.15. Description of commodity:</td><td>I.16. Commodity code (ISO code):</td></tr>
<tr><td>I.17. Total quantity/weight:</td></tr>
<tr><td>I.18. Temperature of the product:
Ambient □ Chilled □ Frozen □</td><td>I.19. Total number of packages:</td></tr>
<tr><td>I.20. Identification of container/seal number:</td><td>I.21. Type of packages:</td></tr>
<tr><td colspan="2">I.22. Commodities intended for use as:

Human consumption □ Aquatic animal feed □
Further processing □ Other technical use □
Other □ If other, specify. Technical use in aquatic animals □ If technical use, specify:</td></tr>
<tr><td colspan="2">I.23.</td></tr>
<tr><td colspan="2">I.24. Identification of commodities:

Amphibian □ Crustacean □
Fish □ Mollusc □</td></tr>
<tr><td>Wild stock □</td><td>Cultured stock □</td></tr>
<tr><td>Species (scientific name):</td><td>Approval number of establishments:</td></tr>
<tr><td colspan="2">Lot ID/date code:</td></tr>
</table>

* Optional.

** If referenced in Part II.

COUNTRY:

Part II: Zoosanitary information		II.a. Certificate reference number:
	The undersigned Certifying Official certifies that the aquatic animal product(s) described above satisfy(ies) the following requirements:	
	Certifying Official:	
	Name and address (in capital letters):	Official position:
	Date:	Signature:
	Stamp:	

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

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. WOAH recognises the need for access to *antimicrobial agents* in veterinary medicine: *antimicrobial agents* are essential for treating and controlling infectious *diseases* in *aquatic animals*. WOAH therefore considers that ensuring continued access to effective *antimicrobial agents* is important.

WOAH 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, WOAH 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.

NB: FIRST ADOPTED IN 2010; MOST RECENT UPDATE ADOPTED IN 2011.

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.

NB: FIRST ADOPTED IN 2011.

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 publicly 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 or farm level, and at the level of the individual *veterinarian* or other *aquatic animal health professional*.

NB: FIRST ADOPTED IN 2012.

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 6.8. of the *Terrestrial Animal Health Code* should be consulted.

It is important to note that the word 'commensal' as used in Chapter 6.8. of the *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*.

NB: FIRST ADOPTED IN 2012.

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 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 *aquatic animal waste*.

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 *aquatic animal waste* and the likelihood for human exposure to resistant microorganisms or resistance determinants through those *aquatic animal waste*;

– 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 WOAH 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 *aquatic animal waste*.

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 *aquatic animal waste* 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 WOAH 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.

NB: FIRST ADOPTED IN 2015.

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) WOAH 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 WOAH recommendations therefore address the welfare of farmed fish at a general level.

NB: FIRST ADOPTED IN 2008.

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 transport

1. 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, $CO_2$and NH_3 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.

NB: FIRST ADOPTED IN 2009; MOST RECENT UPDATE ADOPTED IN 2012.

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 WOAH 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 CO_2 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 (CO_2) in holding water; chilling with ice and CO_2 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.

NB: FIRST ADOPTED IN 2010; MOST RECENT UPDATE ADOPTED IN 2012.

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*: 4.6. Contingency planning; Chapter 4.8. 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 4.6.).
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 4.8.

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.

NB: FIRST ADOPTED IN 2012; MOST RECENT UPDATE ADOPTED IN 2013.

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 *pathogenic agent Batrachochytrium dendrobatidis* of the Division Chytridiomycota and Order Rhizophydiales.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 8.1.2.

Scope

The recommendations in this chapter apply to: all species of the Orders 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.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *B. dendrobatidis* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *B. dendrobatidis*, regardless of the infection with *B. dendrobatidis* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least five minutes, or a time/temperature equivalent that inactivates *B. dendrobatidis*;
2) amphibian skin leather.

Article 8.1.4.

Requirements for self-declaration of freedom from infection with *B. dendrobatidis*

A Member Country may make a self-declaration of freedom from infection with *B. dendrobatidis* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 8.1.5. to 8.1.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 8.1.5.

Country free from infection with *B. dendrobatidis*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. dendrobatidis* if all shared water bodies are within countries or *zones* declared free from infection with *B. dendrobatidis* (see Article 8.1.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. dendrobatidis* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. dendrobatidis* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. dendrobatidis*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. dendrobatidis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *B. dendrobatidis* and subsequently lost its free status due to the detection of *B. dendrobatidis* but the following conditions have been met:
   a) on detection of *B. dendrobatidis*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. dendrobatidis*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. dendrobatidis*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *B. dendrobatidis*; or
      ii) at least the last [one] year without detection of *B. dendrobatidis* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 8.1.6.

Zone free from infection with *B. dendrobatidis*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *B. dendrobatidis* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. dendrobatidis* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. dendrobatidis* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. dendrobatidis*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *B. dendrobatidis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *B. dendrobatidis* and subsequently lost its free status due to the detection of *B. dendrobatidis* in the *zone* but the following conditions have been met:

   a) on detection of *B. dendrobatidis*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. dendrobatidis*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. dendrobatidis*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. dendrobatidis*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 8.1.7.

Compartment free from infection with *B. dendrobatidis*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. dendrobatidis* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *B. dendrobatidis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *B. dendrobatidis* and subsequently lost its free status due to the detection of *B. dendrobatidis* in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. dendrobatidis*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 8.1.9. and 8.1.10. as appropriate; and

   c) one survey for infection with *B. dendrobatidis* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 8.1.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *B. dendrobatidis* following the provisions of Articles 8.1.4. to 8.1.7. (as relevant) may maintain its status as free from infection with *B. dendrobatidis* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 8.1.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *B. dendrobatidis*

When importing *aquatic animals* of a species referred to in Article 8.1.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 8.1.5., 8.1.6. or 8.1.7. (as applicable) and 8.1.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *B. dendrobatidis*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 8.1.3.

Article 8.1.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 8.1.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *B. dendrobatidis* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) in the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *B. dendrobatidis*;
    b) in the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for *B. dendrobatidis* in accordance with Chapter 1.4. to determine their suitability as broodstock;
        iii) produce a first generation (F-1) population in *quarantine*;
        iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *B. dendrobatidis*, and sample and test for

B. dendrobatidis in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.1.1. of the *Aquatic Manual*;

v) if *B. dendrobatidis* is not detected in the F-1 population, it may be defined as free from infection with *B. dendrobatidis* and may be released from *quarantine*;

vi) if *B. dendrobatidis* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 8.1.11.

Importation of aquatic animals or 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* of a species referred to in Article 8.1.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 8.1.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. dendrobatidis* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *B. dendrobatidis* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 8.1.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *B. dendrobatidis*

When importing *aquatic animals* of a species referred to in Article 8.1.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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 is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in point 1 of Article 8.1.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. dendrobatidis* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *B. dendrobatidis* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 8.1.13.

Importation of 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, *aquatic animals* of a 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 consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. dendrobatidis* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *B. dendrobatidis* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 8.1.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *B. dendrobatidis* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *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* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) amphibian meat (skin off and fresh or frozen).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 8.2.

INFECTION WITH *BATRACHOCHYTRIUM SALAMANDRIVORANS*

Article 8.2.1.

For the purposes of the *Aquatic Code*, infection with *Batrachochytrium salamandrivorans* means *infection* with the *pathogenic agent Batrachochytrium salamandrivorans*, of the Division Chytridiomycota and Order Rhizophydiales.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 8.2.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: [alpine newt *(Ichthyosaura alpestris)*, blue-tailed fire-bellied newt *(Cynops cyanurus)*, fire salamander *(Salamandra salamandra)*, eastern newt *(Nothophthalmus viridescens)*, French cave salamander *(Hydromantes strinatii)*, Italian newt *(Lissotriton italicus)*, yellow spotted newt *(Neurergus crocatus)*, Japanese fire-bellied newt *(Cynops pyrrhogaster)*, northern spectacle salamander *(Salamandrina perspicillata)*, Tam Dao salamander *(Paramesotriton deloustali)*, rough-skinned newt *(Taricha granulosa)*, sardinian brook salamander *(Euproctus platycephalus)* and Spanish ribbed newt *(Pleurodeles waltl)*] (under study).

Article 8.2.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *B. salamandrivorans* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *B. salamandrivorans*, regardless of the infection with *B. salamandrivorans* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least five minutes, or a time/temperature equivalent that inactivates *B. salamandrivorans*;

2) amphibian skin leather.

Article 8.2.4.

Requirements for self-declaration of freedom from infection with *B. salamandrivorans*

A Member Country may make a self-declaration of freedom from infection with *B. salamandrivorans* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 8.2.5. to 8.2.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 8.2.5.

Country free from infection with *B. salamandrivorans*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. salamandrivorans* if all shared water bodies are within countries or *zones* declared free from infection with *B. salamandrivorans* (see Article 8.2.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. salamandrivorans* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. salamandrivorans* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. salamandrivorans*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. salamandrivorans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *B. salamandrivorans* and subsequently lost its free status due to the detection of *B. salamandrivorans* but the following conditions have been met:
   a) on detection of *B. salamandrivorans*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. salamandrivorans*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. salamandrivorans*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *B. salamandrivorans*; or
      ii) at least the last [one] year without detection of *B. salamandrivorans* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 8.2.6.

Zone free from infection with *B. salamandrivorans*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *B. salamandrivorans* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. salamandrivorans* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. salamandrivorans* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. salamandrivorans*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *B. salamandrivorans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *B. salamandrivorans* and subsequently lost its free status due to the detection of *B. salamandrivorans* in the *zone* but the following conditions have been met:

   a) on detection of *B. salamandrivorans*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. salamandrivorans*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. salamandrivorans*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. salamandrivorans*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 8.2.7.

Compartment free from infection with *B. salamandrivorans*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. salamandrivorans* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *B. salamandrivorans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *B. salamandrivorans* and subsequently lost its free status due to the detection of *B. salamandrivorans* in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. salamandrivorans*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 8.2.9. and 8.2.10. as appropriate; and

   c) one survey for infection with *B. salamandrivorans* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 8.2.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *B. salamandrivorans* following the provisions of Articles 8.2.4. to 8.2.7. (as relevant) may maintain its status as free from infection with *B. salamandrivorans* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 8.2.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *B. salamandrivorans*

When importing *aquatic animals* of a species referred to in Article 8.2.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with *B. salamandrivorans*, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 8.2.5., 8.2.6.or 8.2.7. (as applicable) and 8.2.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *B. salamandrivorans*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 8.2.3.

Article 8.2.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *B. salamandrivorans*

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 8.2.2. from a country, *zone* or *compartment* not declared free from infection with *B. salamandrivorans*, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below:

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 8.2.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *B. salamandrivorans* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) in the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *B. salamandrivorans*;
   b) in the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for *B. salamandrivorans* in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *B. salamandrivorans*, and sample and test for

B. salamandrivorans in accordance with Chapter 1.4. of the *Aquatic Code* and in Chapter 2.2. of the *Aquatic Manual*;

v) if *B. salamandrivorans* is not detected in the F-1 population, it may be defined as free from infection with *B. salamandrivorans* and may be released from *quarantine*;

vi) if *B. salamandrivorans* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 8.2.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *B. salamandrivorans*

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 8.2.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with *B. salamandrivorans*, 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 processed into one of the products referred to in point 1 of Article 8.2.3. or in point 1 of Article 8.2.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. salamandrivorans* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *B. salamandrivorans* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 8.2.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *B. salamandrivorans*

When importing *aquatic animals* of a species referred to in Article 8.2.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with *B. salamandrivorans*, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in point 1 of Article 8.2.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. salamandrivorans* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *B. salamandrivorans* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 8.2.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *B. salamandrivorans*

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 8.2.2. from a country, *zone* or *compartment* not declared free from infection with *B. salamandrivorans*, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. salamandrivorans* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *B. salamandrivorans* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 8.2.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *B. salamandrivorans* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *B. salamandrivorans*, regardless of the infection with *B. salamandrivorans* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) amphibian meat (skin off and fresh or frozen).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 8.2.2. from a country, *zone* or *compartment* not declared free from infection with *B. salamandrivorans*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2018; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 8.3.

INFECTION WITH *RANAVIRUS* SPECIES

Article 8.3.1.

For the purposes of the *Aquatic Code*, infection with *Ranavirus* species means *infection* with any species of the Genus *Ranavirus* and Family *Iridoviridae* in amphibians.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 8.3.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: all species of the Orders Anura (frogs and toads) and Caudata (salamanders and newts).

Article 8.3.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *Ranavirus* species status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *Ranavirus* species, regardless of the infection with *Ranavirus* species status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 30 minutes, or a time/temperature equivalent that inactivates *Ranavirus* species.

Article 8.3.4.

Requirements for self-declaration of freedom from infection with *Ranavirus* species

A Member Country may make a self-declaration of freedom from infection with *Ranavirus* species for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 8.3.5. to 8.3.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 8.3.5.

Country free from infection with *Ranavirus* species

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *Ranavirus* species if all shared water bodies are within countries or *zones* declared free from infection with *Ranavirus* species (see Article 8.3.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *Ranavirus* species for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 8.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with *Ranavirus* species for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *Ranavirus* species, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *Ranavirus* species, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *Ranavirus* species and subsequently lost its free status due to the detection of *Ranavirus* species but the following conditions have been met:
   a) on detection of *Ranavirus* species, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *Ranavirus* species, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *Ranavirus* species; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *Ranavirus* species; or
      ii) at least the last [one] year without detection of *Ranavirus* species if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 8.3.6.

Zone free from infection with *Ranavirus* species

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *Ranavirus* species if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *Ranavirus* species for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 8.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with *Ranavirus* species for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *Ranavirus* species, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *Ranavirus* species, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *Ranavirus* species and subsequently lost its free status due to the detection of *Ranavirus* species in the *zone* but the following conditions have been met:
   a) on detection of *Ranavirus* species, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *Ranavirus* species, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *Ranavirus* species; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *Ranavirus* species.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 8.3.7.

Compartment free from infection with *Ranavirus* species

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *Ranavirus* species for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *Ranavirus* species, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *Ranavirus* species and subsequently lost its free status due to the detection of *Ranavirus* species in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *Ranavirus* species, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 8.3.9. and 8.3.10. as appropriate; and
   c) one survey for infection with *Ranavirus* species has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 8.3.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *Ranavirus* species following the provisions of Articles 8.3.4. to 8.3.7. (as relevant) may maintain its status as free from infection with *Ranavirus* species provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 8.3.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *Ranavirus* species

When importing *aquatic animals* of a species referred to in Article 8.3.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with *Ranavirus* species, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 8.3.5., 8.3.6. or 8.3.7. (as applicable) and 8.3.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *Ranavirus* species.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 8.3.3.

Article 8.3.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *Ranavirus* species

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 8.3.2. from a country, *zone* or *compartment* not declared free from infection with *Ranavirus* species, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 8.3.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *Ranavirus* species in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) in the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *Ranavirus* species;
    b) in the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for *Ranavirus* species in accordance with Chapter 1.4. to determine their suitability as broodstock;
        iii) produce a first generation (F-1) population in *quarantine*;
        iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *Ranavirus* species, and sample and test for *Ranavirus* species in accordance with Chapter 1.4.of the *Aquatic Code* and Chapter 2.1.3. of the *Aquatic Manual*;
        v) if *Ranavirus* species are not detected in the F-1 population, it may be defined as free from infection with *Ranavirus* species and may be released from *quarantine*;
        vi) if *Ranavirus* species are detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 8.3.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *Ranavirus* species

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 8.3.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with

Ranavirus species, 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 8.3.3. or in point 1 of Article 8.3.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *Ranavirus* species or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *Ranavirus* species or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 8.3.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *Ranavirus* species

When importing *aquatic animals* of a species referred to in Article 8.3.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with *Ranavirus* species, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in point 1 of Article 8.3.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *Ranavirus* species or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *Ranavirus* species or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 8.3.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *Ranavirus* species

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 8.3.2. from a country, *zone* or *compartment* not declared free from infection with *Ranavirus* species, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *Ranavirus* species or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *Ranavirus* species or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 8.3.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *Ranavirus* species status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *Ranavirus* species, regardless of the infection with *Ranavirus* species status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) no *aquatic animal products* listed.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 8.3.2. from a country, *zone* or *compartment* not declared free from infection with *Ranavirus* species, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2024.

SECTION 9.

DISEASES OF CRUSTACEANS

CHAPTER 9.1.

ACUTE HEPATOPANCREATIC NECROSIS DISEASE

Article 9.1.1.

For the purposes of the *Aquatic Code*, acute hepatopancreatic necrosis disease (AHPND) means *infection* with strains of *Vibrio parahaemolyticus* (Vp_{AHPND}), of the Family Vibrionaceae, that contain a ~70-kbp plasmid with genes that encode homologues of the *Photorhabdus* insect-related (Pir) toxins, PirA and PirB.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.1.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: giant tiger prawn *(Penaeus monodon)* and whiteleg shrimp *(Penaeus vannamei)*.

Article 9.1.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the AHPND status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to AHPND, regardless of the AHPND status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least 60 seconds, or a time/temperature equivalent that inactivates Vp_{AHPND};
2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least 60 seconds, or a time/temperature equivalent that inactivates Vp_{AHPND};
3) crustacean oil;
4) chemically extracted chitin.

Article 9.1.4.

Requirements for self-declaration of freedom from infection with AHPND

A Member Country may make a self-declaration of freedom from infection with AHPND for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.1.5. to 9.1.8., as relevant. The self-declaration of

freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.1.5.

Country free from infection with AHPND

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with AHPND if all shared water bodies are within countries or *zones* declared free from infection with AHPND (see Article 9.1.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with AHPND for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of AHPND for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with AHPND, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of AHPND, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with AHPND and subsequently lost its free status due to the detection of AHPND but the following conditions have been met:
   a) on detection of AHPND, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of AHPND, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with AHPND; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of AHPND; or
      ii) at least the last [one] year without detection of AHPND if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.1.6.

Zone free from infection with AHPND

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with AHPND if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with AHPND for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with AHPND for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with AHPND, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of AHPND, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with AHPND and subsequently lost its free status due to the detection of AHPND in the *zone* but the following conditions have been met:
   a) on detection of AHPND, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of AHPND, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with AHPND; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of AHPND.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.1.7.

Compartment free from infection with AHPND

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with AHPND for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of AHPND, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with AHPND and subsequently lost its free status due to the detection of AHPND in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of AHPND, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.1.9. and 9.1.10. as appropriate; and
   c) one survey for infection with AHPND has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.1.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with AHPND following the provisions of Articles 9.1.4. to 9.1.7. (as relevant) may maintain its status as free from infection with AHPND provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.1.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from AHPND

When importing *aquatic animals* of a species referred to in Article 9.1.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from AHPND, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.1.5., 9.1.6. or 9.1.7. (as applicable) and 9.1.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from AHPND.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.1.3.

Article 9.1.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from AHPND

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.1.2. from a country, *zone* or *compartment* not declared free from AHPND, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.1.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate Vp_{AHPND} in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for AHPND.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for Vp_{AHPND} in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of AHPND, and sample and test for Vp_{AHPND} in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.1. of the *Aquatic Manual*;

v) if Vp_{AHPND} is not detected in the F-1 population, it may be defined as free from AHPND and may be released from *quarantine*;

vi) if Vp_{AHPND} is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.1.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from AHPND

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.1.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from AHPND, 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 Article 9.1.3. or in point 1 of Article 9.1.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of Vp_{AHPND} or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of Vp_{AHPND} or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.1.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from AHPND

When importing *aquatic animals* of a species referred to in Article 9.1.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from AHPND, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.1.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of Vp_{AHPND} or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of Vp_{AHPND} or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.1.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from AHPND

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.1.2. from a country, *zone* or *compartment* not declared free from AHPND, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of Vp_{AHPND} or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of Vp_{AHPND} or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.1.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the AHPND status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to Vp_{AHPND}, regardless of the AHPND status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.1.2. from a country, *zone* or *compartment* not declared free from AHPND, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2017; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.2.

INFECTION WITH *APHANOMYCES ASTACI* (CRAYFISH PLAGUE)

Article 9.2.1.

For the purposes of the *Aquatic Code*, infection with *Aphanomyces astaci* means *infection* with the *pathogenic agent Aphanomyces astaci*, of the Family Leptolegniaceae, Phylum Oomycota (water moulds). The *disease* is commonly known as crayfish plague.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.2.2.

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 9.2.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the *A. astaci* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *A. astaci*, regardless of the infection with *A. astaci* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least 60 seconds, or a time/temperature equivalent that inactivates *A. astaci*;
2) frozen crayfish products that have been subjected to minus 20°C or lower temperatures for at least 72 hours;
3) crayfish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least 60 seconds, or a time/temperature equivalent that inactivates *A. astaci*;
4) crayfish oil;
5) chemically extracted chitin.

Article 9.2.4.

Requirements for self-declaration of freedom from infection with *A. astaci*

A Member Country may make a self-declaration of freedom from infection with *A. astaci* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.2.5. to 9.2.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.2.5.

Country free from infection with *A. astaci*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *A. astaci* if all shared water bodies are within countries or *zones* declared free from infection with *A. astaci* (see Article 9.2.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *A. astaci* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *A. astaci* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. astaci*, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *A. astaci*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *A. astaci* and subsequently lost its free status due to the detection of *A. astaci* but the following conditions have been met:

   a) on detection of *A. astaci*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *A. astaci*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *A. astaci*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *A. astaci*; or

      ii) at least the last [one] year without detection of *A. astaci* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.2.6.

Zone free from infection with *A. astaci*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *A. astaci* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *A. astaci* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *A. astaci* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. astaci*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *A. astaci*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *A. astaci* and subsequently lost its free status due to the detection of *A. astaci* in the *zone* but the following conditions have been met:

   a) on detection of *A. astaci*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *A. astaci*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *A. astaci*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *A. astaci*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.2.7.

Compartment free from infection with *A. astaci*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *A. astaci* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of *A. astaci*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *A. astaci* and subsequently lost its free status due to the detection of *A. astaci* in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *A. astaci*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.2.9. and 9.2.10. as appropriate; and

   c) one survey for infection with *A. astaci* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.2.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *A. astaci* following the provisions of Articles 9.2.4. to 9.2.7. (as relevant) may maintain its status as free from infection with *A. astaci* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.2.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *A. astaci*

When importing *aquatic animals* of a species referred to in Article 9.2.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with *A. astaci*, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.2.5., 9.2.6. or 9.2.7. (as applicable) and 9.2.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *A. astaci*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.2.3.

Article 9.2.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *A. astaci*

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.2.2. from a country, *zone* or *compartment* not declared free from infection with *A. astaci*, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.2.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *A. astaci* in accordance with Chapters 4.4., 4.8. and 5.5.
2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *A. astaci*.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for *A. astaci* in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *A. astaci*, and sample and test for *A. astaci* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.2. of the *Aquatic Manual*;
      v) if *A. astaci* is not detected in the F-1 population, it may be defined as free from infection with *A. astaci* and may be released from *quarantine*;
      vi) if *A. astaci* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.2.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *A. astaci*

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.2.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with *A. astaci*, 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 Article 9.2.3. or in point 1 of Article 9.2.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *A. astaci* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *A. astaci* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.2.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *A. astaci*

When importing *aquatic animals* of a species referred to in Article 9.2.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with *A. astaci*, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.2.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *A. astaci* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *A. astaci* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.2.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *A. astaci*

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.2.2. from a country, *zone* or *compartment* not declared free from infection with *A. astaci*, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *A. astaci* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *A. astaci* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.2.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *A. astaci* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *A. astaci* regardless of the infection with *A. astaci* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) no *aquatic animal products* listed.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.2.2. from a country, *zone* or *compartment* not declared free from infection with *A. astaci*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.3.

INFECTION WITH DECAPOD IRIDESCENT VIRUS 1

Article 9.3.1.

For the purposes of the *Aquatic Code*, infection with decapod iridescent virus 1 means *infection* with the *pathogenic agent Decapod iridescent virus 1* (DIV1), of the *Genus Decapodiridovirus* and the Family *Iridoviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.3.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Cambaridae	*Procambarus clarkii*	red swamp crawfish
Palaemonidae	*Macrobrachium nipponense*	oriental river prawn
	Macrobrachium rosenbergii	giant river prawn
	Palaemon carinicauda	ridgetail prawn
Parastacidae	*Cherax quadricarinatus*	red claw crayfish
Penaeidae	*Penaeus japonicus*	kuruma prawn
	Penaeus vannamei	whiteleg shrimp
Portunidae	*Portunus trituberculatus*	swimming crab

Article 9.3.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with DIV1 status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to DIV1, regardless of the infection with DIV1 status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 80°C for at least 30 minutes, or a time/temperature equivalent that inactivates DIV1;

2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 80°C for at least 30 minutes, or a time/temperature equivalent that inactivates DIV1;

3) crustacean oil;

4) chemically extracted chitin.

Article 9.3.4.

Requirements for self-declaration of freedom from infection with DIV1

A Member Country may make a self-declaration of freedom from infection with DIV1 for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.3.5. to 9.3.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.3.5.

Country free from infection with DIV1

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with with DIV1 if all shared water bodies are within countries or *zones* declared free from infection with DIV1 (see Article 9.3.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with DIV1 for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with DIV1, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of DIV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 but the following conditions have been met:

   a) on detection of DIV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with DIV1; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of DIV1; or

      ii) at least the last [one] year without detection of DIV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.3.6.

Zone free from infection with DIV1

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with DIV1 if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with DIV1 for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with DIV1, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of DIV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 in the *zone* but the following conditions have been met:
   a) on detection of DIV1, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with DIV1; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of DIV1.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.3.7.

Compartment free from infection with DIV1

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of DIV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with

aquatic animals from an approved pathogen free source in accordance with the requirements of Articles 9.3.9. and 9.3.10. as appropriate; and

c) one survey for infection with DIV1 has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.3.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with DIV1 following the provisions of Articles 9.3.4. to 9.3.7. (as relevant) may maintain its status as free from infection with DIV1 provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.3.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with DIV1

When importing *aquatic animals* of a species referred to in Article 9.3.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with DIV1, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.3.5., 9.3.6. or 9.3.7. (as applicable) and 9.3.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with DIV1.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.3.3.

Article 9.3.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with DIV1

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.3.2. from a country, *zone* or *compartment* not declared free from infection with DIV1, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.3.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate DIV1 in accordance with Chapters 4.4., 4.8. and 5.5.
2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with DIV1.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for DIV1 in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with DIV1, and sample and test for DIV1 in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.2. of the *Aquatic Manual*;

v) if DIV1 is not detected in the F-1 population, it may be defined as free from infection with DIV1 and may be released from *quarantine*;

vi) if DIV1 is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.3.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with DIV1

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.3.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with DIV1, 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 Article 9.3.3. or in point 1 of Article 9.3.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of DIV1 or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of DIV1 or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.3.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with DIV1

When importing *aquatic animals* of a species referred to in Article 9.3.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with DIV1, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.3.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of DIV1 or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of DIV1 or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.3.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with DIV1

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.3.2. from a country, *zone* or *compartment* not declared free from infection with DIV1, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of DIV1 or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of DIV1 or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.3.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with DIV1 status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to DIV1 regardless of the infection with DIV1 status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) no *aquatic animal products* listed.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.3.2. from a country, *zone* or *compartment* not declared free from infection with DIV1, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2022; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.4.

INFECTION WITH *HEPATOBACTER PENAEI* (NECROTISING HEPATOPANCREATITIS)

Article 9.4.1.

For the purposes of the *Aquatic Code*, infection with *Hepatobacter penaei* (necrotising hepatopancreatitis) means *infection* with the *pathogenic agent Candidatus* Hepatobacter penaei, an obligate intracellular bacterium of the Family Holosporaceae of the Order Rickettsiales.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.4.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: whiteleg shrimp *(Penaeus vannamei)*.

Article 9.4.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *H. penaei* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *H. penaei*, regardless of the infection with *H. penaei* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 95°C for at least five minutes, or a time/temperature equivalent that inactivates *H. penaei*;
2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 95°C for at least five minutes, or a time/temperature equivalent that inactivates *H. penaei*;
3) crustacean oil;
4) chemically extracted chitin.

Article 9.4.4.

Requirements for self-declaration of freedom from infection with *H. penaei*

A Member Country may make a self-declaration of freedom from infection with *H. penaei* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.4.5. to 9.4.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.4.5.

Country free from infection with *H. penaei*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *H. penaei* if all shared water bodies are within countries or *zones* declared free from infection with *H. penaei* (see Article 9.4.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *H. penaei* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *H. penaei* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *H. penaei*, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *H. penaei*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* but the following conditions have been met:

   a) on detection of *H. penaei*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *H. penaei*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *H. penaei*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *H. penaei*; or

      ii) at least the last [one] year without detection of *H. penaei* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.4.6.

Zone free from infection with *H. penaei*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *H. penaei* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *H. penaei* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *H. penaei* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *H. penaei*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *H. penaei*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* in the *zone* but the following conditions have been met:

   a) on detection of *H. penaei*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *H. penaei*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *H. penaei*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *H. penaei*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.4.7.

Compartment free from infection with *H. penaei*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *H. penaei* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of *H. penaei*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *H. penaei*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.4.9. and 9.4.10. as appropriate; and

   c) one survey for infection with *H. penaei* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.4.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *H. penaei* following the provisions of Articles 9.4.4. to 9.4.7. (as relevant) may maintain its status as free from infection with *H. penaei* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.4.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *H. penaei*

When importing *aquatic animals* of a species referred to in Article 9.4.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with *H. penaei*, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.4.5., 9.4.6. or 9.4.7. (as applicable) and 9.4.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *H. penaei*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.4.3.

Article 9.4.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *H. penaei*

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.4.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *H. penaei* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *H. penaei*.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for *H. penaei* in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *H. penaei*, and sample and test for *H. penaei* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.3. of *Aquatic Manual*;

v) if *H. penaei* is not detected in the F-1 population, it may be defined as free from infection with *H. penaei* and may be released from *quarantine*;

vi) if *H. penaei* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.4.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *H. penaei*

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.4.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, 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 Article 9.4.3. or in point 1 of Article 9.4.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.4.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *H. penaei*

When importing *aquatic animals* of a species referred to in Article 9.4.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.4.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.4.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *H. penaei*

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *H. penaei* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.4.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *H. penaei* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *H. penaei*, regardless of the infection with *H. penaei* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from infection with *H. penaei*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2010; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.5.

INFECTION WITH INFECTIOUS HYPODERMAL AND HAEMATOPOIETIC NECROSIS VIRUS

Article 9.5.1.

For the purposes of the *Aquatic Code*, infection with infectious hypodermal and haematopoietic necrosis virus means *infection* with the *pathogenic agent Decapod penstylhamaparvovirus 1*, of the Genus *Penstylhamaparvovirus* and Family *Parvoviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.5.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: blue shrimp *(Penaeus stylirostris)*, giant tiger prawn (*Penaeus monodon)*, northern white shrimp *(Penaeus setiferus)*, whiteleg shrimp *(Penaeus vannamei)* and yellowleg shrimp *(Penaeus californiensis)*.

Article 9.5.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with IHHNV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to IHHNV, regardless of the infection with IHHNV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least two minutes, or a time/temperature equivalent that inactivates IHHNV;

2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least two minutes, or a time/temperature equivalent that inactivates IHHNV;

3) crustacean oil.

Article 9.5.4.

Requirements for self-declaration of freedom from infection with IHHNV

A Member Country may make a self-declaration of freedom from infection with IHHNV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.5.5. to 9.5.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.5.5.

Country free from infection with IHHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IHHNV if all shared water bodies are within countries or *zones* declared free from infection with IHHNV (see Article 9.5.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IHHNV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with IHHNV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHHNV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of IHHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with IHHNV and subsequently lost its free status due to the detection of IHHNV but the following conditions have been met:

   a) on detection of IHHNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of IHHNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with IHHNV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of IHHNV; or

      ii) at least the last [one] year without detection of IHHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.5.6.

Zone free from infection with IHHNV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with IHHNV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IHHNV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with IHHNV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHHNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of IHHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with IHHNV and subsequently lost its free status due to the detection of IHHNV in the *zone* but the following conditions have been met:

   a) on detection of IHHNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of IHHNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with IHHNV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of IHHNV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.5.7.

Compartment free from infection with IHHNV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IHHNV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of IHHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with IHHNV and subsequently lost its free status due to the detection of IHHNV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of IHHNV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.5.9. and 9.5.10. as appropriate; and

   c) one survey for infection with IHHNV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.5.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with IHHNV following the provisions of Articles 9.5.4. to 9.5.7. (as relevant) may maintain its status as free from infection with IHHNV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.5.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with IHHNV

When importing *aquatic animals* of a species referred to in Article 9.5.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with IHHNV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.5.5., 9.5.6. or 9.5.7. (as applicable) and 9.5.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with IHHNV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.5.3.

Article 9.5.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with IHHNV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from infection with IHHNV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.5.3. or other products authorised by the *Competent Authority*; and

    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate IHHNV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.

    a) In the *exporting country*:

        i) identify potential source populations and evaluate their *aquatic animal* health records;

        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with IHHNV.

    b) In the *importing country*:

        i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for IHHNV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with IHHNV, and sample and test for IHHNV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.4. of the *Aquatic Manual*;

v) if IHHNV is not detected in the F-1 population, it may be defined as free from infection with IHHNV and may be released from *quarantine*;

vi) if IHHNV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.5.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with IHHNV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.5.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with IHHNV, 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 Article 9.5.3. or in point 1 of Article 9.5.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IHHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of IHHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.5.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with IHHNV

When importing *aquatic animals* of a species referred to in Article 9.5.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with IHHNV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.5.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IHHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of IHHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.5.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with IHHNV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from infection with IHHNV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IHHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of IHHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.5.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with IHHNV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to IHHNV, regardless of the infection with IHHNV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.5.2. from a country, *zone* or *compartment* not declared free from infection with IHHNV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.6.

INFECTION WITH INFECTIOUS MYONECROSIS VIRUS

Article 9.6.1.

For the purposes of the *Aquatic Code*, infection with infectious myonecrosis virus means *infection* with the *pathogenic agent* infectious myonecrosis virus (IMNV) of the Family Totiviridae (tentative classification).

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.6.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: banana prawn *(Penaeus merguiensis)*, brown tiger prawn *(Penaeus esculentus)* and whiteleg shrimp *(Penaeus vannamei)*.

Article 9.6.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with IMNV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to IMNV, regardless of the infection with IMNV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 75°C for at least five minutes, or a time/temperature equivalent that inactivates IMNV;
2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 75°C for at least five minutes, or a time/temperature equivalent that inactivates IMNV;
3) crustacean oil;
4) chemically extracted chitin.

Article 9.6.4.

Requirements for self-declaration of freedom from infection with IMNV

A Member Country may make a self-declaration of freedom from infection with IMNV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.6.5. to 9.6.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.6.5.

Country free from infection with IMNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IMNV if all shared water bodies are within countries or *zones* declared free from infection with IMNV (see Article 9.6.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IMNV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with IMNV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IMNV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of IMNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with IMNV and subsequently lost its free status due to the detection of IMNV but the following conditions have been met:

   a) on detection of IMNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of IMNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with IMNV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of IMNV; or

      ii) at least the last [one] year without detection of IMNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.6.6.

Zone free from infection with IMNV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with IMNV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IMNV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with IMNV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IMNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of IMNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with IMNV and subsequently lost its free status due to the detection of IMNV in the *zone* but the following conditions have been met:

   a) on detection of IMNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of IMNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with IMNV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of IMNV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.6.7.

Compartment free from infection with IMNV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IMNV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of IMNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with IMNV and subsequently lost its free status due to the detection of IMNV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of IMNV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.6.9. and 9.6.10. as appropriate; and

   c) one survey for infection with IMNV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.6.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with IMNV following the provisions of Articles 9.6.4. to 9.6.7. (as relevant) may maintain its status as free from infection with IMNV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.6.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with IMNV

When importing *aquatic animals* of a species referred to in Article 9.6.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with IMNV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.6.5., 9.6.6. or 9.6.7. (as applicable) and 9.6.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with IMNV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.6.3.

Article 9.6.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with IMNV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.6.2. from a country, *zone* or *compartment* not declared free from infection with IMNV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.6.3. or other products authorised by the *Competent Authority*; and

    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate IMNV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.

    a) In the *exporting country*:

        i) identify potential source populations and evaluate their *aquatic animal* health records;

        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with IMNV.

b) In the *importing country*:

i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for IMNV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with IMNV, and sample and test for IMNV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.5. of the *Aquatic Manual*;

v) if IMNV is not detected in the F-1 population, it may be defined as free from infection with IMNV and may be released from *quarantine*;

vi) if IMNV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.6.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with IMNV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.6.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with IMNV, 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 Article 9.6.3. or in point 1 of Article 9.6.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IMNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of IMNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.6.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with IMNV

When importing *aquatic animals* of a species referred to in Article 9.6.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with IMNV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.6.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IMNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of IMNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.6.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with IMNV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.6.2. from a country, *zone* or *compartment* not declared free from infection with IMNV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IMNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of IMNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.6.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with IMNV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to IMNV, regardless of the infection with IMNV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.6.2. from a country, *zone* or *compartment* not declared free from infection with IMNV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.7.

INFECTION WITH MACROBRACHIUM ROSENBERGII NODAVIRUS (WHITE TAIL DISEASE)

Article 9.7.1.

For the purposes of the *Aquatic Code*, infection with Macrobrachium rosenbergii nodavirus means *infection* with the *pathogenic agent* Macrobrachium rosenbergii nodavirus (MrNV), of the Family Nodaviridae. The *disease* is commonly known as white tail disease.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.7.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: giant river prawn *(Macrobrachium rosenbergii)*.

Article 9.7.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with MrNV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to MrNV, regardless of the infection with MrNV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 50°C for at least five minutes, or a time/temperature equivalent that inactivates MrNV;
2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 50°C for at least five minutes, or a time/temperature equivalent that inactivates MrNV;
3) crustacean oil;
4) chemically extracted chitin.

Article 9.7.4.

Requirements for self-declaration of freedom from infection with MrNV

A Member Country may make a self-declaration of freedom from infection with MrNV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.7.5. to 9.7.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.7.5.

Country free from infection with MrNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with MrNV if all shared water bodies are within countries or *zones* declared free from infection with MrNV (see Article 9.7.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with MrNV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with MrNV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with MrNV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of MrNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with MrNV and subsequently lost its free status due to the detection of MrNV but the following conditions have been met:

   a) on detection of MrNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of MrNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with MrNV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of MrNV; or

      ii) at least the last [one] year without detection of MrNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.7.6.

Zone free from infection with MrNV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with MrNV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with MrNV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with MrNV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with MrNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of MrNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with MrNV and subsequently lost its free status due to the detection of MrNV in the *zone* but the following conditions have been met:

   a) on detection of MrNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of MrNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with MrNV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of MrNV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.7.7.

Compartment free from infection with MrNV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with MrNV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of MrNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with MrNV and subsequently lost its free status due to the detection of MrNV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of MrNV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.7.9. and 9.7.10. as appropriate; and

   c) one survey for infection with MrNV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.7.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with MrNV following the provisions of Articles 9.7.4. to 9.7.7. (as relevant) may maintain its status as free from infection with MrNV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.7.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with MrNV

When importing *aquatic animals* of a species referred to in Article 9.7.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with MrNV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.7.5., 9.7.6. or 9.7.7. (as applicable) and 9.7.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with MrNV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.7.3.

Article 9.7.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with MrNV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.7.2. from a country, *zone* or *compartment* not declared free from infection with MrNV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.7.3. or other products authorised by the *Competent Authority*; and

    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate MrNV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.

    a) In the *exporting country*:

        i) identify potential source populations and evaluate their *aquatic animal* health records;

        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with MrNV.

b) In the *importing country*:

i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for MrNV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with MrNV, and sample and test for MrNV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.6. of the *Aquatic Manual*;

v) if MrNV is not detected in the F-1 population, it may be defined as free from infection with MrNV and may be released from *quarantine*;

vi) if MrNV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.7.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with MrNV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.7.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with MrNV, 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 Article 9.7.3. or in point 1 of Article 9.7.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of MrNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of MrNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.7.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with MrNV

When importing *aquatic animals* of a species referred to in Article 9.7.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with MrNV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.7.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of MrNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of MrNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.7.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with MrNV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.7.2. from a country, *zone* or *compartment* not declared free from infection with MrNV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of MrNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of MrNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.7.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with MrNV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to MrNV, regardless of the infection with MrNV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.7.2. from a country, *zone* or *compartment* not declared free from infection with MrNV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2008; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.8.

INFECTION WITH TAURA SYNDROME VIRUS

Article 9.8.1.

For the purposes of the *Aquatic Code*, infection with Taura syndrome virus means *infection* with the *pathogenic agent* Taura syndrome virus (TSV), of the Genus *Aparavirus*, Family Dicistroviridae and Order Picornavirales.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 9.8.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: greasyback shrimp *(Metapenaeus ensis)*, northern brown shrimp *(Penaeus aztecus)*, giant tiger prawn *(Penaeus monodon)*, northern white shrimp *(Penaeus setiferus)*, blue shrimp *(Penaeus stylirostris)* and whiteleg shrimp *(Penaeus vannamei)*.

Article 9.8.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with TSV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to TSV, regardless of the infection with TSV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 70°C for at least 108 minutes, or a time/temperature equivalent that inactivates TSV;

2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 70°C for at least 108 minutes, or a time/temperature equivalent that inactivates TSV;

3) crustacean oil;

4) chemically extracted chitin.

Article 9.8.4.

Requirements for self-declaration of freedom from infection with TSV

A Member Country may make a self-declaration of freedom from infection with TSV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.8.5. to 9.8.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.8.5.

Country free from infection with TSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with TSV if all shared water bodies are within countries or *zones* declared free from infection with TSV (see Article 9.8.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with TSV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with TSV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TSV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of TSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with TSV and subsequently lost its free status due to the detection of TSV but the following conditions have been met:

   a) on detection of TSV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of TSV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with TSV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of TSV; or

      ii) at least the last [one] year without detection of TSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.8.6.

Zone free from infection with TSV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with TSV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with TSV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with TSV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TSV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of TSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with TSV and subsequently lost its free status due to the detection of TSV in the *zone* but the following conditions have been met:

   a) on detection of TSV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of TSV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with TSV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of TSV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.8.7.

Compartment free from infection with TSV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with TSV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of TSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with TSV and subsequently lost its free status due to the detection of TSV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of TSV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.8.9. and 9.8.10. as appropriate; and

   c) one survey for infection with TSV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.8.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with TSV following the provisions of Articles 9.8.4. to 9.8.7. (as relevant) may maintain its status as free from infection with TSV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.8.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with TSV

When importing *aquatic animals* of a species referred to in Article 9.8.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with TSV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.8.5., 9.8.6. or 9.8.7. (as applicable) and 9.8.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with TSV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.8.3.

Article 9.8.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with TSV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.8.2. from a country, *zone* or *compartment* not declared free from infection with TSV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.8.3. or other products authorised by the *Competent Authority*; and

    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate TSV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.

    a) In the *exporting country*:

        i) identify potential source populations and evaluate their *aquatic animal* health records;

        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with TSV.

    b) In the *importing country*:

        i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for TSV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with TSV, and sample and test for TSV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.7. of the *Aquatic Manual*;

v) if TSV is not detected in the F-1 population, it may be defined as free from infection with TSV and may be released from *quarantine*;

vi) if TSV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.8.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with TSV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.8.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with TSV, 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 Article 9.8.3. or in point 1 of Article 9.8.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of TSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of TSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.8.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with TSV

When importing *aquatic animals* of a species referred to in Article 9.8.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with TSV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.8.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of TSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of TSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.8.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with TSV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.8.2. from a country, *zone* or *compartment* not declared free from infection with TSV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of TSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of TSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.8.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with TSV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to TSV, regardless of the infection with TSV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp or decapod crustacea (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.8.2. from a country, *zone* or *compartment* not declared free from infection with TSV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

Article 9.9.1.

For the purposes of the *Aquatic Code*, infection with white spot syndrome virus means *infection* with the *pathogenic agent* white spot syndrome virus (WSSV), of the Genus *Whispovirus* and Family Nimaviridae.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.9.2.

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.

Article 9.9.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with WSSV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to WSSV, regardless of the infection with WSSV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 seconds, or a time/temperature equivalent that inactivates WSSV;

2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 seconds, or a time/temperature equivalent that inactivates WSSV;

3) crustacean oil;

4) chemically extracted chitin.

Article 9.9.4.

Requirements for self-declaration of freedom from infection with WSSV

A Member Country may make a self-declaration of freedom from infection with WSSV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.9.5. to 9.9.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.9.5.

Country free from infection with WSSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with WSSV if all shared water bodies are within countries or *zones* declared free from infection with WSSV (see Article 9.9.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with WSSV for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with WSSV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with WSSV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of WSSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with WSSV and subsequently lost its free status due to the detection of WSSV but the following conditions have been met:

   a) on detection of WSSV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of WSSV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with WSSV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of WSSV; or

      ii) at least the last [one] year without detection of WSSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.9.6.

Zone free from infection with WSSV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with WSSV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with WSSV for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with WSSV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with WSSV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of WSSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with WSSV and subsequently lost its free status due to the detection of WSSV in the *zone* but the following conditions have been met:

   a) on detection of WSSV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of WSSV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with WSSV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of WSSV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.9.7.

Compartment free from infection with WSSV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with WSSV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of WSSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with WSSV and subsequently lost its free status due to the detection of WSSV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of WSSV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.9.9. and 9.9.10. as appropriate; and

   c) one survey for infection with WSSV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.9.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with WSSV following the provisions of Articles 9.9.4. to 9.9.7. (as relevant) may maintain its status as free from infection with WSSV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.9.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with WSSV

When importing *aquatic animals* of a species referred to in Article 9.9.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with WSSV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.9.5., 9.9.6. or 9.9.7. (as applicable) and 9.9.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with WSSV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.9.3.

Article 9.9.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with WSSV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.9.2. from a country, *zone* or *compartment* not declared free from infection with WSSV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.9.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate WSSV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with WSSV.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for WSSV in accordance with Chapter 1.4. to determine their suitability as broodstock;
        iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with WSSV, and sample and test for WSSV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.8. of the *Aquatic Manual*;

v) if WSSV is not detected in the F-1 population, it may be defined as free from infection with WSSV and may be released from *quarantine*;

vi) if WSSV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.9.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with WSSV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.9.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with WSSV, 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 Article 9.9.3. or in point 1 of Article 9.9.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of WSSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of WSSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.9.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with WSSV

When importing *aquatic animals* of a species referred to in Article 9.9.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with WSSV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.9.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of WSSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of WSSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.9.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with WSSV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.9.2. from a country, *zone* or *compartment* not declared free from infection with WSSV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of WSSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of WSSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.9.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with WSSV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to WSSV, regardless of the infection with WSSV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp or decapod crustacea (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.9.2. from a country, *zone* or *compartment* not declared free from infection with WSSV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 1997; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 9.10.

INFECTION WITH YELLOW HEAD VIRUS GENOTYPE 1

Article 9.10.1.

For the purposes of the *Aquatic Code*, infection with yellow head virus genotype 1 means *infection* with the *pathogenic agent* yellow head virus genotype 1 (YHV1), of the Genus *Okavirus*, Family Roniviridae, Order Nidovirales.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 9.10.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: Jinga shrimp *(Metapenaeus affinis)*, giant tiger prawn *(Penaeus monodon)*, dagger blade grass shrimp *(Palaemonetes pugio)*, blue shrimp *(Penaeus stylirostris)* and whiteleg shrimp *(Penaeus vannamei)*.

Article 9.10.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with YHV1 status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to YHV1, regardless of the infection with YHV1 status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 15 minutes, or a time/temperature equivalent that inactivates YHV1;
2) crustacean *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 15 minutes, or a time/temperature equivalent that inactivates YHV1;
3) crustacean oil;
4) chemically extracted chitin.

Article 9.10.4.

Requirements for self-declaration of freedom from infection with YHV1

A Member Country may make a self-declaration of freedom from infection with YHV1 for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 9.10.5. to 9.10.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 9.10.5.

Country free from infection with YHV1

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with YHV1 if all shared water bodies are within countries or *zones* declared free from infection with YHV1 (see Article 9.10.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with YHV1 for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with YHV1, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of YHV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 but the following conditions have been met:

   a) on detection of YHV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with YHV1; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of YHV1; or

      ii) at least the last [one] year without detection of YHV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 9.10.6.

Zone free from infection with YHV1

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with YHV1 if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with YHV1 for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with YHV1, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of YHV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 in the *zone* but the following conditions have been met:

   a) on detection of YHV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with YHV1; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of YHV1.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 9.10.7.

Compartment free from infection with YHV1

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of YHV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.10.9. and 9.10.10. as appropriate; and

   c) one survey for infection with YHV1 has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 9.10.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with YHV1 following the provisions of Articles 9.10.4. to 9.10.7. (as relevant) may maintain its status as free from infection with YHV1 provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 9.10.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with YHV1

When importing *aquatic animals* of a species referred to in Article 9.10.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with YHV1, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 9.10.5., 9.10.6. or 9.10.7. (as applicable) and 9.10.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with YHV1.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 9.10.3.

Article 9.10.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with YHV1

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 9.10.2. from a country, *zone* or *compartment* not declared free from infection with YHV1, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 9.10.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate YHV1 in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following.
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with YHV1.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for YHV1 in accordance with Chapter 1.4. to determine their suitability as broodstock;
        iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with YHV1, and sample and test for YHV1 in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.2.9. of the *Aquatic Manual*;

v) if YHV1 is not detected in the F-1 population, it may be defined as free from infection with YHV1 and may be released from *quarantine*;

vi) if YHV1 is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 9.10.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with YHV1

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 9.10.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with YHV1, 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 Article 9.10.3. or in point 1 of Article 9.10.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of YHV1 or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of YHV1 or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 9.10.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with YHV1

When importing *aquatic animals* of a species referred to in Article 9.10.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with YHV1, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 9.10.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of YHV1 or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of YHV1 or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 9.10.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with YHV1

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 9.10.2. from a country, *zone* or *compartment* not declared free from infection with YHV1, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of YHV1 or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of YHV1 or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 9.10.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with YHV1 status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to YHV1, regardless of the infection with YHV1 status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) frozen peeled shrimp (shell off, head off).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 9.10.2. from a country, *zone* or *compartment* not declared free from infection with YHV1, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

SECTION 10.

DISEASES OF FISH

CHAPTER 10.1.

INFECTION WITH EPIZOOTIC HAEMATOPOIETIC NECROSIS VIRUS

Article 10.1.1.

For the purposes of the *Aquatic Code*, infection with epizootic haematopoietic necrosis virus means *infection* with the *pathogenic agent* epizootic haematopoietic necrosis virus (EHNV), of the Genus *Ranavirus* and Family *Iridoviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.1.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Esocidae	*Esox lucius*	Northern pike
Galaxiidae	*Galaxias olidus*	Mountain galaxias
Ictaluridae	*Ameiurus melas*	Black bullhead
Melanotaeniidae	*Melanotaenia fluviatilis*	Crimson spotted rainbowfish
Percidae	*Perca fluviatilis*	European perch
	Sander lucioperca	Pike-perch
Percichthyidae	*Macquaria australasica*	Macquarie perch
Poeciliidae	*Gambusia holbrooki*	Eastern mosquito fish
	Gambusia affinis	Mosquito fish
Salmonidae	*Oncorhynchus mykiss*	Rainbow trout
Terapontidae	*Bidyanus bidyanus*	Silver perch

Article 10.1.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with EHNV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to EHNV, regardless of the infection with EHNV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 15 minutes, or a time/temperature equivalent that inactivates EHNV;
2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 15 minutes, or a time/temperature equivalent that inactivates EHNV;
3) fish oil;
4) fish skin leather.

Article 10.1.4.

Requirements for self-declaration of freedom from infection with EHNV

A Member Country may make a self-declaration of freedom from infection with EHNV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.1.5. to 10.1.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.1.5.

Country free from infection with EHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with EHNV if all shared water bodies are within countries or *zones* declared free from infection with EHNV (see Article 10.1.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with EHNV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with EHNV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with EHNV, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of EHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with EHNV and subsequently lost its free status due to the detection of EHNV but the following conditions have been met:
   a) on detection of EHNV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of EHNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with EHNV; and

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

i) at least the last [two] years in wild and farmed *susceptible species* without detection of EHNV; or

ii) at least the last [one] year without detection of EHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.1.6.

Zone free from infection with EHNV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with EHNV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with EHNV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with EHNV for at least the last [ten] years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with EHNV, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of EHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with EHNV and subsequently lost its free status due to the detection of EHNV in the *zone* but the following conditions have been met:

a) on detection of EHNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of EHNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with EHNV; and

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of EHNV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.1.7.

Compartment free from infection with EHNV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with EHNV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of EHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with EHNV and subsequently lost its free status due to the detection of EHNV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of EHNV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.1.9. and 10.1.10. as appropriate; and

   c) one survey for infection with EHNV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.1.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with EHNV following the provisions of Articles 10.1.4. to 10.1.7. (as relevant) may maintain its status as free from infection with EHNV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.1.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with EHNV

When importing *aquatic animals* of a species referred to in Article 10.1.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with EHNV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.1.5., 10.1.6. or 10.1.7. (as applicable) and 10.1.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with EHNV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.1.3.

Article 10.1.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with EHNV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from infection with EHNV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.1.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate EHNV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with EHNV.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for EHNV in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with EHNV, and sample and test for EHNV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.1. of the *Aquatic Manual*;
      v) if EHNV is not detected in the F-1 population, it may be defined as free from infection with EHNV and may be released from *quarantine*;
      vi) if EHNV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.1.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with EHNV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.1.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with EHNV, 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 Article 10.1.3. or in point 1 of Article 10.1.14., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of EHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of EHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.1.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with EHNV

When importing *aquatic animals* of a species referred to in Article 10.1.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with EHNV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.1.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of EHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of EHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.1.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with EHNV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from infection with EHNV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of EHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of EHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.1.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with EHNV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to EHNV regardless of the infection with EHNV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from infection with EHNV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

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 *infection* with the *pathogenic agent A. invadans* (syn. *A. piscicida*). The *disease* was previously referred to as epizootic ulcerative syndrome.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.2.2.

Scope

The recommendations in this chapter apply to: yellowfin seabream *(Acantopagrus 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 (*Clarias* 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)*, catfishes (Siluridae spp.), 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)*, terapon (*Terapon* sp.) and three-spot gourami *(Trichogaster trichopterus)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 10.2.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *A. invadans* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *A. invadans*, regardless of the infection with *A. invadans* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least one minute, or a time/temperature equivalent that inactivates *A. invadans*;
2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least one minute, or a time/temperature equivalent that inactivates *A. invadans*;
3) fish oil;
4) frozen eviscerated fish;
5) frozen fish fillets or steaks.

Article 10.2.4.

Requirements for self-declaration of freedom from infection with *A. invadans*

A Member Country may make a self-declaration of freedom from infection with *A. invadans* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.2.5. to 10.2.8., as relevant. The self-declaration

of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.2.5.

Country free from infection with *A. invadans*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *A. invadans* if all shared water bodies are within countries or *zones* declared free from infection with *A. invadans* (see Article 10.2.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *A. invadans* for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 10.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with *A. invadans* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. invadans*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *A. invadans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *A. invadans* and subsequently lost its free status due to the detection of *A. invadans* but the following conditions have been met:
   a) on detection of *A. invadans*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *A. invadans*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *A. invadans*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *A. invadans*; or
      ii) at least the last [one] year without detection of *A. invadans* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.2.6.

Zone free from infection with *A. invadans*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *A. invadans* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *A. invadans* for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 10.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with *A. invadans* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. invadans*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *A. invadans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *A. invadans* and subsequently lost its free status due to the detection of *A. invadans* in the *zone* but the following conditions have been met:

   a) on detection of *A. invadans*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *A. invadans*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *A. invadans*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *A. invadans*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.2.7.

Compartment free from infection with *A. invadans*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *A. invadans* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of *A. invadans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *A. invadans* and subsequently lost its free status due to the detection of *A. invadans* in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *A. invadans*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.2.9. and 10.2.10. as appropriate; and

c) one survey for infection with *A. invadans* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.2.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *A. invadans* following the provisions of Articles 10.2.4. to 10.2.7. (as relevant) may maintain its status as free from infection with *A. invadans* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.2.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *A. invadans*

When importing *aquatic animals* of a species referred to in Article 10.2.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.2.5., 10.2.6. or 10.2.7. (as applicable) and 10.2.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *A. invadans*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.2.3.

Article 10.2.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *A. invadans*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.2.3. or other products authorised by the *Competent Authority*; and

   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *A. invadans* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

   a) In the *exporting country*:

      i) identify potential source populations and evaluate their *aquatic animal* health records;

      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *A. invadans*.

   b) In the *importing country*:

      i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for *A. invadans* in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *A. invadans*, and sample and test for *A. invadans* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.2. of the *Aquatic Manual*;

v) if *A. invadans* is not detected in the F-1 population, it may be defined as free from infection with *A. invadans* and may be released from *quarantine*;

vi) if *A. invadans* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.2.11.

Importation of aquatic animals or 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* of a species referred to in Article 10.2.2., or *aquatic animal products* derived thereof, 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 Article 10.2.3. or in point 1 of Article 10.2.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *A. invadans* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *A. invadans* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.2.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *A. invadans*

When importing *aquatic animals* of a species referred to in Article 10.2.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in Article 10.2.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *A. invadans* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *A. invadans* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.2.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *A. invadans*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *A. invadans* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *A. invadans* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.2.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *A. invadans* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *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 animal products* that have been prepared and packaged for retail trade and comply with Article 10.2.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.3.

INFECTION WITH *GYRODACTYLUS SALARIS*

Article 10.3.1.

For the purposes of the *Aquatic Code*, infection with *Gyrodactylus salaris* means *infection* with the *pathogenic agent Gyrodactylus salaris*, a viviparous freshwater ectoparasite, of the Family Gyrodactylidae and Class Monogenea.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.3.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: Arctic char *(Salvelinus alpinus)*, Atlantic salmon *(Salmo salar)*, brown trout *(Salmo trutta)*, grayling *(Thymallus thymallus)*, North American brook trout *(Salvelinus fontinalis)* and rainbow trout *(Oncorhynchus mykiss)*.

Article 10.3.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *G. salaris* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *G. salaris*, regardless of the infection with *G. salaris* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 40°C for at least one minute, or a time/temperature equivalent that inactivates *G. salaris*;
2) naturally dried eviscerated fish (i.e. sun-dried or wind-dried);
3) frozen eviscerated fish that have been subjected to minus 18°C or lower temperatures;
4) frozen fish fillets or steaks that have been subjected to minus 18°C or lower temperatures;
5) chilled eviscerated fish that have been harvested from seawater with a salinity of at least 25 parts per thousand (ppt) for a continuous period of at least 14 days;
6) chilled fish fillets or steaks derived from fish that have been harvested from seawater with a salinity of at least 25 ppt for a continuous period of at least 14 days;
7) chilled fish products from which the skin, fins and gills have been removed;
8) non-viable fish roe;
9) fish oil;
10) fish *meal*;
11) fish skin leather.

Article 10.3.4.

Requirements for self-declaration of freedom from infection with *G. salaris*

A Member Country may make a self-declaration of freedom from infection with *G. salaris* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.3.5. to 10.3.8., as relevant. The self-declaration of

freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.3.5.

Country free from infection with *G. salaris*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *G. salaris* if all shared water bodies are within countries or *zones* declared free from infection with *G. salaris* (see Article 10.3.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *G. salaris* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *G. salaris* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *G. salaris*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *G. salaris* and subsequently lost its free status due to the detection of *G. salaris* but the following conditions have been met:
   a) on detection of *G. salaris*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *G. salaris*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *G. salaris*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *G. salaris*; or
      ii) at least the last [one] year without detection of *G. salaris* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.3.6.

Zone free from infection with *G. salaris*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *G. salaris* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *G. salaris* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *G. salaris* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *G. salaris*, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *G. salaris* and subsequently lost its free status due to the detection of *G. salaris* in the *zone* but the following conditions have been met:
   a) on detection of *G. salaris*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *G. salaris*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *G. salaris*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *G. salaris*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.3.7.

Compartment free from infection with *G. salaris*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *G. salaris* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *G. salaris* and subsequently lost its free status due to the detection of *G. salaris* in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *G. salaris*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.3.9. and 10.3.10. as appropriate; and
   c) one survey for infection with *G. salaris* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.3.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *G. salaris* following the provisions of Articles 10.3.4. to 10.3.7. (as relevant) may maintain its status as free from infection with *G. salaris* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.3.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *G. salaris*

When importing *aquatic animals* of a species referred to in Article 10.3.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.3.5., 10.3.6. or 10.3.7. (as applicable) and 10.3.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *G. salaris*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.3.3.

Article 10.3.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *G. salaris*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in the points below:

1)

a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility;

and

b) the treatment of all transport water, equipment, effluent and waste materials to inactivate *G. salaris* in accordance with Chapters 4.4., 4.8. and 5.5.;

OR

2) immediately prior to movement, the *aquatic animals* have been for a continuous period of at least 14 days:

a) held in water with a salinity of at least 25 parts per thousand;

and

b) had no contact with other *aquatic animals* of the species referred to in Article 10.3.2.;

3) in the case of eggs, they have been disinfected by a method demonstrated to be effective against *G. salaris* and following *disinfection* do not come into contact with anything which may affect their health status.

Article 10.3.11.

Importation of aquatic animals or 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* of a species referred to in Article 10.3.2., or *aquatic animal products* derived thereof, 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 Article 10.3.3. or in point 1 of Article 10.3.13., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *G. salaris* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of *G. salaris* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.3.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *G. salaris*

When importing *aquatic animals* of a species referred to in Article 10.3.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with *G. salaris*, the *Competent Authority* of the *importing country* should require that:

1) an *international aquatic animal health certificate* is 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 *aquatic animals* of a species referred to in Article 10.3.2. have been introduced during that period;

OR

2) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to Article 10.3.3. or other products authorised by the *Competent Authority*; and
3) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *G. salaris* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
4) all effluent and waste materials from the *quarantine* facilities are treated to ensure inactivation of *G. salaris* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.3.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *G. salaris*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *G. salaris* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities are treated to ensure inactivation of *G. salaris* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

NB: FIRST ADOPTED IN 1997; MOST RECENT UPDATE ADOPTED IN 2024.

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 means *infection* with the *pathogenic agent* highly polymorphic region (HPR)-deleted infectious salmon anaemia virus (ISAV), or the non-pathogenic HPR0 (non-deleted highly polymorphic region) ISAV, of the Genus *Isavirus* and Family *Orthomyxoviridae*. Both genotypes should be notified in accordance with Chapter 1.1.

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 the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: Atlantic salmon *(Salmo salar)*, brown trout *(Salmo trutta)* and rainbow trout *(Onchorynchus mykiss)*.

Article 10.4.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with ISAV status of the exporting country, zone or compartment

In this article, all statements referring to ISAV include HPR deleted ISAV and HPR0 ISAV.

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to ISAV, regardless of the infection with ISAV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least five minutes, or a time/temperature equivalent that inactivates ISAV;

2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least five minutes, or a time/temperature equivalent that inactivates ISAV;

3) fish oil;

4) fish skin leather.

Article 10.4.4.

Requirements for self-declaration of freedom from infection with ISAV

A Member Country may make a self-declaration of freedom from infection with ISAV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.4.5. to 10.4.10., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.4.5.

Country free from infection with ISAV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with ISAV if all shared water bodies are within countries or *zones* declared free from infection with ISAV (see Article 10.4.7.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with ISAV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with ISAV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with ISAV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with ISAV and subsequently lost its free status due to the detection of ISAV but the following conditions have been met:

   a) on detection of ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of ISAV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with ISAV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of ISAV; or

      ii) at least the last [one] year without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.4.6.

Country free from infection with HPR-deleted ISAV

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 water bodies with other countries, it can only make a self-declaration of freedom from infection with HPR0 ISAV if all shared water bodies are within countries or *zones* declared free from infection with HPR0 ISAV (see Article 10.4.8.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with HPR0 ISAV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with HPR0 ISAV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with HPR0 ISAV, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of HPR0 ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with HPR0 ISAV and subsequently lost its free status due to the detection of HPR0 ISAV but the following conditions have been met:
   a) on detection of HPR0 ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of HPR0 ISAV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with HPR0 ISAV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of HPR0 ISAV; or
      ii) at least the last [one] year without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.4.7.

Zone free from infection with ISAV

In this article, all statements referring to a *zone* free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with ISAV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with ISAV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with ISAV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with ISAV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with ISAV and subsequently lost its free status due to the detection of ISAV in the *zone* but the following conditions have been met:

   a) on detection of ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of ISAV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with ISAV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of ISAV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.4.8.

Zone free from infection with HPR-deleted ISAV

In this article, all statements refer to a *zone* free from infection with HPR-deleted ISAV but not necessarily free from infection with HPR0 ISAV.

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with HPR-deleted ISAV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with HPR-deleted ISAV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with HPR-deleted ISAV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with HPR-deleted ISAV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of HPR-deleted ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with HPR-deleted ISAV and subsequently lost its free status due to the detection of HPR-deleted ISAV in the *zone* but the following conditions have been met:
   a) on detection of HPR-deleted ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of HPR-deleted ISAV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with HPR-deleted ISAV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of HPR-deleted ISAV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.4.9.

Compartment free from infection with ISAV

In this article, all statements referring to a *compartment* free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with ISAV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with ISAV and subsequently lost its free status due to the detection of ISAV in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of ISAV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.4.13. and 10.4.14. as appropriate; and
   c) one survey for infection with ISAV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.4.10.

Compartment free from infection with HPR-deleted ISAV

In this article, all statements refer to a *compartment* free from infection with HPR-deleted ISAV but not necessarily free from infection with HPR0 ISAV.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with HPR-deleted ISAV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] years without detection of HPR-deleted ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with HPR-deleted ISAV and subsequently lost its free status due to the detection of HPR-deleted ISAV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of HPR-deleted ISAV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.4.13. and 10.4.14. as appropriate; and

   c) one survey for infection with HPR-deleted ISAV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.4.11.

Maintenance of free status for infection with ISAV

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 Articles 10.4.5., 10.4.7. and 10.4.9. (as relevant) may maintain its status as free from infection with ISAV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.4.12.

Maintenance of free status for infection with HPR-deleted ISAV

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 HPR0 ISAV following the provisions of Articles 10.4.6., 10.4.8. and 10.4.10. (as relevant) may maintain its status as free from infection with HPR0 ISAV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.4.13.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with ISAV

In this article, all statements referring to a country, *zone* or *compartment* free from infection with ISAV include HPR-deleted ISAV and HPR0 ISAV.

When importing *aquatic animals* of a species referred to in Article 10.4.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.4.5., 10.4.7. or 10.4.9. (as applicable) and 10.4.11., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with ISAV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in of Article 10.4.3.

Article 10.4.14.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with HPR-deleted ISAV

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* of a species referred to in Article 10.4.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.4.6., 10.4.8. or 10.4.10. (as applicable) and 10.4.12., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with HPR-deleted ISAV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.4.3.

Article 10.4.15.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with ISAV

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.4.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate ISAV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with ISAV.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for ISAV in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with ISAV, and sample and test for ISAV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.5. of the *Aquatic Manual*;
      v) if ISAV is not detected in the F-1 population, it may be defined as free from infection with ISAV and may be released from *quarantine*;
      vi) if ISAV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.4.16.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with ISAV

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* of a species referred to in Article 10.4.2., or *aquatic animal products* derived thereof, 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 Article 10.4.3. or in point 1 of Article 10.4.19., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.4.17.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed, and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with ISAV

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing *aquatic animals* of a species referred to in Article 10.4.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed*, and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in Article 10.4.3. or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.4.18.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with infection with ISAV

In this article, all statements referring to infection with ISAV includes HPR deleted ISAV and HPR0 ISAV.

When importing, for use in laboratories or zoos, *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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.4.19.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with ISAV status of the exporting country, zone or compartment

In this article, all statements referring to infection with ISAV includes HPR deleted ISAV and HPR0 ISAV.

1) *Competent Authorities* should not require any conditions related to 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* that have been prepared and packaged for retail trade and comply with Article 10.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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 10.4.20.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infection with 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 at least the following:

   a) the likelihood that water used during the *disinfection* of the eggs is contaminated with ISAV;

   b) the prevalence of infection with ISAV in broodstock (including results from testing of ovarian fluid and milt).

2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should request that *risk* mitigation measures are applied, including:

   a) *disinfection* of the eggs prior to importing, in accordance with recommendations in Chapter 4.5.; and

   b) that between *disinfection* and importation, eggs should not come into contact with anything which may affect their health status.

   The *Competent Authority* should consider internal measures, such as additional *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* certifying that the procedures described in point 2 a) and b) of this article have been fulfilled.

NB: FIRST ADOPTED IN 1995; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.5.

INFECTION WITH SALMONID ALPHAVIRUS

Article 10.5.1.

For the purposes of the *Aquatic Code*, infection with salmonid alphavirus means *infection* with any genotype of the *pathogenic agent* salmonid alphavirus (SAV), of the Genus *Alphavirus* and 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 the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: Arctic charr *(Salvelinus alpinus)*, Atlantic salmon *(Salmo salar)*, common dab *(Limanda limanda)* and rainbow trout *(Onchorynchus mykiss)*.

Article 10.5.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with SAV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to SAV, regardless of the infection with SAV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes, or a time/temperature equivalent that inactivates SAV;

2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes or a time/temperature equivalent that inactivates SAV;

3) fish oil;

4) fish skin leather.

Article 10.5.4.

Requirements for self-declaration of freedom from infection with SAV

A Member Country may make a self-declaration of freedom from infection with SAV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.5.5. to 10.5.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.5.5.

Country free from infection with SAV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with SAV if all shared water bodies are within countries or *zones* declared free from infection with SAV (see Article 10.5.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with SAV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with SAV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SAV, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of SAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with SAV and subsequently lost its free status due to the detection of SAV but the following conditions have been met:
   a) on detection of SAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of SAV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with SAV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of SAV; or
      ii) at least the last [one] year without detection of SAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.5.6.

Zone free from infection with SAV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with SAV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with SAV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with SAV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SAV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of SAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with SAV and subsequently lost its free status due to the detection of SAV in the *zone* but the following conditions have been met:

   a) on detection of SAV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of SAV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with SAV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of SAV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.5.7.

Compartment free from infection with SAV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with SAV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of SAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with SAV and subsequently lost its free status due to the detection of SAV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of SAV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.5.9. and 10.5.10. as appropriate; and

   c) one survey for infection with SAV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen

Article 10.5.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with SAV following the provisions of Articles 10.5.4. to 10.5.7. (as relevant) may maintain its status as free from infection with SAV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.5.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with SAV

When importing *aquatic animals* of a species referred to in Article 10.5.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.5.5., 10.5.6. or 10.5.7. (as applicable) and 10.5.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with SAV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.5.3.

Article 10.5.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with SAV

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.5.3. or other products authorised by the *Competent Authority*; and

    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate SAV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with SAV.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for SAV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with SAV, and sample and test for SAV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.6. of the *Aquatic Manual*;

v) if SAV is not detected in the F-1 population, it may be defined as free from infection with SAV and may be released from *quarantine*;

vi) if SAV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.5.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with SAV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.5.2., or *aquatic animal products* derived thereof, 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 Article 10.5.3. or in point 1 of Article 10.5.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of SAV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of SAV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.5.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with SAV

When importing *aquatic animals* of a species referred to in Article 10.5.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in Article 10.5.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of SAV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of SAV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.5.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with SAV

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of SAV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of SAV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.5.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with SAV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to 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* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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 10.5.15.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infection with SAV

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 at least the following:

   a) the likelihood that water used during the *disinfection* of the eggs is contaminated with SAV;

   b) the prevalence of infection with SAV in broodstock (including results from testing of ovarian fluid and milt).

2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should request that *risk* mitigation measures are applied, including:

   a) *disinfection* of the eggs prior to importing, in accordance with recommendations in Chapter 4.5.; and

b) that between *disinfection* and importation, eggs should not come into contact with anything which may affect their health status.

The *Competent Authority* should consider internal measures, such as additional *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* certifying that the procedures described in point 2(a) and (b) of this article have been fulfilled.

NB: FIRST ADOPTED IN 2014; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.6.

INFECTION WITH INFECTIOUS HAEMATOPOIETIC NECROSIS VIRUS

Article 10.6.1.

For the purposes of the *Aquatic Code*, infection with infectious haematopoietic necrosis virus means *infection* with the *pathogenic agent* Salmonid novirhabdovirus (commonly known as infectious haematopoietic necrosis virus [IHNV]) of the Genus *Novirhabdovirus* and Family *Rhabdoviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.6.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Esocidae	*Esox lucius*	pike
Salmonidae	*Onchorynchus clarkii*	cutthroat trout
	Oncorhynchus keta	chum salmon
	Oncorhynchus kisutch	coho salmon
	Oncorhynchus masou	masu salmon
	Oncorhynchus mykiss	rainbow trout
	Oncorhynchus nerka	sockeye salmon
	Oncorhynchus tshawytscha	chinook salmon
	Salmo marmoratus	marble trout
	Salmo salar	Atlantic salmon
	Salmo trutta	brown trout
	Salvelinus alpinus	Arctic charr
	Salvelinus fontinalis	brook trout
	Salvelinus namaycush	lake trout

Article 10.6.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with IHNV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to IHNV, regardless of the infection with IHNV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 90°C for at least 30 seconds, or a time/temperature equivalent that inactivates IHNV;

2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 90°C for at least 30 seconds, or a time/temperature equivalent that inactivates IHNV;
3) fish oil;
4) fish skin leather.

Article 10.6.4.

Requirements for self-declaration of freedom from infection with IHNV

A Member Country may make a self-declaration of freedom from infection with IHNV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.6.5. to 10.6.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.6.5.

Country free from infection with IHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IHNV if all shared water bodies are within countries or *zones* declared free from infection with IHNV (see Article 10.6.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IHNV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with IHNV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHNV, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of IHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with IHNV and subsequently lost its free status due to the detection of IHNV but the following conditions have been met:
   a) on detection of IHNV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of IHNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with IHNV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of IHNV; or
      ii) at least the last [one] year without detection of IHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.6.6.

Zone free from infection with IHNV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with IHNV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IHNV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with IHNV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of IHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with IHNV and subsequently lost its free status due to the detection of IHNV in the *zone* but the following conditions have been met:

   a) on detection of IHNV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of IHNV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with IHNV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of IHNV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.6.7.

Compartment free from infection with IHNV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with IHNV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of IHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with IHNV and subsequently lost its free status due to the detection of IHNV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of IHNV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.6.9. and 10.6.10. as appropriate; and

   c) one survey for infection with IHNV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen

Article 10.6.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with IHNV following the provisions of Articles 10.6.4. to 10.6.7. (as relevant) may maintain its status as free from infection with IHNV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.6.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with IHNV

When importing *aquatic animals* of a species referred to in Article 10.6.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with IHNV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.6.5., 10.6.6. or 10.6.7. (as applicable) and 10.6.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with IHNV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.6.3.

Article 10.6.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with IHNV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.6.2. from a country, *zone* or *compartment* not declared free from infection with IHNV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred

to in Article 10.6.3. or other products authorised by the *Competent Authority*; and

c) the treatment of all transport water, equipment, effluent and waste materials to inactivate IHNV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with IHNV.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for IHNV in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with IHNV, and sample and test for IHNV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.4. of the *Aquatic Manual*;
      v) if IHNV is not detected in the F-1 population, it may be defined as free from infection with IHNV and may be released from *quarantine*;
      vi) if IHNV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.6.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with IHNV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.6.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with IHNV, 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 Article 10.6.3. or in point 1 of Article 10.6.14., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of IHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.6.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with IHNV

When importing *aquatic animals* of a species referred to in Article 10.6.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with IHNV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.6.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of IHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.6.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with IHNV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.6.2. from a country, *zone* or *compartment* not declared free from infection with IHNV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of IHNV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of IHNV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.6.14.

Importation (or transit) of aquatic animal products for retail trade for human consumption regardless of the infection with IHNV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to IHNV regardless of the infection with IHNV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.6.2. from a country, *zone* or *compartment* not declared free from infection with IHNV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.6.15.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infection with IHNV

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 infection with IHNV, the *Competent Authority* of the *importing country* should assess at least the following:

   a) the likelihood that water used during the *disinfection* of the eggs is contaminated with IHNV;

   b) the prevalence of infection with IHNV in broodstock (including results from testing of ovarian fluid and milt).

2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should request that *risk* mitigation measures are applied, including:

   a) *disinfection* of the eggs prior to importing, in accordance with recommendations in Chapter 4.5.; and

b) that between *disinfection* and importation, eggs should not come into contact with anything which may affect their health status.

The *Competent Authority* should consider internal measures, such as additional *disinfection* of the eggs upon arrival in the *importing country*.

3) 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 infection with IHNV, 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* certifying that the procedures described in point 2 a) and b) of this article have been fulfilled.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.7.

INFECTION WITH KOI HERPESVIRUS

Article 10.7.1.

For the purposes of the *Aquatic Code*, infection with koi herpesvirus means *infection* with the *pathogenic agent* koi herpesvirus (KHV) of the Genus *Cyprinivirus* and Family *Alloherpesviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.7.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: all varieties and subspecies of common carp (*Cyprinus carpio*) and common carp hybrids (e.g. *Cyprinus carpio* x *Carassius auratus* and *Cyprinus carpio* x *Carassius carassius*).

Article 10.7.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with KHV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to KHV, regardless of the infection with KHV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 50°C for at least one minute, or a time/temperature equivalent that inactivates KHV;
2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 50°C for at least one minute, or a time/temperature equivalent that inactivates KHV;
3) fish oil.

Article 10.7.4.

Requirements for self-declaration of freedom from infection with KHV

A Member Country may make a self-declaration of freedom from infection with KHV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.7.5. to 10.7.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.7.5.

Country free from infection with KHV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with KHV if all shared water bodies are within countries or *zones* declared free from infection with KHV (see Article 10.7.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with KHV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with KHV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with KHV, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of KHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with KHV and subsequently lost its free status due to the detection of KHV but the following conditions have been met:
   a) on detection of KHV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of KHV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with KHV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of KHV; or
      ii) at least the last [one] year without detection of KHV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.7.6.

Zone free from infection with KHV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with KHV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with KHV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with KHV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with KHV, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of KHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with KHV and subsequently lost its free status due to the detection of KHV in the *zone* but the following conditions have been met:
   a) on detection of KHV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of KHV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with KHV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of KHV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.7.7.

Compartment free from infection with KHV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with KHV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of KHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with KHV and subsequently lost its free status due to the detection of KHV in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of KHV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.7.9. and 10.7.10. as appropriate; and
   c) one survey for infection with KHV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.7.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with KHV following the provisions of Articles 10.7.4. to 10.7.7. (as relevant) may maintain its status as free from infection with KHV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.7.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with KHV

When importing *aquatic animals* of a species referred to in Article 10.7.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with KHV, 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*. The *international aquatic animal health certificate* should

state that, on the basis of the procedures described in Articles 10.7.5., 10.7.6. or 10.7.7. (as applicable) and 10.7.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with KHV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.7.3.

Article 10.7.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with KHV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.7.2. from a country, *zone* or *compartment* not declared free from infection with KHV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.7.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate KHV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with KHV.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for KHV in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with KHV, and sample and test for KHV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.7. of the *Aquatic Manual*;
      v) if KHV is not detected in the F-1 population, it may be defined as free from infection with KHV and may be released from *quarantine*;
      vi) if KHV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.7.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with KHV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.7.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with KHV, 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 Article 10.7.3. or in point 1 of Article 10.7.14., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of KHV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of KHV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.7.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with KHV

When importing *aquatic animals* of a species referred to in Article 10.7.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with KHV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.7.3. or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of KHV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of KHV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.7.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with KHV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.7.2. from a country, *zone* or *compartment* not declared free from infection with KHV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, containers and packaging material used in transport are treated to ensure inactivation of KHV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of KHV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.7.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with KHV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to KHV regardless of the infection with KHV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.7.2. from a country, *zone* or *compartment* not declared free from infection with KHV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2007; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.8.

INFECTION WITH RED SEA BREAM IRIDOVIRUS

Article 10.8.1.

For the purposes of the *Aquatic Code*, infection with red sea bream iridovirus means *infection* with the *pathogenic agent* red sea bream iridovirus (RSIV) of the Genus *Megalocytivirus* and Family *Iridoviridae*.

Information on methods for *diagnosis* is 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.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with RSIV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to RSIV, regardless of the infection with RSIV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates RSIV;
2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates RSIV;
3) fish oil;
4) fish skin leather.

Article 10.8.4.

Requirements for self-declaration of freedom from infection with RSIV

A Member Country may make a self-declaration of freedom from infection with RSIV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.8.5. to 10.8.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.8.5.

Country free from infection with RSIV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with RSIV if all shared water bodies are within countries or *zones* declared free from infection with RSIV (see Article 10.8.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with RSIV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with RSIV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with RSIV, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of RSIV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with RSIV and subsequently lost its free status due to the detection of RSIV but the following conditions have been met:
   a) on detection of RSIV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of RSIV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with RSIV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of RSIV; or
      ii) at least the last [one] year without detection of RSIV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.8.6.

Zone free from infection with RSIV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with RSIV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with RSIV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with RSIV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with RSIV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of RSIV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with RSIV and subsequently lost its free status due to the detection of RSIV in the *zone* but the following conditions have been met:

   a) on detection of RSIV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of RSIV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with RSIV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of RSIV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.8.7.

Compartment free from infection with RSIV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with RSIV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of RSIV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with RSIV and subsequently lost its free status due to the detection of RSIV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of RSIV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.8.9. and 10.8.10. as appropriate; and

   c) one survey for infection with RSIV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen

Article 10.8.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with RSIV following the provisions of Articles 10.8.4. to 10.8.7. (as relevant) may maintain its status as free from infection with RSIV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.8.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with RSIV

When importing *aquatic animals* of a species referred to in Article 10.8.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with RSIV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.8.5., 10.8.6. or 10.8.7. (as applicable) and 10.8.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with RSIV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.8.3.

Article 10.8.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with RSIV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.8.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate RSIV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with RSIV.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for RSIV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with RSIV, and sample and test for RSIV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.8. of the *Aquatic Manual*;

v) if RSIV is not detected in the F-1 population, it may be defined as free from infection with RSIV and may be released from *quarantine*;

vi) if RSIV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.8.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with RSIV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.8.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with RSIV, 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 Article 10.8.3. or in point 1 of Article 10.8.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4.and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.8.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with RSIV

When importing *aquatic animals* of a species referred to in Article 10.8.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.8.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.8.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with RSIV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.8.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with RSIV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to RSIV regardless of the infection with RSIV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.9.

INFECTION WITH SPRING VIRAEMIA OF CARP VIRUS

Article 10.9.1.

For the purposes of the *Aquatic Code*, infection with spring viraemia of carp virus means *infection* with the *pathogenic agent* spring viraemia of carp virus (SVCV) of the Genus *Sprivivirus* and Family *Rhabdoviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.9.2.

Scope

The recommendations in this Chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Cyprinidae	*Abramis brama*	bream
	Aristithys nobilis	bighead carp
	Carassius auratus	goldfish
	Ctenopharyngodon idella	grass carp
	Cyprinus carpio	common carp (all varieties and subspecies)
	Danio rerio	zebrafish
	Notemigonus crysoleucas	golden shiner
	Pimephales promelas	fathead minnow
	Percocypris pingi	Jinsha barbel carp
	Rutilus kutum	Caspian white fish
	Rutilus rutilus	roa
Siluridae	Silurus glanis	Wels catfish

Article 10.9.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with SVCV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to SVCV, regardless of the infection with SVCV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes, or a time/temperature equivalent inactivates SVCV;
2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes, or a time/temperature equivalent that inactivates SVCV;
3) fish oil.

Article 10.9.4.

Requirements for self-declaration of freedom from infection with SVCV

A Member Country may make a self-declaration of freedom from infection with SVCV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.9.5. to 10.9.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.9.5.

Country free from infection with SVCV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with SVCV if all shared water bodies are within countries or *zones* declared free from infection with SVCV (see Article 10.9.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with SVCV for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with SVCV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SVCV, as described in the corresponding Chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of SVCV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with SVCV and subsequently lost its free status due to the detection of SVCV but the following conditions have been met:

   a) on detection of SVCV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of SVCV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with SVCV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of SVCV; or

      ii) at least the last [one] year without detection of SVCV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.9.6.

Zone free from infection with SVCV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with SVCV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with SVCV for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with SVCV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SVCV, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of SVCV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with SVCV and subsequently lost its free status due to the detection of SVCV in the *zone* but the following conditions have been met:
   a) on detection of SVCV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of SVCV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with SVCV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of SVCV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.9.7.

Compartment free from infection with SVCV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with SVCV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of SVCV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with SVCV and subsequently lost its free status due to the detection of SVCV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of SVCV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.9.9. and 10.9.10. as appropriate; and

c) one survey for infection with SVCV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen

Article 10.9.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with SVCV following the provisions of Articles 10.9.4. to 10.9.7. (as relevant) may maintain its status as free from infection with SVCV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.9.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with SVCV

When importing *aquatic animals* of a species referred to in Article 10.9.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with SVCV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.9.5., 10.9.6. or 10.9.7. (as applicable) and 10.9.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with SVCV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.9.3.

Article 10.9.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with SVCV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from infection with SVCV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.9.3. or other products authorised by the *Competent Authority*; and

   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate SVCV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

   a) In the *exporting country*:

      i) identify potential source populations and evaluate their *aquatic animal* health records;

      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with SVCV.

   b) In the *importing country*:

      i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for SVCV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with SVCV, and sample and test for SVCV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.9. of the *Aquatic Manual*;

v) if SVCV is not detected in the F-1 population, it may be defined as free from infection with SVCV and may be released from *quarantine*;

vi) if SVCV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.9.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with SVCV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.9.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with SVCV, 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 Article 10.9.3. or in point 1 of Article 10.9.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of SVCV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of SVCV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.9.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, resear or pharmaceutical use, from a country, zone or compartment not declared free from infection with SVCV

When importing *aquatic animals* of a species referred to in Article 10.9.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, resear or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with SVCV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.9.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of SVCV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of SVCV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.9.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with SVCV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from infection with SVCV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of SVCV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of SVCV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.9.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with SVCV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to SVCV regardless of the infection with SVCV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from infection with SVCV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.10.

INFECTION WITH VIRAL HAEMORRHAGIC SEPTICAEMIA VIRUS

Article 10.10.1.

For the purposes of the *Aquatic Code*, infection with viral haemorrhagic septicaemia virus means *infection* with the *pathogenic agent* viral haemorrhagic septicaemia virus (VHSV), of the Genus *Novirhabdovirus* and Family *Rhabdoviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.10.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Ammodytidae	*Ammodytes hexapterus*	Pacific sand lance
Carangidae	*Trachurus mediterraneus*	Mediterranean horse mackerel
Centrarchidae	*Ambloplites rupestris*	Rock bass
	Lepomis gibbosus	Pumpkinseed
	Lepomis macrochirus	Bluegill
	Micropterus dolomieu	Smallmouth bass
	Micropterus salmoides	Largemouth bass
	Pomoxis nigromaculatus	Black crappie
Clupeidae	*Alosa immaculata*	Pontic shad
	Sardina pilchardus	Pilchard
	Clupea harengus	Atlantic herring
	Clupea pallasii pallasii	Pacific herring
	Dorosoma cepedianum	American gizzard shad
	Sardinops sagax	South American pilchard
	Sprattus sprattus	European sprat
Cyclopteridae	*Cyclopterus lumpus*	Lumpfish
Cyprinidae	*Danio rerio*	Zebra fish
	Notropis hudsonius	Spottail shiner
	Notropis atherinoides	Emerald shiner
	Pimephales notatus	Bluntnose minnow
	Pimephales promelas	Fathead minnow
Embiotocidae	*Cymatogaster aggregata*	Shiner perch
Engraulidae	*Engraulis encrasicolus*	European anchovy

Family	Scientific name	Common name
Esocidae	*Esox lucius*	Northern pike
	Esox masquinongy	Muskellunge
Fundulidae	*Fundulus heteroclitus*	Mummichog
Gadidae	*Gadus macrocephalus*	Pacific cod
	Gadus morhua	Atlantic cod
	Merlangius merlangus	Whiting
	Micromesistius poutassou	Blue whiting
	Trisopterus esmarkii	Norway pout
Gasterosteidae	*Gasterosteus aculeatus*	Three-spine stickleback
Gobiidae	*Neogobius melanostomus*	Round goby
	Pomatoschistus minutus	Sand goby
Ictaluridae	*Ameiurus nebulosus*	Brown bullhead
Labridae	*Centrolabrus exoletus*	Rock cook wrasse
	Ctenolabrus rupestris	Goldsinny wrasse
	Labrus bergylta	Ballan wrasse
	Labrus mixtus	Cuckoo wrasse
	Symphodus melops	Corkwing wrasse
Lotidae	*Gaidropsarus vulgaris*	Three-bearded rockling
Moronidae	*Morone americana*	White perch
	Morone chrysops	White bass
	Morone saxatilis	Striped bass
Mullidae	*Mullus barbatus*	Red mullet
Osmeridae	*Thaleichthys pacificus*	Eulachon
Paralichthyidae	*Paralichthys olivaceus*	Bastard halibut
Percidae	*Sander vitreus*	Walleye
	Perca flavescens	Yellow perch
Petromyzontidae	*Lampetra fluviatilis*	River lamprey
Pleuronectidae	*Limanda limanda*	Common dab
	Platichthys flesus	European flounder
	Pleuronectes platessus	European plaice
Rajidae	*Raja clavata*	Thornback ray
Salmonidae	*Coregonus artedii*	Lake cisco
	Coregonus clupeaformis	Lake whitefish
	Coregonus lavaretus	Common whitefish
	Oncorhynchus kisutch	Coho salmon
	Oncorhynchus mykiss	Rainbow trout
	Oncorhynchus mykiss X *Oncorhynchus kisutch* hybrids	Rainbow trout X coho salmon hybrids
	Oncorhynchus tshawytscha	Chinook salmon
	Salmo marmoratus	Marble trout

Family	Scientific name	Common name
Salmonidae	*Salmo salar*	Atlantic salmon
	Salmo trutta	Brown trout
	Salvelinus namaycush	Lake trout
	Thymallus thymallus	Grayling
Scophthalmidae	*Scophthalmus maximus*	Turbot
Sciaenidae	*Aplodinotus grunniens*	Freshwater drum
Scombridae	*Scomber japonicus*	Pacific Cchub mackerel
Soleidae	*Solea senegalensis*	Senegalese sole
Uranoscopidae	*Uranoscopus scaber*	Atlantic stargazer

Article 10.10.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with VHSV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to VHSV, regardless of the infection with VHSV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes, or a time/temperature equivalent that inactivates VHSV;
2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes, or a time/temperature equivalent that inactivates VHSV;
3) naturally dried, eviscerated fish (i.e. sun-dried or wind-dried);
4) fish oil;
5) fish skin leather.

Article 10.10.4.

Requirements for self-declaration of freedom from infection with VHSV

A Member Country may make a self-declaration of freedom from infection with VHSV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.10.5. to 10.10.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.10.5.

Country free from infection with VHSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with VHSV if all shared water bodies are within countries or *zones* declared free from infection with VHSV (see Article 10.10.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with VHSV for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 10.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with VHSV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with VHSV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of VHSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with VHSV and subsequently lost its free status due to the detection of VHSV but the following conditions have been met:

   a) on detection of VHSV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of VHSV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with VHSV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of VHSV; or

      ii) at least the last [one] year without detection of VHSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.10.6.

Zone free from infection with VHSV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with VHSV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with VHSV for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 10.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with VHSV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with VHSV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of VHSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with VHSV and subsequently lost its free status due to the detection of VHSV in the *zone* but the following conditions have been met:

   a) on detection of VHSV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of VHSV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with VHSV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of VHSV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.10.7.

Compartment free from infection with VHSV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with VHSV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of VHSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with VHSV and subsequently lost its free status due to the detection of VHSV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of VHSV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.10.9. and 10.10.10. as appropriate; and

   c) one survey for infection with VHSV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen

Article 10.10.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with VHSV following the provisions of Articles 10.10.4. to 10.10.7. (as relevant) may maintain its status as free from infection with VHSV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.10.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with VHSV

When importing *aquatic animals* of a species referred to in Article 10.10.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with VHSV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.10.5., 10.10.6. or 10.10.7. (as applicable) and 10.10.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with VHSV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.10.3.

Article 10.10.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with VHSV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.10.2. from a country, *zone* or *compartment* not declared free from infection with VHSV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.10.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate VHSV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with VHSV.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for VHSV in accordance with Chapter 1.4. to determine their suitability as broodstock;
        iii) produce a first generation (F-1) population in *quarantine*;
        iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with VHSV, and sample and test for VHSV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.10. of the *Aquatic Manual*;
        v) if VHSV is not detected in the F-1 population, it may be defined as free from infection with VHSV and may be released from *quarantine*;
        vi) if VHSV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.10.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with VHSV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.10.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with VHSV, 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 Article 10.10.3. or in point 1 of Article 10.10.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of VHSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of VHSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.10.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with VHSV

When importing *aquatic animals* of a species referred to in Article 10.10.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with VHSV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.10.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of VHSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of VHSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.10.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with VHSV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.10.2. from a country, *zone* or *compartment* not declared free from infection with VHSV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of VHSV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of VHSV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.10.14.

Importation (or transit) of aquatic animal products for retail trade for human consumption regardless of the infection with VHSV status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to VHSV regardless of the infection with VHSV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.10.2. from a country, *zone* or *compartment* not declared free from infection with VHSV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.10.15.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infection with VHSV

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 infection with VHSV, the *Competent Authority* of the *importing country* should assess at least the following:

   a) the likelihood that water used during the *disinfection* of the eggs is contaminated with VHSV;

   b) the prevalence of infection with VHSV in broodstock (including results from testing of ovarian fluid and milt).

2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should request that *risk* mitigation measures are applied, including:

   a) *disinfection* of the eggs prior to importing, in accordance with recommendations in Chapter 4.5.; and

   b) that between *disinfection* and importation, eggs should not come into contact with anything which may affect their health status.

   The *Competent Authority* should consider internal measures, such as additional *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 infection with VHSV, 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* certifying that the procedures described in point 2 a) and b) of this article have been fulfilled.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

CHAPTER 10.11.

INFECTION WITH TILAPIA LAKE VIRUS

Article 10.11.1.

For the purposes of the *Aquatic Code*, infection with tilapia lake virus (TiLV) means *infection* with the *pathogenic agent Tilapia tilapinevirus*, of the Genus *Tilapinevirus* and the Family *Amnoonviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 10.11.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Cichlidae	*Oreochromis aureus x O. niloticus*	blue-Nile tilapia hybrid
	Oreochromis mossambicus	Mozambique tilapia
	Oreochromis niloticus	Nile tilapia
	Oreochromis niloticus x O. mossambicus	red hybrid tilapia
	Sarotherodon galilaeus	mango tilapia

Article 10.11.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with TiLV status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to TiLV, regardless of the infection with TiLV status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 120 minutes, or a time/temperature equivalent that inactivates TiLV;
2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 120 minutes, or a time/temperature equivalent that inactivates TiLV;
3) fish oil;
4) fish skin leather.

Article 10.11.4.

Requirements for self-declaration of freedom from infection with TILV

A Member Country may make a self-declaration of freedom from infection with TiLV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.11.5.to 10.11.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code*, including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 10.11.5.

Country free from infection with TiLV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with TiLV if all shared water bodies are within countries or *zones* declared free from infection with TiLV (see Article 10.11.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with TiLV for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with TiLV for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TiLV, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of TiLV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with TILV and subsequently lost its free status due to the detection of TiLV but the following conditions have been met:
   a) on detection of TiLV, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of TiLV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with TiLV; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of TiLV; or
      ii) at least the last [one] year without detection of TiLV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 10.11.6.

Zone free from infection with TILV

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with TiLV if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with TiLV for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with TiLV for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TiLV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of TiLV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with TILV and subsequently lost its free status due to the detection of TiLV in the *zone* but the following conditions have been met:

   a) on detection of TiLV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of TiLV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with TiLV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of TiLV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 10.11.7.

Compartment free from infection with TiLV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with TiLV for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [one] year without detection of TiLV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with TILV and subsequently lost its free status due to the detection of TiLV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of TiLV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.11.9. and 10.11.10. as appropriate; and

   c) one survey for infection with TiLV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.11.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with TiLV following the provisions of Articles 10.11.4. to 10.11.7. (as relevant) may maintain its status as free from infection with TiLV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.11.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with TiLV

When importing *aquatic animals* of a species referred to in Article 10.11.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with TiLV, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.11.5., 10.11.6. or 10.11.7. (as applicable) and 10.11.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with TiLV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.11.3.

Article 10.11.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with TiLV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.11.2. from a country, *zone* or *compartment* not declared free from infection with TiLV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.11.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate TiLV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with TiLV.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for TiLV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with TiLV, and sample and test for TiLV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter X.X.6. of the *Aquatic Manual*;

v) if TiLV is not detected in the F-1 population, it may be defined as free from infection with TiLV and may be released from *quarantine*;

vi) if TiLV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.11.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with TiLV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.11.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with TILV, 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 Article 10.11.3. or in point 1 of Article 10.11.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of TiLV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of TiLV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.11.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with TiLV

When importing *aquatic animals* of a species referred to in Article 10.11.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with TiLV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.11.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of TiLV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of TiLV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.11.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with TiLV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.11.2. from a country, *zone* or *compartment* not declared free from infection with TiLV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of TiLV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of TiLV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.11.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with TiLV status of the exporting country, zone or compartment

1) [*Competent Authorities* should not require any conditions related to TiLV, regardless of the infection with TiLV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled)] (under study).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.11.2. from a country, *zone* or *compartment* not declared free from infection with TiLV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

NB: FIRST ADOPTED IN 2023; MOST RECENT UPDATE ADOPTED IN 2024.

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 *pathogenic agent* Haliotid herpesvirus 1 (HaHV-1), of the Genus *Aurivirus* and Family *Malacoherpesviridae*.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.1.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: blacklip abalone (*Haliotis rubra*), greenlip abalone (*Haliotis laevigata*), hybrids of greenlip x blacklip abalone (*Haliotis laevigata* x *Haliotis rubra*) and small abalone (*Haliotis diversicolor*).

Article 11.1.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with abalone herpesvirus status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to abalone herpesvirus regardless of the infection with abalone herpesvirus status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 50°C for at least five minutes, or a time/temperature equivalent that inactivates AbHV.

Article 11.1.4.

Requirements for self-declaration of freedom from infection with abalone herpesvirus

A Member Country may make a self-declaration of freedom from infection with abalone herpesvirus for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 11.1.5. to 11.1.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 11.1.5.

Country free from infection with abalone herpesvirus

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with abalone herpesvirus if all shared water bodies are within countries or *zones* declared free from infection with abalone herpesvirus (see Article 11.1.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with abalone herpesvirus for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with abalone herpesvirus for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with abalone herpesvirus, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of AbHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with abalone herpesvirus and subsequently lost its free status due to the detection of AbHV but the following conditions have been met:

   a) on detection of AbHV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of AbHV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with abalone herpesvirus; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of AbHV; or

      ii) at least the last [one] year without detection of AbHV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 11.1.6.

Zone free from infection with abalone herpesvirus

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with abalone herpesvirus if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with abalone herpesvirus for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with abalone herpesvirus for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with abalone herpesvirus, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of AbHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with abalone herpesvirus and subsequently lost its free status due to the detection of AbHV in the *zone* but the following conditions have been met:

   a) on detection of AbHV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of AbHV, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with abalone herpesvirus; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of AbHV.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 11.1.7.

Compartment free from infection with abalone herpesvirus

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with abalone herpesvirus for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of AbHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with abalone herpesvirus and subsequently lost its free status due to the detection of AbHV in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of AbHV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.1.9. and 11.1.10. as appropriate; and

   c) one survey for infection with abalone herpesvirus has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 11.1.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with abalone herpesvirus following the provisions of Articles 11.1.4. to 11.1.7. (as relevant) may maintain its status as free from infection with abalone herpesvirus provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 11.1.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with abalone herpesvirus

When importing *aquatic animals* of a species referred to in Article 11.1.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 11.1.5., 11.1.6. or 11.1.7. (as applicable) and 11.1.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with abalone herpesvirus.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 11.1.3.

Article 11.1.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with abalone herpesvirus

IWhen importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 11.1.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate abalone herpesvirus in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with abalone herpesvirus.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for AbHV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with abalone herpesvirus, and sample and test for AbHV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.4.1. of the *Aquatic Manual*;

v) if AbHV is not detected in the F-1 population, it may be defined as free from infection with abalone herpesvirus and may be released from *quarantine*;

vi) if AbHV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 11.1.11.

Importation of aquatic animals or 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* of a species referred to in Article 11.1.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 11.1.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of AbHV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of AbHV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 11.1.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with abalone herpesvirus

When importing *aquatic animals* of a species referred to in Article 11.1.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in point 1 of Article 11.1.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers*, and packaging material used in transport are treated to ensure inactivation of AbHV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of AbHV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 11.1.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with abalone herpesvirus

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of AbHV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of AbHV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 11.1.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with abalone herpesvirus status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to 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* that have been prepared and packaged for retail trade and which comply with Article 5.4.2.:

   a) off the shell and eviscerated abalone meat (chilled or frozen).

   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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal products* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2010; MOST RECENT UPDATE ADOPTED IN 2024.

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 the *pathogenic agent Bonamia exitiosa* of the Family Haplosporidiidae.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.2.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: Argentinean flat oyster *(Ostrea puelchana)*, Ariake cupped oyster (*Magallana* [syn. *Crassostrea*] *ariakensis*), Australian mud oyster *(Ostrea angasi)*, Chilean flat oyster *(Ostrea chilensis)*, crested oyster *(Ostrea equestris)*, eastern oyster *(Crassostrea virginica)*, European flat oyster *(Ostrea edulis)* and Olympia oyster *(Ostrea lurida)*.

Article 11.2.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *B. exitiosa* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *B. exitiosa*, regardless of the infection with *B. exitiosa* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least 15 minutes, or a time/temperature equivalent that inactivates *B. exitiosa*;

2) frozen oyster meat;

3) frozen half-shell oyster.

Article 11.2.4.

Requirements for self-declaration of freedom from infection with *B. exitiosa*

A Member Country may make a self-declaration of freedom from infection with *B. exitiosa* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 11.2.5. to 11.2.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 11.2.5.

Country free from infection with *B. exitiosa*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. exitiosa* if all shared water bodies are within countries or *zones* declared free from infection with *B. exitiosa* (see Article 11.2.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. exitiosa* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. exitiosa* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. exitiosa*, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. exitiosa*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *B. exitiosa* and subsequently lost its free status due to the detection of *B. exitiosa* but the following conditions have been met:

   a) on detection of *B. exitiosa*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. exitiosa*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. exitiosa*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *B. exitiosa*; or

      ii) at least the last [one] year without detection of *B. exitiosa* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 11.2.6.

Zone free from infection with *B. exitiosa*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *B. exitiosa* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. exitiosa* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. exitiosa* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. exitiosa*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *B. exitiosa*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *B. exitiosa* and subsequently lost its free status due to the detection of *B. exitiosa* in the *zone* but the following conditions have been met:

   a) on detection of *B. exitiosa*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. exitiosa*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. exitiosa*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. exitiosa*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 11.2.7.

Compartment free from infection with *B. exitiosa*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. exitiosa* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *B. exitiosa*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *B. exitiosa* and subsequently lost its free status due to the detection of *B. exitiosa* in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. exitiosa*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.2.9. and 11.2.10. as appropriate; and

   c) one survey for infection with *B. exitiosa* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 11.2.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *B. exitiosa* following the provisions of Articles 11.2.4. to 11.2.7. (as relevant) may maintain its status as free from infection with *B. exitiosa* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 11.2.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *B. exitiosa*

When importing *aquatic animals* of a species referred to in Article 11.2.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 11.2.5., 11.2.6. or 11.2.7. (as applicable) and 11.2.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *B. exitiosa*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 11.2.3.

Article 11.2.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *B. exitiosa*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 11.2.3. or other products authorised by the *Competent Authority*; and
    c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *B. exitiosa* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
    a) In the *exporting country*:
        i) identify potential source populations and evaluate their *aquatic animal* health records;
        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *B. exitiosa*.
    b) In the *importing country*:
        i) import the F-0 population into a *quarantine* facility;
        ii) test the F-0 population for *B. exitiosa* in accordance with Chapter 1.4. to determine their suitability as broodstock;
        iii) produce a first generation (F-1) population in *quarantine*;

iv) culture F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *B. exitiosa*, and sample and test for *B. exitiosa* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.4.2. of the *Aquatic Manual*;

v) if *B. exitiosa* is not detected in the F-1 population, it may be defined as free from infection with *B. exitiosa* and may be released from *quarantine*;

vi) if *B. exitiosa* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 11.2.11.

Importation of aquatic animals or 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* of a species referred to in Article 11.2.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 11.2.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. exitiosa* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *B. exitiosa* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 11.2.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *B. exitiosa*

When importing *aquatic animals* of a species referred to in Article 11.2.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in point 1 of Article 11.2.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers*, and packaging material used in transport are treated to ensure inactivation of *B. exitiosa* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *B. exitiosa* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 11.2.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *B. exitiosa*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. exitiosa* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *B. exitiosa* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 11.2.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *B. exitiosa* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *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 animal products* that 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* 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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal products* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2003; MOST RECENT UPDATE ADOPTED IN 2024.

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 the *pathogenic agent Bonamia ostreae* of the Family Haplosporidiidae.

Information on methods for *diagnosis* are provided in the *Aquatic Manual*.

Article 11.3.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: Ariake cupped oyster (*Magallana* [syn. *Crassostrea*] *ariakensis*), Chilean flat oyster *(Ostrea chilensis)*and European flat oyster *(Ostrea edulis)*.

Article 11.3.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *B. ostreae* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *B. ostreae*, regardless of the infection with *B. ostreae* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 100°C for at least 15 minutes, or a time/temperature equivalent that inactivates *B. ostreae*;
2) frozen oyster meat;
3) frozen half-shell oysters.

Article 11.3.4.

Requirements for self-declaration of freedom from infection with *B. ostreae*

A Member Country may make a self-declaration of freedom from infection with *B. ostreae* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 11.3.5. to 11.3.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 11.3.5.

Country free from infection with *B. ostreae*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. ostreae* if all shared water bodies are within countries or *zones* declared free from infection with *B. ostreae* (see Article 11.3.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. ostreae* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. ostreae* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. ostreae*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. ostreae*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *B. ostreae* and subsequently lost its free status due to the detection of *B. ostreae* but the following conditions have been met:
   a) on detection of *B. ostreae*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. ostreae*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. ostreae*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *B. ostreae*; or
      ii) at least the last [one] year without detection of *B. ostreae* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 11.3.6.

Zone free from infection with *B. ostreae*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *B. ostreae* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. ostreae* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *B. ostreae* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. ostreae*, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *B. ostreae*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *B. ostreae* and subsequently lost its free status due to the detection of *B. ostreae* in the *zone* but the following conditions have been met:
   a) on detection of *B. ostreae*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. ostreae*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *B. ostreae*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *B. ostreae*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 11.3.7.

Compartment free from infection with *B. ostreae*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *B. ostreae* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *B. ostreae*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *B. ostreae* and subsequently lost its free status due to the detection of *B. ostreae* in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *B. ostreae*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.3.9. and 11.3.10. as appropriate; and
   c) one survey for infection with *B. ostreae* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 11.3.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *B. ostreae* following the provisions of Articles 11.3.4. to 11.3.7. (as relevant) may maintain its status as free from infection with *B. ostreae* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 11.3.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *B. ostreae*

When importing *aquatic animals* of a species referred to in Article 11.3.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health*

certificate should state that, on the basis of the procedures described in Articles 11.3.5., 11.3.6. or 11.3.7. (as applicable) and 11.3.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *B. ostreae*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 11.3.3.

Article 11.3.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *B. ostreae*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 11.3.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *B. ostreae* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *B. ostreae*.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for *B. ostreae* in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *B. ostreae*, and sample and test for *B. ostreae* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.4.3. of the *Aquatic Manual*;
      v) if *B. ostreae* is not detected in the F-1 population, it may be defined as free from infection with *B. ostreae* and may be released from *quarantine*;
      vi) if *B. ostreae* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 11.3.11.

Importation of aquatic animals or 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* of a species referred to in Article 11.3.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 11.3.14., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. ostreae* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *B. ostreae* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 11.3.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *B. ostreae*

When importing *aquatic animals* of a species referred to in Article 11.3.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in point 1 of Article 11.3.3. or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers*, and packaging material used in transport are treated to ensure inactivation of *B. ostreae* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of *B. ostreae* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 11.3.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *B. ostreae*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *B. ostreae* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *B. ostreae* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 11.3.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *B. ostreae* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *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 animal products* that 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* 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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal products* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

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 the *pathogenic agent M. refringens* (including O and M types) of the Family Marteiliidae.

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.4.2.

Scope

The recommendations in this chapter apply to: blue mussel *(Mytilus edulis)*, dwarf oyster *(Ostrea stentina)*, European flat oyster *(Ostrea edulis)*, European razor clam *(Solen marginatus)*, golden mussel *(Xenostrobus securis)*, Mediterranean mussel *(Mytilus galloprovincialis)* and striped venus clam *(Chamelea gallina)*.

Article 11.4.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *M. refringens* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *M. refringens*, regardless of the infection with *M. refringens* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 121°C for at least three minutes and 36 seconds, or a time/temperature equivalent that inactivates *M. refringens*.

Article 11.4.4.

Requirements for self-declaration of freedom from infection with *M. refringens*

A Member Country may make a self-declaration of freedom from infection with *M. refringens* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 11.4.5. to 11.4.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 11.4.5.

Country free from infection with *M. refringens*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *M. refringens* if all shared water bodies are within countries or *zones* declared free from infection with *M. refringens* (see Article 11.4.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. refringens* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *M. refringens* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. refringens*, as described in the corresponding chapter of the Aquatic Manual; and
   b) *basic biosecurity conditions* as described n Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *M. refringens*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *M. refringens* and subsequently lost its free status due to the detection of *M. refringens* but the following conditions have been met:
   a) on detection of *M. refringens*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. refringens*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *M. refringens*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *M. refringens*; or
      ii) at least the last [one] year without detection of *M. refringens* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 11.4.6.

Zone free from infection with *M. refringens*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *M. refringens* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. refringens* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *M. refringens* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. refringens*, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *M. refringens*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *M. refringens* and subsequently lost its free status due to the detection of *M. refringens* in the *zone* but the following conditions have been met:
   a) on detection of *M. refringens*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. refringens*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *M. refringens*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *M. refringens*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 11.4.7.

Compartment free from infection with *M. refringens*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. refringens* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *M. refringens*, and *basic biosecurity conditions* have been continuously met for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *M. refringens* and subsequently lost its free status due to the detection of *M. refringens* in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. refringens*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.4.9. and 11.4.10. as appropriate; and
   c) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [one] year without detection of *M. refringens*.

Article 11.4.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *M. refringens* following the provisions of Articles 11.4.4. to 11.4.7. (as relevant) may maintain its status as free from infection with *M. refringens* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 11.4.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *M. refringens*

When importing *aquatic animals* of a species referred to in Article 11.4.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 11.4.5., 11.4.6. or 11.4.7. (as applicable) and 11.4.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *M. refringens*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 11.4.3.

Article 11.4.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *M. refringens*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 11.4.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *M. refringens* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *M. refringens*.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for *M. refringens* in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *M. refringens*, and sample and test for *M. refringens* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.4.4. of the *Aquatic Manual*;
      v) if *M. refringens* is not detected in the F-1 population, it may be defined as free from infection with *M. refringens* and may be released from *quarantine*;
      vi) if *M. refringens* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 11.4.11.

Importation of aquatic animals or 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* of a species referred to in Article 11.4.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 11.4.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. refringens* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. refringens* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 11.4.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *M. refringens*

When importing *aquatic animals* of a species referred to in Article 11.4.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in point 1 of Article 11.4.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers*, and packaging material used in transport are treated to ensure inactivation of *M. refringens* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. refringens* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 11.4.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *M. refringens*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. refringens* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *M. refringens* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 11.4.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *M. refringens*

1) *Competent Authorities* should not require any conditions related to *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 *aquatic animal products* that 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* 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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal products* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

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 the *pathogenic agent P. marinus* of the Family Perkinsidae

Information on methods for *diagnosis* is provided in the *Aquatic Manual*.

Article 11.5.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Ostreidae	*Crassostrea corteziensis*	Cortez oyster
	Crassostrea virginica	American cupped oyster
	Magallana [syn. *Crassostrea*] *ariakensis*	Ariake cupped oyster
	Saccostrea palmula	palmate oyster

Article 11.5.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *P. marinus* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *P. marinus*, regardless of the infection with *P. marinus* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes, or a time/temperature equivalent that inactivates *P. marinus*.

Article 11.5.4.

Requirements for self-declaration of freedom from infection with *P. marinus*

A Member Country may make a self-declaration of freedom from infection with *P. marinus* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 11.5.5. to 11.5.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and

2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and

3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 11.5.5.

Country free from infection with *P. marinus*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *P. marinus* if all shared water bodies are within countries or *zones* declared free from infection with *P. marinus* (see Article 11.5.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *P. marinus* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *P. marinus* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. marinus*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *P. marinus*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *P. marinus* and subsequently lost its free status due to the detection of *P. marinus* but the following conditions have been met:
   a) on detection of *P. marinus*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *P. marinus*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *P. marinus*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *P. marinus*; or
      ii) at least the last [one] year without detection of *P. marinus* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 11.5.6.

Zone free from infection with *P. marinus*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *P. marinus* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *P. marinus* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *P. marinus* for at least the last [ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. marinus*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *P. marinus*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *P. marinus* and subsequently lost its free status due to the detection of *P. marinus* in the *zone* but the following conditions have been met:

   a) on detection of *P. marinus*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *P. marinus*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *P. marinus*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *P. marinus*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 11.5.7.

Compartment free from infection with *P. marinus*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *P. marinus* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *P. marinus*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *P. marinus* and subsequently lost its free status due to the detection of *P. marinus* in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *P. marinus*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.5.9. and 11.5.10. as appropriate; and

c) one survey for infection with *P. marinus* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 11.5.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *P. marinus* following the provisions of Articles 11.5.4. to 11.5.7. (as relevant) may maintain its status as free from infection with *P. marinus* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 11.5.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *P. marinus*

When importing *aquatic animals* of a species referred to in Article 11.5.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 11.5.5., 11.5.6. or 11.5.7. (as applicable) and 11.5.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *P. marinus*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 11.5.3.

Article 11.5.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *P. marinus*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 11.5.3. or other products authorised by the *Competent Authority*; and

   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *P. marinus* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *P. marinus*.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for *P. marinus* in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *P. marinus*, and sample and test for *P. marinus* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.4.5. of the *Aquatic Manual*;
      v) if *P. marinus* is not detected in the F-1 population, it may be defined as free from infection with *P. marinus* and may be released from *quarantine*;
      vi) if *P. marinus* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 11.5.11.

Importation of aquatic animals or 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* of a species referred to in Article 11.5.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 11.5.14., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *P. marinus* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of *P. marinus* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 11.5.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *P. marinus*

When importing *aquatic animals* of a species referred to in Article 11.5.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in point 1 of Article 11.5.3. or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers*, and packaging material used in transport are treated to ensure inactivation of *P. marinus* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of *P. marinus* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 11.5.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *P. marinus*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *P. marinus* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *P. marinus* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 11.5.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *P. marinus*

1) *Competent Authorities* should not require any conditions related to *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 *aquatic animal products* that 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* 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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal products* being used for any purpose other than for human consumption.
2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2000; MOST RECENT UPDATE ADOPTED IN 2024.

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*, *Venerupis aurea*, *Ruditapes decussatus* and *Ruditapes philippinarum*), abalone (*Haliotis rubra*, *Haliotis laevigata*, *Haliotis Cyclobates* and *Haliotis 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.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *P. olseni* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *P. olseni*, regardless of the infection with *P. olseni* status of the *exporting country*, *zone* or *compartment*::

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 60°C for at least 60 minutes, or a time/temperature equivalent that inactivates *P. olseni*.

Article 11.6.4.

Requirements for self-declaration of freedom from infection with *P. olseni*

A Member Country may make a self-declaration of freedom from infection with *P. olseni* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 11.6.9. to 11.6.14., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 11.6.5.

Country free from infection with *P.olseni*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *P. olseni* if all shared water bodies are within countries or *zones* declared free from infection with *P. olseni* (see Article 11.6.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *P. olseni* for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 11.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with *P. olseni* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. olseni*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *P. olseni*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *P. olseni* and subsequently lost its free status due to the detection of *P. olseni* but the following conditions have been met:
   a) on detection of *P. olseni*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *P. olseni*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *P. olseni*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of P. olseni; or
      ii) at least the last [one] year without detection of *P. olseni* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 11.6.6.

Zone free from infection with *P. olseni*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *P. olseni* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *P. olseni* for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 11.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with *P. olseni* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. olseni*, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *P. olseni*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *P. olseni* and subsequently lost its free status due to the detection of *P. olseni* in the *zone* but the following conditions have been met:
   a) on detection of *P. olseni*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *P. olseni*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *P. olseni*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *P. olseni*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 11.6.7.

Compartment free from infection with *P. olseni*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *P. olseni* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *P. olseni*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *P. olseni* and subsequently lost its free status due to the detection of *P. olseni* in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *P. olseni*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.6.9. and 11.6.10. as appropriate; and
   c) one survey for infection with *P. olseni* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 11.6.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *P. olseni* following the provisions of Articles 11.6.4. to 11.6.7. (as relevant) may maintain its status as free from infection with *P. olseni* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 11.6.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *P. olseni*

When importing *aquatic animals* of a species referred to in Article 11.6.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health*

certificate should state that, on the basis of the procedures described in Articles 11.6.5., 11.6.6. or 11.6.7. (as applicable) and 11.6.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *P. olseni*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 11.6.3.

Article 11.6.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *P. olseni*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 11.6.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *P. olseni* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *P. olseni*.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for *P.olseni* in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *P. olseni*, and sample and test for *P. olseni* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.4.3. of the *Aquatic Manual*;
      v) if *P. olseni* is not detected in the F-1 population, it may be defined as free from infection with *P. olseni* and may be released from *quarantine*;
      vi) if *P. olseni* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 11.6.11.

Importation of aquatic animals or 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* of a species referred to in Article 11.6.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 11.6.14., or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *P. olseni* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *P. olseni* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 11.6.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *P. olseni*

When importing *aquatic animals* of a species referred to in Article 11.6.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in point 1 of Article 11.6.3. or other products authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers*, and packaging material used in transport are treated to ensure inactivation of *P. olseni* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials are treated to ensure inactivation of *P. olseni* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 11.6.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *P. olseni*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and
2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *P. olseni* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and
3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *P. olseni* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and
4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 11.6.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *P. olseni* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *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 *aquatic animal products* that 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* 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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal products* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2001; MOST RECENT UPDATE ADOPTED IN 2024.

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 *(Haliotis sorenseni)*, red abalone *(Haliotis rufescens)*, pink abalone *(Haliotis corrugata)*, green abalone (*Haliotis tuberculata* and *Haliotis fulgens*), flat abalone *(Haliotis wallalensis)* and Japanese abalone *(Haliotis discus-hannai)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 11.7.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *X. californiensis* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *X. californiensis*, regardless of the infection with *X. californiensis* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 95°C for at least five minutes, or a time/temperature equivalent that inactivates *X. californiensis*.

Article 11.7.4.

Requirements for self-declaration of freedom from infection with *X. californiensis*

A Member Country may make a self-declaration of freedom from infection with *X. californiensis* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 11.7.5. to 11.7.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

1) complies with the provisions of Chapter 3.1.; and
2) uses appropriate methods of *diagnosis*, as recommended in the *Aquatic Manual*; and
3) meets all requirements of Chapter 1.4. that are relevant to the self-declaration of freedom.

Article 11.7.5.

Country free from infection with *X. californiensis*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *X. californiensis* if all shared water bodies are within countries or *zones* declared free from infection with *X. californiensis* (see Article 11.7.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *X. californiensis* for its entire *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *X. californiensis* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *X. californiensis*, as described in the corresponding chapter of the *Aquatic Manual*; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *X. californiensis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *X. californiensis* and subsequently lost its free status due to the detection of *X. californiensis* but the following conditions have been met:
   a) on detection of *X. californiensis*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *X. californiensis*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *X. californiensis*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:
      i) at least the last [two] years in wild and farmed *susceptible species* without detection of *X. californiensis*; or
      ii) at least the last [one] year without detection of *X. californiensis* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free zone* as described in Article 1.4.4.

Article 11.7.6.

Zone free from infection with *X. californiensis*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *X. californiensis* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *X. californiensis* for a *zone* within its *territory* if it can demonstrate that:

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 [six] months;

OR

2) there has been no occurrence of infection with *X. californiensis* for at least the last [ten] years, and:
   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *X. californiensis*, as described in Article 1.4.8. of Chapter 1.4.; and
   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of *X. californiensis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *X. californiensis* and subsequently lost its free status due to the detection of *X. californiensis* in the *zone* but the following conditions have been met:
   a) on detection of *X. californiensis*, the affected area was declared an *infected zone* and a *protection zone* was established; and
   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *X. californiensis*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and
   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *X. californiensis*; and
   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of *X. californiensis*.

In the meantime, a part of the *zone* outside the *infected zone* and *protection zone* may be declared a new *free zone* as described in Article 1.4.4.

Article 11.7.7.

Compartment free from infection with *X. californiensis*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *X. californiensis* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last [two] years without detection of *X. californiensis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *X. californiensis* and subsequently lost its free status due to the detection of *X. californiensis* in the *compartment* but the following conditions have been met:
   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *X. californiensis*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and
   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.7.9. and 11.7.10. as appropriate; and
   c) one survey for infection with *X. californiensis* has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 11.7.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *X. californiensis* following the provisions of Articles 11.7.4. to 11.7.7. (as relevant) may maintain its status as free from infection with *X. californiensis* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 11.7.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *X. californiensis*

When importing *aquatic animals* of a species referred to in Article 11.7.2., or *aquatic animal products* derived thereof, 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*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 11.7.5., 11.7.6. or 11.7.7. (as applicable) and 11.7.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *X. californiensis*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in point 1 of Article 11.7.3.

Article 11.7.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with infection with *X. californiensis*

When importing, for *aquaculture*, *aquatic animals* of a 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* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:
   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and
   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in point 1 of Article 11.7.3. or other products authorised by the *Competent Authority*; and
   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *X. californiensis* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:
   a) In the *exporting country*:
      i) identify potential source populations and evaluate their *aquatic animal* health records;
      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *X. californiensis*.
   b) In the *importing country*:
      i) import the F-0 population into a *quarantine* facility;
      ii) test the F-0 population for *X. californiensis* in accordance with Chapter 1.4. to determine their suitability as broodstock;
      iii) produce a first generation (F-1) population in *quarantine*;
      iv) culture F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *X. californiensis*, and sample and test for *X. californiensis* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.4.7. of the *Aquatic Manual*;
      v) if *X. californiensis* is not detected in the F-1 population, it may be defined as free from infection with *X. californiensis* and may be released from *quarantine*;
      vi) if *X. californiensis* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 11.7.11.

Importation of aquatic animals or 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* of a species referred to in Article 11.7.2., or *aquatic animal products* derived thereof, 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 in point 1 of Article 11.7.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *X. californiensis* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *X. californiensis* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 11.7.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with with *X. californiensis*

When importing *aquatic animals* of a species referred to in Article 11.7.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, 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* or containment facilities until processed into one of the products referred to in point 1 of Article 11.7.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers*, and packaging material used in transport are treated to ensure inactivation of *X. californiensis* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *X. californiensis* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 11.7.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *X. californiensis*

When importing, for use in laboratories or zoos, *aquatic animals* of a 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 ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *X. californiensis* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *X. californiensis* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 11.7.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with with *X. californiensis*

1) *Competent Authorities* should not require any conditions related to *X. californiensis*, regardless of the infection with *X. californiensis* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit

of the following *aquatic animal products* that have been prepared and packaged for retail trade and which comply with Article 5.4.2.:

a) off the shell, eviscerated abalones (chilled or frozen).

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 *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal products* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a 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.

NB: FIRST ADOPTED IN 2002; MOST RECENT UPDATE ADOPTED IN 2024.

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