Annex 3. Item 4. – Work plan and priorities

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway would like to commend the Aquatic Animal Health Standards Commission for its work. Norway reiterates its continued commitment to participate in the work of WOAH and to offer technical support as needed by the Aquatic Animals Commission and its ad hoc groups for future work on the Aquatic Code and Manual. Norway would particularly like to thank the Aquatic Animals Commission for continuing to engage the Norwegian broodstock industry in drafting an additional article for the draft new Chapter 4.Z. Control of pathogenic agents in traded gametes and fertilised eggs of fish.

WORK PLAN FOR THE AQUATIC ANIMALS COMMISSION

(including provisional timelines for commenting and adoption)

Aquatic Code			
Chapter/Subject	**Status**		
	February 2024	**May GS 2024**	**September 2024**
Monitor emerging diseases and consider any required actions	On-going		
Glossary definitions: 'Competent Authority', 'Veterinary Authority' and 'Aquatic Animal Health Services'	Review comments (2nd round)	Propose for adoption	–
Glossary definitions: 'aquatic animal products'	Review comments (1st round)	Propose for adoption	–
Chapter 1.3. 'Diseases listed by WOAH' – Listing of infection with infectious spleen and kidney necrosis virus species	Review comments (3rd round)	Propose for adoption	–
Article 1.1.5. of Chapter 1.1. 'Notification of diseases and provision of epidemiological information'	Review comments (2nd round)	Propose for adoption	–
Chapter 4.3. 'Application of Compartmentalisation'	Review responses to discussion paper, revise and provide for information	–	Draft revised Chapter 4.3. and present for comment
Draft new Chapter 4.X. 'Emergency disease preparedness'	Review comments (1st round)	–	Review comments (2nd round)

Aquatic Code			
Chapter/Subject	**Status**		
	February 2024	**May GS 2024**	**September 2024**
Draft new Chapter 4.Y. 'Disease outbreak management'	Review comments (1st round)	–	Review comments (2nd round)
Draft new Chapter 4.Z. 'Control of pathogenic agents in traded milt and fertilised eggs of fish'	Review comments (1st round)	–	Review comments (2nd round)
Draft new Chapter 5.X. 'Movement of ornamental aquatic animals'	Review comments (1st round)	–	Review comments (2nd round)
Susceptible Species Assessment of new evidence for previously assessed diseases (as necessary)	On-going		
Safe commodities **Articles 8.X.3. – Amphibian**	Review comments (3rd round)	Propose for adoption	–
Safe commodities **Articles 9.X.3. – Crustacean**	Review comments (2nd round)	Propose for adoption	–
Safe commodities **Articles 10.X.3. – Fish**	Review comments (2nd round)	Propose for adoption	–
Safe commodities **Articles 11.X.3. – Mollusc**	Review comments (3rd round)	Propose for adoption	–
Assessment of default periods in Articles X.X.4.-X.X.8. for disease-specific chapters	Present assessment of default periods with proposed changes	–	–
Model Articles X.X.5. and X.X.6. for disease-specific chapters	Review comments (1st round)	Propose for adoption	–
Susceptible Species – Crustacean diseases – Articles 9.X.1. and 9.X.2. for: **– Infection with decapod iridescent virus** **– Infection with white spot syndrome virus** **– Infection with *Aphanomyces astaci* (Crayfish plague)**	DIV1: Review comments (1st round)	DIV1: Propose for adoption	–
	WSSV: Review *ad hoc* Group report and present amended articles for comment	–	WSSV: Review comments (1st round)
	–	–	Crayfish plague: Review interim *ad hoc* Group report
Article 10.6.2. of Chapter 10.6. Infection with infectious haematopoietic necrosis virus	Review comments (1st round)	Propose for adoption	–
Susceptible Species – Fish diseases – Articles 10.X.1. and 10.X.2. for: **– Infection with Tilapia lake virus** **– Infection with *Aphanomyces invadans* (Epizootic ulcerative syndrome)**	TiLV: Review comments (1st round)	TiLV: Propose for adoption	–
	EUS: Review interim *ad hoc* Group report	–	EUS: Review *ad hoc* Group report and present amended articles for comment

Aquatic Code			
Chapter/Subject	**Status**		
	February 2024	**May GS 2024**	**September 2024**
Susceptible species – Mollusc diseases – Articles 11.X.1. and 11.X.2. for: **– Infection with *Perkinsus marinus*** **– Infection with *Perkinsus olseni*** **– Infection with *Xenohaliotis californiensis***	*Perkinsus marinus*: Review comments (2nd round)	*Perkinsus marinus*: Propose for adoption	–
	Perkinsus olseni: Review *ad hoc* Group report and present amended articles for comment	–	*Perkinsus olseni*: Review comments (1st round)
	–	–	*Xenohaliotis californiensis*: Review *ad hoc* Group report and present amended articles for comment

Aquatic Manual			
Chapter/Subject	**Status**		
	February 2024	**May GS 2024**	**September 2024**
Chapter 1.1.1. 'Quality management in veterinary testing laboratories'	Provide comments to BSC	Propose for adoption	–
Chapter 1.1.2. 'Validation of diagnostic assays for infectious diseases of aquatic animals'	Review first draft	–	Review second draft presented by two AAC members with input from RLs
Chapter 2.2.0. 'General information: diseases of crustaceans'	Review comments (3rd round)	Propose for adoption	–
Chapter 2.2.2. 'Infection with *Aphanomyces astaci* (Crayfish plague)'	Review comments (3rd round)	Propose for adoption	–
Chapter 2.2.4. 'Infection with infectious hypodermal and haematopoietic necrosis virus'	–	–	Review updated draft and present for Member comments
Chapter 2.2.6. 'Infection with Macrobrachium rosenbergii nodavirus (white tail disease)'	Review comments (2nd round)	Propose for adoption	–
Chapter 2.2.9. 'Infection with yellow head virus genotype 1'	Review comments (2nd round)	Propose for adoption	–
Chapter 2.2.X. 'Infection with decapod iridescent virus 1'	Review comments (1st round)	Propose for adoption	–
Chapter 2.3.4. 'Infection with HPR-deleted or HPR0 infectious salmon anaemia virus'	–	–	Review updated draft and present for Member comments
Chapter 2.3.9. 'Infection with spring viraemia of carp virus'	Review validation or publication of real-time PCR	–	Review updated draft and present for Member comments

Aquatic Manual			
Chapter/Subject	**Status**		
	February 2024	**May GS 2024**	**September 2024**
Chapter 2.3.X. 'Infection with tilapia lake virus'	–	–	Review first draft and present for Member comments
Chapter 2.4.0. 'General information: diseases of molluscs'	Review comments (1st round)	Propose for adoption	–
Chapter 2.4.1. 'Infection with abalone herpes virus'	Review comments (1st round)	Propose for adoption	–
Chapter 2.4.4. 'Infection with *Marteilia refringens*'	Review comments (1st round)	Propose for adoption	–
Chapter 2.4.2. 'Infection with *Bonamia exitiosa*'	Review updated draft	–	Review updated draft and present for comments
Chapter 2.4.3. 'Infection with *Bonamia ostreae*'	Review updated draft	–	Review updated draft and present for comments
Section 2.2.1. and 2.2.2. of Chapter 2.2.8. 'Infection with white spot syndrome virus'	Review *ad hoc* Group report and present amended sections for comment	–	Review comments (1st round)
Sections 2.2.1. and 2.2.2. of Chapter 2.4.5. 'Infection with *Perkinsus marinus*'	Review comments (2nd round)	Propose for adoption	–
Section 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *Perkinsus olseni*'	Review *ad hoc* Group report and present amended sections for comment	–	Review comments (1st round)

Annex 40. Item 7.1. – Draft new Chapter 4.X. 'Emergency disease preparedness'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.X.

EMERGENCY DISEASE PREPAREDNESS

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed changes to this Chapter.

Article 4.X.1.

Purpose

To describe the essential elements of an emergency disease preparedness framework which a *Competent Authority* should develop in accordance with country priorities and resources to ensure that *outbreaks* of important and *emerging aquatic animal diseases* can be rapidly identified and efficiently managed, and which will guide a country, *zone* or *compartment*, towards a suitable path to recovery.

An important *aquatic animal disease* is one which has been identified by the *Competent Authority* in accordance with Article 4.X.6. Such *diseases* may be listed in Chapter 1.3., or they may be *emerging diseases* or other *aquatic animal diseases*.

Article 4.X.2.

Scope

This chapter describes recommendations for the development of an emergency disease preparedness framework. This framework encompasses all the elements that will enable the *Competent Authority* to activate an efficient response to a *disease outbreak*, thereby minimising the impact on *aquatic animal* populations, trade, the economy, and the financial resources that are required to manage *disease outbreaks*. The specific actions which are necessary to operationalise the framework in the event of a *disease outbreak* are described in Chapter 4.Y.

Article 4.X.3.

Introduction

*Aquatic animal disease*s have the potential to spread quickly, often with serious consequences. In many parts of the world, these *disease* events appear to be increasing in frequency and severity, due to increased *aquaculture* production and *international trade*. This chapter provides recommendations for a *Competent Authority* to identify and coordinate the elements of a framework, which will achieve a suitable level of preparedness for those emergencies.

When developing the framework, it is of fundamental importance to ensure that the *aquatic animal disease*s which are important to a country, *zone* or *compartment*, are identified in advance (i.e. in peacetime) by the *Competent Authority*, and that their future control is supported by adequate legislative and funding measures. The statutory list of important *disease*s that is developed after

conducting a *risk analysis* as described in 4.X.6.*,* may include *aquatic animal disease*s which are listed in Chapter 1.3., as well as other *disease*s which have been identified as being of importance to the country, *zone* or *compartment*.

Also in peacetime, the *Competent Authority* should take a systematic approach to planning every element of the framework that will be applied from the point at which an important *disease* is suspected during the alert phase, through the activation of the *contingency plan* in the emergency phase, to the point at which the recovery phase begins and the emergency officially ends.

The *Competent Authority* should consider whether the *contingency plan* and recovery plan elements of the emergency disease preparedness framework apply either to a specific *aquatic animal disease* or to a group of such *diseases*. The *Competent Authority* should decide in peacetime, which of these approaches best meets their needs, taking into account *aquatic animal diseases* that are listed in their country, the relevant *susceptible species,* and types of production.

Article 4.X.4.

General principles

Emergency *disease* preparedness is a core function of the *Competent Authority.* The various elements that are necessary to ensure that the *Competent Authority* is prepared to deal with an *outbreak* of an important *disease*, are elaborated in a framework. The framework is constructed in peacetime before the occurrence of a *disease outbreak*.

The ultimate success of the framework will be influenced by the quality of the preparations which have been made by the *Competent Authority*, and the commitment and coordination of the *Aquatic Animal Health Services*, and relevant industry stakeholders.

The general principles to be considered when developing an emergency disease preparedness framework are as follows:

1) legal provisions and funding should be available to allow a *Competent Authority* to execute all elements of the framework and to manage disease outbreaks in compliance with the *contingency plan*, and with the detailed operational measures which are referred to in Chapter 4.Y.;

2) risk analysis should be used in advance of, during and after a *disease outbreak* as described in Article 4.X.6. The *risk analysis* that is carried out in advance will identify the important *aquatic animal diseases* which will be subject to emergency measures. The *risk analysis* that is carried out during and after the *disease outbreak* will inform the response and recovery actions which will be taken by the *Competent Authority*, ~~and~~ the *Aquatic Animal Health Services*, and industry stakeholders;

3) a *contingency plan should be developed* for a specific *aquatic animal disease* or group of related *aquatic animal diseases*, following appropriate consultation with the *Aquatic Animal Health Services*, which contains at least the components outlined in points (a) to (f) of Article 4.X.7. The *contingency plan* is:

   a) partially activated in compliance with Article 4.Y.4.~~Chapter 4.Y.~~ when the presence of an important *disease* is suspected during the 'alert phase';

   b) fully activated in compliance with Article 4.Y.5.~~Chapter 4.Y.~~ once the *disease* emergency has commenced during the 'emergency phase'.

4) simulation exercises should be planned and executed to test, and ultimately to improve, relevant elements of the *disease* preparedness framework. Simulation exercises support~~ensure that~~ *Competent Authorities* and *Aquatic Animal Health Services* to be~~are~~ trained and properly equipped and resourced~~to manage suspicion and confirmation of an important *disease* in their *territory,*~~ in accordance with Article 4.X.8.;

5) all elements of the framework should be regularly reviewed and revised as described in Article 4.X.9.;

6) a 'recovery plan' should be prepared as described in Article 4.X.11., which will be based on *risk analysis* and on the recovery options which are described in Article 4.X.10.

Article 4.X.5.

Legal provisions and funding

There are certain pre-requisites for an emergency disease preparedness framework including~~. Such pre-requisites include~~ that the *Competent Authority* has:

1) ~~recourse to~~ *aquatic animal* health legislation which underpins the execution of all the elements and actions that are necessary to manage suspicion and confirmation of an *outbreak* of an important *aquatic animal disease* as described in Article 4.X.6.*;*

2) access to emergency resources including funds which are sufficient to allow the execution of the relevant elements of the *disease* preparedness framework as well as the operational measures which are set out in Chapter 4.Y.

Any delay in the ability of the *Competent Authority* to rely on legal provisions, or to access finance, can hamper the effective management of a *disease* emergency. Delays should be avoided, or at least minimised, by ensuring that all the administrative steps that must be followed to transmit the necessary funds from the central funding authority to the *Competent Authority* are identified.

Article 4.X.6.

Risk analysis

Risk analysis plays an important role before, during and after a *disease outbreak*. It is therefore, of critical importance that this expertise is available to the *Competent Authority* to ensure that the emergency disease preparedness framework can be efficiently executed. This article elaborates the principles described in Chapter 2.1. and applies them in the context of emergency *disease* preparedness.

Identification of *aquatic animal diseases* which will be subject to emergency measures

Risk analysis should be used by the *Competent Authority* to determine which important *diseases* of *aquatic animal*s present a threat and should, therefore, be subject to emergency measures in the event of a *disease outbreak*.

The *risk analysis* should take account of a country's circumstances. In particular, the knowledge of relevant wild and farmed *aquatic animal* species in the *territory*, as well as their geographic distribution, *disease* status and economic and trade importance, are critical to the completion of an effective *risk analysis*. Such *risk analysis* should also include information on the most important routes of introduction, transmission pathways, life cycle stages, persistence in the environment, likelihood of eradication, which will inform *disease* control strategies and response options which are referred to in Article 4.X.10.

The list of important *aquatic animal* dise*ases* that may be subject to emergency measures should be under regular~~continual~~ review by the *Competent Authority*. The *risk analysis* should utilise~~take into account~~ the latest relevant scientific findings and should be repeated regularly to assess the threat of *emerging diseases.* Changes in the species farmed, and in the distribution or virulence of known *pathogenic agents* should inform changes in national *disease* listings. *Competent Authorities* should ensure they collate the data required for completing and updating *risk analysis.*

Surveillance activities

Suspicion of an *outbreak* of an important *aquatic animal disease*, which is subject to statutory control, often results from *surveillance* activities. Therefore, emergency *disease* preparedness systems are heavily reliant on the *surveillance* and reporting activities carried out by the *Aquatic Animal Health Services*, and relevant industry stakeholders in accordance with Chapter 1.4. The outcomes from an emergency disease preparedness framework are fundamentally reliant on the quality of *surveillance* and reporting activities.

In addition, when the presence of an important *aquatic animal disease* is suspected or has been confirmed, *risk analysis* has a crucial role to play in prioritising *surveillance* activities as part of forward and backward epidemiological tracing, and establishing *protection zones* and *infected zones*.

Response actions during the *disease* emergency

As part of preparedness planning, *risk analysis~~assessment~~* protocols should be developed to support decision making by the *Competent Authority* during an *outbreak*. The *risk analysis* should be able to identify the *risk* mitigation measures and protocols that~~Protocols~~ are required to cover a range of *disease* control options e.g. the possibility to on-grow stock on an infected *aquaculture establishment* to slaughter weight (which will include an assessment of the *risk* of spread within a particular water body), and the possibility to move live *aquatic animals* within *infected zones*.

A *risk analysis~~assessment~~* of depopulation activities should be undertaken to ensure that they are carried out with the minimum risk of *disease* spread. In addition, prior to repopulation, a *risk analysis~~assessment~~* should be completed to determine if further *risk* mitigation measures are required to prevent reinfection of the new stock of *aquatic animals*.

Article 4.X.7.

Contingency plan

The *Competent Authority* should decide whether the *contingency plan* applies either to a specific *aquatic animal disease* or to a group of such *diseases* which, because of their similarity to each other, may be managed effectively using the same principles e.g. certain finfish *diseases* that occur in freshwater, certain mollusc *diseases* that occur in seawater.

The *Competent Authority* should also consider that because of the nature of *emerging diseases*, the *contingency plan* and the recovery plan, which are devised for such *aquatic animal diseases*, should be generic. Such generic plans will, however, require rapid and effective fine-tuning, once the details of the *emerging disease* have become known, and the *Competent Authority* has assessed that the *disease* in question should be subject to emergency *disease* preparedness measures.

The *contingency plan* should include at least the following components:

1) the establishment of a clear chain of command within the country, from the central level to the regional and local levels, with the *Competent Authority* in overall command. This chain of command should include decision makers from the *Aquatic Animal Health Services* who may not deal directly with *aquatic animal* health, but who play a role in the emergency disease preparedness framework;

2) a framework for cooperation between the *Competent Authority*, ~~and the~~ *Aquatic Animal Health Services* and industry stakeholders. This cooperation should:

    a) ensure that all actions, and roles and responsibilities which form part of the plan are well understood and discussed in advance of and during, any *disease outbreaks*, thereby ensuring that rapid and effective decisions can be made when necessary;

    b) result in the establishment of at least the following groups which meet at frequencies which may vary depending on the phase of the emergency:

        i) a formally recognised emergency management group which is chaired by the *Competent Authority*;

        ii) specialist sub-groups which will provide specific advice to the emergency management group~~Emergency Task Force~~ for consideration e.g. epidemiology group, laboratory group, logistics group, communications group, environmental group, producers' group, mental health and psychological support group.

3) identification of, and arrangements for access to, appropriate:

    a) central and local *disease* control centres;

    b) laboratories;

    c) equipment;

    d) trained personnel;

    e) communications and media liaison;

    f) data management or information systems;

    g~~f~~) additional materials and resources that may be required, including for instance, telecommunications, transport, vaccines, experts (e.g. in the areas of logistics, fisheries management, environmental protection);

    h~~g~~) service providers (e.g. waste disposal contractors, Personal Protective Equipment (PPE) suppliers, chemical suppliers, standby generators).

4) the general *biosecurity* and *disease* control measures which will be taken in the event of suspicion or confirmation of the presence of an important *aquatic animal disease* to which the *contingency plan* applies. The general *biosecurity* measures which will apply to *aquaculture establishments* should follow the guidance on~~comply with~~ the measures which are described in Chapter 4.1. Coordination of control measures with neighbouring countries with shared waterbodies should be taken into account;

5) concerning specific *disease* control measures, the duration of the *fallowing* period that may apply following de-population, cleaning and *disinfection*, should be considered~~, using *risk assessment*~~. The duration of the fallowing period~~Such an assessment~~ should take into account relevant factors such as the nature of the relevant *pathogenic agent*, the type and extent of the production system, hydrographical factors and the nature of local wild *aquatic animal* populations. ~~The *risk assessment* should also inform the need for synchronised~~Synchronised *fallowing* of a number of *aquaculture establishments*, should be considered in certain circumstances;

6) possible response options that can be applied to manage a *disease outbreak*, based on *risk assessment*. Such response options would depend on the progression of the *disease outbreak* and could include measures such as eradication, containment through *biosecurity* measures, mitigation of *disease* consequences, or no *disease* response;

7) *risk communication* strategy which will apply during each stage of the process, both within and between the various authorities and services and with relevant stakeholders. For example, the *contingency plan* should set out the nature and timing of communications with the personnel who are described in points 2(b)(i) and (ii) above, as well as taking community engagement into account, where appropriate. The *risk communication* strategy should be based on the principles of *risk communication* described in Chapter 2.1.

The actions necessary to operationalise points 1 to 7 above are described in Chapter 4.Y.

Article 4.X.8.

Simulation exercises

Simulation exercises are a crucial component of emergency *disease* preparedness. The objectives of such exercises are to validate and test the functionality and suitability of the *contingency plan* and the operational measures which are described in Chapter 4.Y. Simulation exercises will also validate and test the capacity of *Competent Authorities*, ~~and~~ *Aquatic Animal Health Services*, and industry stakeholders to respond to an important *aquatic animal disease*. The emergency disease preparedness framework should include a requirement for the regular completion of simulation exercises to test that all personnel are adequately trained and prepared for the tasks which have been allocated to them. An outcome report should be produced following each simulation exercise, describing the actions necessary to close any gaps which have been identified in the *contingency plan*, or other amendments which are required to the operational measures which are described in Chapter 4.Y.

The *Competent Authority* should set a minimum frequency for the completion of such exercises, to ensure readiness to efficiently execute the various elements of the *contingency plan,* should it be activated. Simulation exercises may be organised within a country or among the *Competent Authorities* and *Aquatic Animal Health Services* of countries or *zones* with shared waterbodies where relevant.

A simulation exercise should have clearly defined objectives with respect to the elements of the emergency disease preparedness framework or *outbreak* response capability that is being evaluated. The objectives will inform the type of exercise, participation and the exercise design.

The planning, organisation, and completion of simulation exercises should take account of the following points:

1) different types of exercises may be used e.g. tabletop, limited field exercises or more extensive field exercises;

2) the scale, frequency and scope of the exercises should be based on *risk* prioritisation, which has been completed by the *Competent Authority,* taking account of any new *risk* factors which have been identified;

3) exercises should include the *Competent Authority* at different administrative levels, as well as the *Aquatic Animal Health Services,* and relevant industry stakeholders that will be involved in the application of the *contingency plan* in the event of a *disease* emergency;

4) exercises should test the capacity of the *Competent Authority* to manage every element of the emergency disease preparedness framework, from the initial *disease* alert to the end of the recovery phase;

5) once completed, each simulation exercise should be thoroughly evaluated by the organiser, and an outcome report should be prepared, with the objective of identifying:

   a) the elements of the emergency disease preparedness framework that are fit-for-purpose, and those that are not;

   b) the readiness and capacity of the *Competent Authority*, ~~and~~ the *Aquatic Animal Health Services*, and industry stakeholders to respond to the elements of the emergency disease preparedness framework, that were tested during the exercise.

   c) any gaps/issues raised and any actions to be taken forward, including a timeframe within which these should be addressed.

Article 4.X.9.

Revision and review

The *Competent Authority* should establish a mechanism to improve its emergency disease preparedness framework through regular review, and where necessary, revision of its various elements.

The list of *aquatic animal diseases* which are subject to the emergency disease preparedness framework should be under regular~~continual~~ review, as described in Article 4.X.6.

Review and revision of the *contingency plan* and the operational measures which are set out in Chapter 4.Y. should take into account, the outcomes from the evaluation of the simulation exercises described in Article 4.X.8., and the implementation of an emergency *disease* response, where this is relevant.

The review process consequently may necessitate a revision of the *contingency plan* or other elements of the emergency disease preparedness framework. Such exercises and responses should also be used to highlight the training needs of personnel from the *Competent Authority* and the *Aquatic Animal Health Services,* and to inform the possible revision of the legislation which underpins the framework.

The regular review and revision of the emergency disease preparedness framework should also take into account measures to strengthen the *contingency plan* or to prevent another *disease* emergency event~~,~~ (e.g. updated scientific information including diagnostic tests, improvements in technology or relevant industry practices, as well as any other new elements which will improve the overall suitability and effectiveness of the framework).

All revisions which are made as a result of the review process described above should be communicated to the *Aquatic Animal Health Services* and industry stakeholders within an agreed timeframe.

Article 4.X.10.

Response Options

The *Competent Authority* should take into account that the initial objective of successfully completing an eradication programme and re-gaining *disease* freedom in a country, *zone* or *compartment* following a *disease outbreak*, may change as *the outbreak* develops.

While the purpose of the recovery plan, may be to re-establish the *disease-free* situation which existed before the *disease outbreak* occurred, it should be considered that in certain cases, the *aquatic animal health status* which is achieved after the emergency has ended, may not be the same as the one which existed before the *outbreak* occurred. Various response options should, therefore, be set out in the emergency disease preparedness framework, upon which the recovery plan can be based, depending on the epidemiological situation which exists at the end of the emergency.

Concerning the *aquatic animal diseases* which are listed in Chapter 1.3., and taking into account Chapter 1.4., the possible options the *Competent Authority* could consider as part of their recovery plan are as follows:

1) demonstrate the re-establishment of disease freedom at country, *zone* or *compartment* level;

2) establish a *disease free zone* in a previously *disease free country*;

3) establish a redefined (reduced) *disease free zone*;

4) establish one or more *disease-free compartments*;

5) relinquish *disease* free status and take measures to contain the *disease*;

6) take measures which are designed to mitigate the impacts of the *disease*;

7) accept that none of the options outlined above are feasible and no official disease control measures will be applied.

If *disease* control operations are halted before regaining the pre-*outbreak disease* free status at country or *zone* level, the recovery plan should set out how the *Competent Authority* could explore the potential to establish redefined *disease free zones* or *compartments.*

Where the options described in points 1 to 6 above are not possible for epidemiological, logistical or economic reasons, the *Competent Authority* may accept an evolution from the original *disease* free status, to one where the *disease* has become endemic, but where the epidemiological situation is stable.

Concerning important *aquatic animal diseases* which are not listed in Chapter 1.3., but which are listed in the national legislation of a country, the *Competent Authority* may decide to apply a similar range of options to those described in points 1 to 4 above. However, these would not fall within the scope of the official *disease free* statuses that may be established for a country, *zone* or *compartment*, as described in Chapter 1.4.

Article 4.X.11.

Recovery plan

The *Competent Authority* should decide whether the recovery plan applies either to a specific *aquatic animal disease* or to a group of such diseases which, because of their similarity to each other, may be managed effectively using the same principles e.g. certain finfish *diseases* that occur in freshwater, certain mollusc *diseases* that occur in seawater.

The recovery plan should be activated when the end of the emergency has been declared by the *Competent Authority*. The point at which the emergency ends, and the nature of the recovery plan, will be determined by *risk* *analysis*~~*assessment*~~, which will take account of the following factors as well as the options described in Article 4.X.10.:

1) the current geographic distribution of the *pathogenic agent;*

2) whether or not, the *disease* has become established in wild *aquatic animal* populations;

3) the costs and feasibility of establishing and maintaining *disease*-freedom at the level of country, *zone* or *compartment,* taking into account hydrological and epidemiological connections;

4) the socio-economic impact of the possible recovery option(s);

5) any *risk* the *disease* may pose to vulnerable wild *aquatic animal* populations in the infected or adjacent areas.

Concerning the response options described in points 1 to 6 of Article 4.X.10., the recovery plan should include details of the actions which the *Competent Authority* and the operators of *aquaculture establishments* should take to:

6) prepare a self-declaration of freedom from *disease*, as referred to in points 1 to 4 of Article 4.X.10.; or

7) put in place appropriate *biosecurity* measures in compliance with Chapter 4.1., to ensure the disease is contained, as referred to in point 5 of Article 4.X.10.; or

8) put in place the mitigation measures which are referred to in point 6 of Article 4.X.10.~~,~~ (e.g. vaccination, change of production species, or change in husbandry practices);

9) consider research requirements to support the actions referred to in points 6 to 8.

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Annex 41. Item 7.1. – Draft new Chapter 4.Y. 'Disease outbreak management'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.Y.

DISEASE OUTBREAK MANAGEMENT

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed changes to this Chapter.

Article 4.Y.1.

Purpose

To provide recommendations concerning the actions which should be taken by the *Competent Authority* and the *Aquatic Animal Health Services* to manage the emergency response to suspicion or confirmation of the presence of an important *aquatic animal disease*, and activate its contingency plans as described in Chapter 4.X.

Article 4.Y.2.

Scope

To provide recommendations concerning the actions to be taken by the *Competent Authority* and the *Aquatic Animal Health Services,* from the point at which an important *disease*, as described in Article 4.X.6., is suspected in a *free country*, *free zone* or *free compartment*, or has been suspected or confirmed in an epidemiologically linked population, to the point at which the recovery phase begins. These actions operationalise the elements described in Chapter 4.X., which are required to manage the *disease outbreak*.

Article 4.Y.3.

General Principles

The successful management of an emergency response should take the following principles into account:

1) the actions to be taken by the *Competent Authority* and the *Aquatic Animal Health Services*, should be based on the emergency *disease* preparedness framework which has been developed in accordance with Chapter 4.X.;

2) the operational elements of the emergency *disease* preparedness framework should be described in an Operations Manual. The Operations Manual may be a single document or a series of documents which together, ~~The *Competent Authority* can rely on the Operations Manual to~~ provide guidance on all aspects of the emergency response, including actions to be taken during the alert, emergency, and recovery phases;

3) the initial response objective following a *disease outbreak* is to eradicate the *disease*, thereby allowing a country, *zone* or *compartment* to return to *disease* freedom. However, should the progression of the *outbreak* prevent this objective from being achieved, other actions should be described, which will assist the *Competent Authority* to pursue an alternative pathway to recovery;

4) the actions described in the Operations Manual should be executed in a timely and co-ordinated fashion, by competent personnel, who have access to all the resources which are necessary to manage the *disease outbreak*.

Article 4.Y.4.

Alert phase

The alert phase begins when there is suspicion of the presence of an important *disease* of *aquatic animals*, generally as a consequence of active or *passive surveillance* in the country, or in another country, which is a neighbour or a trading partner.

The main actions to be taken into account during the alert phase of an emergency should take the following factors into account:

~~1) the alert phase begins when there is suspicion of the presence of an important *disease* of *aquatic animals*, generally as a consequence of active or *passive surveillance* in the country, or in another country, which is a neighbour or a trading partner. During this phase, the *Competent Authority* will take steps to detect the presence of the *disease* and to prevent possible *disease* spread;~~

1~~2~~) following the commencement of this phase, an epidemiological investigation should be initiated in order to:

a) confirm or rule out the presence of the *disease*, in the shortest possible time frame;

b) establish a working case definition for outbreak investigation where this is necessary (e.g. in the case of a disease which is not listed in Chapter 1.3., or of an emerging disease);

c~~b~~) determine if the *disease* has spread from or to *aquaculture establishments* or waterbodies other than the one in which the original suspicion was raised.

2~~3~~) during the epidemiological investigation:

a) *risk*-based *surveillance* is used to prioritise which *aquatic animal* populations, identified through tracing, should be prioritised for sampling. For example, *aquaculture establishments* which are highly connected to the *aquaculture establishment* or waterbody in which the suspicion arose, through movements of live *aquatic animals* and other transmission pathways, as described in Article 4.1.7., should be considered~~prioritised~~ for clinical inspection and sampling;

b) the samples should be submitted to laboratories identified in the *Contingency Plan,* as described in Chapter 4.X., as being suitably equipped and staffed to produce reliable results in the shortest possible timeframe.

3~~4~~) during the alert phase, taking into account Chapter 4.1., the *Competent Authority* should take steps to prevent *disease* spread by implementing *biosecurity* measures in the *aquaculture establishment* or waterbody in question. Additional specific *disease* control measures should also be considered, such as:

a) prohibiting the movement of *aquatic animals* and *aquatic animal products* as well as equipment, *vehicles*, *feed*, contaminated water and *aquatic animal waste* to or from the *aquaculture establishment* or waterbody, unless authorised by the *Competent Authority* based on a *risk assessment*;

b) extending the measures described above to other *aquaculture establishments* or waterbodies that have an epidemiological link with the *aquaculture establishment* or waterbody in which the suspicion arose.

4~~5~~) whilst awaiting the outcome of the epidemiological investigation referred to in point 1 a)~~described~~ above, in the case of suspicion of a *disease* outbreak in a previously *free country* or *free zone*, the *Competent Authority* should inform ~~communicate with~~ the emergency management group, as described in Chapter 4.X., and where necessary, convene a meeting to advise them of developments and review the *Contingency Plan*. The objectives of this review are to:

a) reinforce the structure of the chain of command and the framework for cooperation which are described in Article 4.X.6.;

b) ensure the *Contingency Plan*, as described in Chapter 4.X., is ready to be fully activated should the presence of the *disease* in question be confirmed in the country, *zone*, *compartment*; and

c) make any updates which are necessary to ensure the *Contingency Plan* is ready for immediate activation.

5~~6~~) whilst confirmation of the presence of the *disease* in question is ongoing, the *Competent Authority* should communicate with relevant personnel, industry stakeholders, diagnostic laboratories, and contractors, putting them on alert to ensure they review their readiness to act quickly in compliance with the *Contingency Plan*, should the *disease* be confirmed. Such communications are made using the contact details which are kept in accordance with Chapter 4.X.;

6~~7~~) the *Competent Authority* should endeavour to ensure that the alert phase is short enough to minimise *disease* spread, and long enough to ensure the suspicion has been accurately confirmed or ruled out;

7~~8~~) should the suspicion not be confirmed, the alert phase is terminated, and any outcomes which warrant review of the *Contingency Plan*, are made;

8~~9~~) the alert phase ends when the presence of an important *disease* is either confirmed or ruled out by the *Competent Authority.* Relevant actors in the *Aquatic Animal Health Services* should be communicated with to advise them that the alert phase is being terminated, and that the situation is either moving back to peacetime or forward to the emergency phase as described in Article 4.Y.5.

Article 4.Y.5.

Emergency Phase

The emergency phase of *disease outbreak* management commences when the presence of an important *disease* has been confirmed. The steps which should be taken during the emergency phase are set out in the *Contingency Plan*, and the associated detailed actions are set out in the Operations Manual, taking the following factors into account:

1) the chain of command as described in Article 4.Y.6.;

2) the appropriate facilities, ~~skills,~~ resources, personnel and skills as described in Article 4.Y.7.;

3) the *Biosecurity* and other *disease* control measures as described in Article 4.Y.8.

Article 4.Y.6

Chain of command

As soon as the *disease outbreak* has been confirmed, the *Competent Authority* convenes a meeting of the emergency management group as described in Chapter 4.X., and the activation of all elements of the *contingency plan* commences.

The ~~first meeting of the emergency management group considers at least the~~ following issues should be considered, with the assistance of relevant specialist sub-groups:

1) the most up-to-date epidemiological information available concerning the *disease* emergency, including:

a) location of confirmed case(s) including grid references and maps;

b) inventory of species kept in the infected *aquaculture establishment(s)* and the numbers ~~and weights of the *aquatic animals*~~;

c) clinical situation including description of clinical signs and estimates of morbidity and mortality;

d) identification of the index *case*;

e) details of *susceptible species* in the vicinity of the confirmed case(s);

f) outcomes from preliminary tracing and *surveillance*;

g) outcome from preliminary *risk assessment*.

2) immediate response objectives and options, taking into account the available epidemiological information referred to above, including:

a) official confirmation of the *disease outbreak* to the operators concerned;

b) international notification in accordance with Chapter 1.1.;

c) the reinforcement of the preliminary *biosecurity* measures described in point 4 of Article 4.Y.4. which were put in place during the 'alert phase', the imposition of new biosecurity and other *disease* control measures described in Article 4.Y.8., or both.

3) trade issues which are likely to arise, both within the country and with trading partners elsewhere;

4) review of appropriate facilities, skills and resources, as well as the legal, administrative and financial arrangements which are in place to ~~ensure all relevant enablers are in place~~ enable the Competent Authority to immediately manage the *disease* emergency. This review should include:

a) details of the infrastructure, skill sets and other necessary resources which are available to support the effective management of the *disease* emergency;

b~~a~~) details of the legal instrument which supports the provision of funding for the management of disease emergencies concerning *aquatic animals*;

c~~b~~) contact details for the relevant department which will process the request for funds, and which ensure that payments are executed smoothly once the *contingency plan* has been activated;

~~c) details concerning the mechanisms by which the funds will be transferred, in addition to the frequency of transfer and the personnel who are authorised to draw down the funding~~.

5) agreed messages, format ~~for~~, and timing of, communications with the *Aquatic Animal Health Services* who are responding to the emergency, relevant trading partners, and the public. Communications may be based on generic templates which have been prepared in peacetime and are adapted as appropriate to the circumstances~~Those communications are based on generic draft press releases and letters to the *Aquatic Animal Health Services* which have been prepared in peacetime, and which are appropriately fine-tuned to meet the current circumstances~~;

6) a schedule for future meetings throughout the emergency phase of the response, as well as a distribution list for the minutes of those meetings. Flexibility should be introduced to allow~~allowing for flexibility to schedule~~ meetings to be scheduled at short notice, should this be required.

Article 4.Y.7.

Appropriate facilities, skills, resources

1) Disease control centres

a) The *Competent Authority* establishes a central *disease* control centre and where necessary, an appropriate number of local *disease* control centres. Those centres, identified in the *Contingency Plan,* should be capable of providing at least the following:

i) appropriate information technology and telecommunication infrastructure;

ii) information systems to manage data collection concerning *aquaculture establishments*, details of sample collection and associated laboratory results, as well as the imposition of *disease* control measures on affected *aquaculture establishments* and other relevant stakeholders~~transporters~~;

iii) space for preparing and storing sampling kits for dispatch to the field;

iv) *disinfection* points for staff who are involved in sampling and inspection of *aquaculture establishments*, *vehicles* and other premises;

v) storage area for fields kits, personal protective equipment, cleaning and *disinfection* materials;

vi) *biosecurity* measures which are appropriate for the specific facilities and the purpose for which they are used.

b) The personnel from the *Aquatic Animal Health Services* who staff the central and local *disease* control centres have been identified in the *Contingency Plan.* Operationally, this group includes technical, administrative and legal personnel, as necessary, who are fully trained to complete the following tasks in accordance with detailed standard procedures which are set out in the Operations Manual:

i) clinical inspections of *aquaculture establishments*, other establishments and wild aquatic animals ~~and wild aquatic habitats,~~ as relevant;

ii) sample collection and transportation;

iii) preparation and issuance of legal notices;

iv) management of general biosecurity measures and other specific disease control measures;

v) communications with relevant personnel and stakeholders;

vi) data and record management;

vii) human resources management including workplace health and safety.

2) Laboratories

a) During the emergency, the *Aquatic Animal Health Services* should submit samples to the laboratories which have been identified in the *Contingency Plan.* Those laboratories provide rapid and accurate testing and reporting, which is dependent on the following resources:

i) appropriately trained and competent staff;

ii) appropriate equipment, which has been suitably serviced and is fit-for-purpose;

iii) a sufficient range and quantity of consumables;

iv) appropriate information systems to ensure sample traceability and reporting of laboratory results;

v) *biosecurity* measures which are suitable to contain the *pathogenic agent* in question.

Contact details of the staff which are referred to in point (i) and the companies which provide the services and goods, which are referred to in points (ii), (iii) and (iv), are detailed in the Operations Manual.

b) For *listed diseases*, laboratory methods should follow the relevant chapter of the ~~WOAH~~ *Aquatic Manual.* For diseases other than *listed diseases*, a procedure identified in the Operations Manual should be utilised, or another method which has been validated for the purpose of use.

3) Service Providers

The availability of relevant service providers during the emergency phase is of crucial importance, in particular, considering that a *disease outbreak* may extend to multiple *aquaculture establishments* in dispersed locations, and potentially to wild *aquatic animals*. Action should, therefore, be taken to ensure the availability of:

a) mortality management providers involved in retrieval and/or transport, who have capacity for the required daily tonnage;

b) sanitary slaughter facilities, which can cater for the required daily tonnage;

c) predatory animal and bird control specialists;

d) telecommunications providers;

e) communication specials or journalist for media liaison;

f~~e~~) telecommunications providers;

g~~d~~) providers of laboratory equipment and consumables who have an acceptable lead-in time for delivery of new and replacement items;

h~~e~~) companies which service relevant laboratory equipment and which have an acceptable response time for critical pieces of equipment;

i~~f~~) providers of vaccines/ veterinary medicines, who can supply an appropriate number of doses and have a suitable lead-in time for delivery;

j~~g~~) experts in areas which are relevant to the successful management of the emergency, and who have appropriate skills (e.g. in the areas of logistics, fisheries management, environmental protection, vaccination or treatment of *aquatic animals*), and who are available to deal with emergency situations;

k~~h~~) back-up providers for each type of service, should they be required for an extensive *disease outbreak*.

Subject to the relevant regulatory requirements which apply in a country, contact~~Contact~~ details of the providers referred to in points a) to k~~h~~) above are detailed in the Operations Manual.

Article 4.Y.8.

Biosecurity and other disease control measures

The actions which the *Competent Authority* should take~~s~~ concerning *biosecurity* and other *disease* control measures during the emergency phase, are described in the Operations Manual and may include:

1) defining the *infected zone* and *protection zones* which apply in freshwater or marine environments, as relevant, following confirmation of a *disease outbreak*, and taking into account the recommendations of Chapter 4.2.;

2) appropriate classification of the health status of *aquaculture establishments* to define their *disease* status or *risk* of infection;

3~~2~~) providing maps which will demonstrate the *infected zone* and the surrounding *protection zone*, as well as the *aquaculture establishments* which are located within those *zones*;

4~~3~~) coordinating actions concerning *biosecurity* and other *disease* control measures with other *Competent Authorities*, when the establishment of such *infected zone* or *protection zones* impacts neighbouring countries;

5~~4~~) specifying relevant *biosecurity* and other specific *disease* control measures including:

a) controlling the movement of *aquatic animals*, *aquatic animal products*, *feed*, ~~and~~ equipment, *vehicles*, waste, fomites and *vectors* to or from the infected establishment(s) or *infected zone*, unless authorised by the *Competent Authority* following *risk assessment*;

b) extending the movement controls referred to above, to other *aquaculture establishments* or waterbodies which have an epidemiological link with the *aquaculture establishment* in which the suspicion arose;

c) exemptions from the movement prohibitions described above, should *risk assessment* have indicated that these represent an acceptable *risk* (e.g. emergency harvesting, on-site processing, cooking for human consumption), or alternatively that more stringent movement measures are required due to the developing *disease* situation;

d) specifying the procedures to be used when *aquatic animals* are slaughtered or killed, depending on their species, size and the number of *aquatic animals* involved, including:

i) details of the equipment and where relevant, veterinary products to be used, and their suppliers;

ii) the appointment of a named Welfare Officer to ensure that procedures are carried out to the highest possible standards, and in the case of fish, to ensure that slaughtering or killing is carried out in accordance with Chapter 7.4.;

iii) details of the *biosecurity* measures required to ensure the slaughter or killing process does not cause *disease* spread. This includes measures for the containment and safe disposal of dead or destroyed stock. Also measures which apply to *vehicles* which are authorised to move animals or products from the infected establishments (or from additional establishments, as directed by the *Competent Authority*), to processing factories or animal by product establishments;

c~~iv~~) the vaccination options that may be employed, depending on the circumstances of the *disease outbreak*, including:

i) no vaccination;

ii) vaccination which is implemented in aquaculture establishments within the infected zone i.e. suppressive vaccination, the aim of which is to reduce the spread of disease from the infected zone;

iii) vaccination which is implemented outside the infected zone where the disease has not been suspected or confirmed i.e. protective vaccination, the aim of which is to prevent the spread of the disease in populations of aquatic animals which are at risk of infection;

iv) a combination of suppressive and protective vaccination.

f~~e~~) the decontamination options which are available, taking into account the recommendations of Chapter 4.4.. A list of the cleaning agents, *disinfectants* and equipment that are appropriate to use, are commercially available, authorised for use by the relevant *Competent Authority*, and which meet the decontamination requirements concerning the *pathogenic agent* in question~~,~~ should also be specified;

g~~f~~) procedures for the containment of wastewaters which are produced following equipment, facility and *vehicle* *disinfection* activities, which have been drawn up in accordance with the instructions of the *Competent Authorities* with responsibility for discharges to the environment;

h) where relevant, specifying the procedures to be used for the containment, *disinfection* and disposal of *disease* contaminated water used for *aquatic animal* production.

Article 4.Y.9.

Recovery phase

The recovery phase of *disease outbreak* management is activated when the end of the emergency has been declared by the *Competent Authority*. This phase takes into consideration the recovery plan described in Chapter 4.X., and the associated detailed actions which are set out in the Operations Manual.

1. Return to freedom.

In cases where the recovery phase includes the intention~~ambition~~ to return to *disease* freedom in accordance with ~~Pathway 4 as referred to in~~ Chapter 1.4. (Pathway 4), either for:

a) the entity (country, *zone* or *compartment*), which was previously *disease* free; or ~~to make a *self-declaration of freedom from disease* for~~

b) a smaller entity or entities (*zone*(s) or *compartment*(s));

this phase should begin with a review of the *basic biosecurity conditions* which applied before the *disease outbreak* occurred. This review will determine if additional *sanitary measures* are required to strengthen the *basic biosecurity conditions* which will apply in the entity for which the new declaration of freedom will be made.

This step will be followed in due course, by the re-population of *aquatic animals*, the required surveillance (as per Chapter 1.4.) and the re-commencement of trade. The ultimate aims of the recovery phase are to successfully return to peacetime operations.

2. In cases where the recovery phase does not include the ambition to return to disease-freedom, the actions which are necessary to either contain the *disease*, or to mitigate the impacts of the *disease*, should be identified and set out in the Operations Manual.

   a) Containment. Where the aim of the recovery plan is to contain the *disease*, the following measures may be described:

      i) zoning and movement controls;

      ii) *biosecurity* measures, as described in Chapter 4.1.;

      iii) *disinfection* of *aquaculture establishments* and equipment, as described in Chapter 4.4.;

      iv) periodic *fallowing*, as described in Chapter 4.7.;

      v) handling, disposal and treatment of *aquatic animal waste*, as described in Chapter 4.8.

   b) Mitigation. Where the aim of the recovery plan is to mitigate the impact of the *disease*, the following measures may be described:

      i) vaccination, using one or more of the strategies, which are referred to in Article 4.Y.5.;

      ii) the possibility to change to the production of a species of *aquatic animals*, which are not susceptible to the *disease* which caused the emergency;

      iii) the possibility to change production and husbandry practices, so that *risk* factors which are known to result in morbidity or mortality of *susceptible species* are minimised as far as possible;

      iv) training which may be provided to operators to create improved awareness of the *disease* in question, as well as the steps that can be taken at establishment level to mitigate its impact.

3. In addition, the recovery plan may include details of:

   a) the steps that are necessary to:

      i) allow relevant movement controls to be partially or completely lifted (including permitting arrangements), so that affected trade may recommence within the country;

      ii) start communications with producers and international partners, with a view to supporting an early recommencement of *international trade*, or to seek alternative trading partners.

   b) any increased *surveillance* or *biosecurity* measures which may apply to facilitate resumption of trade, and that is undertaken once~~as~~ trade recommences within the country and with international partners;

   c) any resources that the *Competent Authority* intends to provide including research, monetary, technical, or other relevant supports;

   d) any review of national legislation and *disease outbreak* management procedures that may be required to underpin the recovery plan that has been developed concerning the *disease outbreak* in question;

   e) ongoing communication with *Aquatic Animal Health Services* to explain relevant details of the recovery plan and to reinforce the role the *Aquatic Animal Health Services* play in future *disease* prevention and control.

Annex 42. Item 7.2. – Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

CONTROL OF PATHOGENIC AGENTS IN TRADED GAMETES~~MILT~~ AND FERTILISED EGGS OF FISH

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway would like to thank the Aquatic Animal Commission for the continued work on this draft new chapter. Specific comments are provided below. Norway would additionally encourage the Aquatic Animal Commission to revisit the use of "should" throughout the chapter. Norway suggests the general use of "must", rather than "should", for obligatory actions.

Article 4.Z.1.

Purpose

To provide recommendations for trade of *gametes*~~milt~~ and *fertilised eggs* of fish intended for *aquaculture* purposes and to define *risk management*~~mitigation~~ for trade~~import~~ to a *free country*, *free zone* or *free compartment* when:

1) the intention is to grow out and harvest the traded fish~~imported *aquatic animals*~~; or

2) the intention is to establish a new stock for *aquaculture*.

For disease-specific recommendations, refer to Article 10.X.15. (and Article 10.4.20. for infection with ISAV)~~Section 10~~.

Article 4.Z.2.

Scope

This chapter describes general recommendations for safe trade in *gametes*~~milt~~ and *fertilised eggs* of fish from an area other than a *free country*, *free zone* or *free compartment*. These recommendations include the measures outlined in Article 4.Z.3. which cumulatively reduce the *risk* of transfer of *infection* to *aquatic animal* populations in a *free country, free zone* or *free compartment*.

Trade of *gametes*~~milt~~ and *fertilised eggs* of fish from a *free country*, *free zone* or *free compartment* should meet the requirements in Articles 10.X.9. (and Article 10.4.14. for infection with ISAV) of the fish disease-specific chapters, and is not addressed in this chapter.

Article 4.Z.3.

Specific measures required for trade of gametes~~milt~~ and fertilised eggs of fish

Trade of *gametes*~~milt~~ and *fertilised eggs* of fish from a country, *zone* or *compartment* not declared free from infection with the *listed diseases* of concern should meet the following requirements:

1) the health status of the broodstock at the *aquaculture establishment* of origin must~~should~~ be determined. Only populations of broodstock which test free from the *pathogenic agents* of concern are suitable for movement~~supply~~ to *collection and incubation centres*, as described in Article 4.Z.4.;

Norway	**Category**: Change **Proposed amended text**: 1) the health status of the broodstock at the *aquaculture establishment* of origin must~~should~~ be determined. Only populations of broodstock which test ~~free from~~ negative for the *pathogenic agents* of concern are suitable for movement~~supply~~ to *collection and incubation centres*, as described in Article 4.Z.4.; **Rationale:** This chapter does not cover trade of gamets and fertilised eggs from free countries, zones or compartments. To improve clarity Norway therefore suggests rephrasing part of this sentence to specify that the broodstock should test negative for the pathogenic agent of concern.

2) *gametes*~~milt~~ and *fertilised eggs* should originate~~come~~ from a *collection and incubation centre* which has been approved for that purpose by the *Competent Authority* of the place of origin, and which operates in compliance with the conditions described in Articles 4.Z.5., 4.Z.6. and 4.Z.7.;

3) in the event of a positive detection in a *collection and incubation centre*, the *Competent Authority* of the *importing country* should assess the *risks* associated with importation of *gametes* and *fertilised eggs* from that establishment, taking all relevant factors into account, including the *biosecurity plan* which is applied to prevent cross contamination of gametes and fertilised eggs from individual parents which have tested negative;

4~~3~~) ~~the~~ *fertilised eggs* should be~~have been~~ surface disinfected prior to the export using a method proven to inactivate *pathogenic agents*, for salmonid eggs as described in Chapter 4.5.~~ and in accordance with the recommendations in the fish disease-specific chapters (Articles 10.X.15. for infection with SAV, infection with IHNV, and infection with VHSV; Article 10.4.20. for infection with ISAV)~~;

5~~4~~) when intended for *international trade*, the consignment should be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* stating~~which should state~~ that the *gametes*~~milt~~ and the *fertilised eggs* originate~~come~~ from parents which have tested free from the relevant *disease*, and which meet the requirements in points 1, ~~and~~ 2 and 4.

Norway	**Category**: Addition, Change **Proposed amended text**: 4) when intended for *international trade*, the consignment should be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* stating~~which should state~~ that the *gametes*~~milt~~ and the *fertilised eggs* originate~~come~~ from parents which have *individually* tested ~~free from~~ *negative for* the relevant ~~*disease*~~ *pathogenic agents*, and which meet the requirements in points 1~~, and~~ 2 and 4. **Rationale:** To improve clarity and ensure consistency with point 2 of Article 4.Z.6 Norway suggests that it is specified that the parent stock should have been individually tested. The fish should test negative for the pathogenic agents of concern, not the disease. See also the comment above.

Application of the measures recommended in this chapter should comply with the requirements of Chapters 5.1., 5.2. and 5.3.

Article 4.Z.4.

Health status of broodstock at the aquaculture establishment~~place~~ of origin

Aquaculture establishments keeping broodstock for movement to a *collection and incubation centre* for the production of~~and~~ *gametes*~~milt~~ and *fertilised eggs* of fish ~~from a country, *zone* or *compartment* not declared free from infection with a *listed disease*,~~ should meet the following requirements:

1) it should be approved for that purpose by the *Competent Authority* and be under its official control;

Norway	**Category**: Addition **Proposed amended text**: 1) it should be approved for that purpose by the Competent Authority and be under its official control *and subject to its official surveillance programme*; **Rationale:** Official surveillance programmes are an important component of the official control system of the Competent Authority.

2) it should implement~~have in place~~ a *biosecurity plan* which has been drawn up in accordance with Chapter 4.1.;

3) the broodstock should be tested for the *pathogenic agents* of concern as close as possible to the date on which they enter~~prior to entry to~~ the *collection and incubation centre* using a sample size that is sufficiently large to demonstrate with 95% confidence that the *pathogenic agent* would be detected if present above a prevalence of 2%, using the diagnostic methods provided in the *Aquatic Manual*. If the results of this testing produce a positive result, the broodstock should not be moved to the *collection and incubation centre*;

4) broodstock intended for movement to a *collection and incubation centre* should be clinically healthy at the time of movement, should not originate~~be~~ from a population experiencing recent or ongoing mortality, and should not be exposed to animals or other sources of *disease* that can~~of a~~ lower their health status following the testing referred to in~~at~~ point 3.

Norway	**Category**: Change **Proposed amended text**: 4) broodstock intended for movement to a *collection and incubation centre* should be clinically healthy at the time of movement, should not originate~~be~~ from a population experiencing recent or ongoing mortality, and should not be exposed to animals or other sources of ~~*disease*~~ *pathogenic agents* that can~~of a~~ lower their health status following the testing referred to in~~at~~ point 3. **Rationale:** It is the pathogenic agents that are of concern, not the diseases themselves.

Article 4.Z.5.

Collection and incubation centres

Collection and incubation centres should be approved by the *Competent Authority* for that purpose on the basis that the *collection and incubation centre* ~~should~~:

1) is~~be~~ under the supervision of an *Aquatic Animal Health Professional* or *veterinarian*, who takes overall responsibility for its operation;

2) implement~~have~~ a *biosecurity plan* which has been drawn up in accordance with Chapter 4.1.;

3) is~~be~~ structured to contain epidemiologically separate individual broodstock or groups of broodstock;

4) has~~have in place~~ a ~~valid traceability~~ system in place to ensure that milt~~each batch of *gametes*~~ or *fertilised eggs* can be traced back to an epidemiologically separate individual or group, and which includes~~include~~ documentation ~~and auditing~~ of test~~ing~~ results~~, *disease* history and movements of *aquatic animals*~~;

5) is~~be~~ separated into dedicated areas for:

   a) holding broodstock prior to *gamete* collection;

   b~~a~~) ~~a~~ collection of~~room for~~ eggs and milt;

   c) milt testing and storage;

   d) disinfection of *fertilised eggs*;

   e~~b~~) ~~an~~ incubation of~~centre for~~ *fertilised eggs*;

   ~~c) a milt laboratory and milt storage area;~~

   f~~d~~) administration ~~offices~~.

6) is~~be~~ subject to inspections carried out~~and pass audits~~ by the *Competent Authority* or a~~an approved~~ third party approved by the *Competent Authority* at a frequency sufficient to ensure that the *collection and incubation centre* is in compliance with~~least once per year against the requirements of~~ this chapter.

Article 4.Z.6.

Testing of broodstock at the collection and incubation centre

Broodstock for the production of~~and~~ *gametes*~~milt~~ and *fertilised eggs* of fish, should meet the following requirements at the *collection and incubation centre*:

1) stripping and sampling should be carried out under the supervision of the *Aquatic Animal Health Professional* or *veterinarian* who has responsibility for the *collection and incubation centre*;

2) at stripping the broodstock should be individually sampled, and tested for the *listed diseases* of concern, in accordance with the methods for diagnosis provided in the *Aquatic Manual,* in a laboratory that has been approved by the *Competent Authority*;

Norway	**Category**: Change **Proposed amended text**: 2) at stripping the broodstock should be individually sampled, and tested for the *listed ~~diseases~~ pathogenic agents* of concern, in accordance with the methods for diagnosis provided in the *Aquatic Manual,* in a laboratory that has been approved by the *Competent Authority*; **Rationale:** It is the pathogenic agents that are of concern, not the diseases themselves.

3~~2~~) fish that test positive, and any *gametes* or *fertilised eggs*~~milt or eggs~~ derived from them should not be traded;

4) details of the results from testing relevant cohorts of broodstock as described in paragraph 1 should be provided to the *Competent Authority* of an *importing country* on request;

5) in accordance with the *biosecurity plan* for the *collection and incubation centre,*~~and~~ all gametes and fish from the~~that~~ epidemiological group that tested positive should be disposed of in a biosecure manner. Affected facilities should be disinfected to ensure that cross-contamination of other batches of *gametes* or *fertilised eggs*~~milt or eggs~~ does not occur;

6) *fertilised eggs* should be surface disinfected using a method proven to inactive *pathogenic agents*, for salmonid eggs as described in Chapter 4.5.

Article 4.Z.7.

Conditions applicable to the collection and storage of milt and preparation of milt samples ~~in the laboratory~~

The following conditions should be in place ~~at the laboratory~~ for milt collection and storage:

1) the integrity of the traceability system as described in Article 4.Z.5. should be maintained at all times;

2) receptacles used to freeze milt should be sterilized before use;

3) diluents should be produced in a way to protect against contamination with *pathogenic agents*;

Norway	**Category**: General **Proposed amended text**: N/A at this stage **Rationale:** Norway wonders whether it is relevant to also state that the diluent should be as sterile as possible, thereby including protection against contamination from both non-pathogenic and pathogenic agents?

4) frozen milt should be stored in hermetically sealed containers in a separate room.

Norway	**Category**: General **Proposed amended text**: N/A at this stage **Rationale:** Norway suggests that the Aquatic Animal Commission specifies minimum temperature requirements for the storage of the frozen milt.

Annex 43. Item 7.2. – Model Article 10.X.10. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Article 10.4.15. for Chapter 10.4. 'Infection with ISAV'

Model Article 10.X.10. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV', and Chapter 10.10. Infection with VHSV'

CHAPTER 10.X.

INFECTION WITH [PATHOGEN X]

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports these proposed Model Articles.

[…]

Article 10.X.10.

Importation of aquatic animals, excluding gametes and fertilised eggs, for aquaculture from a country, zone or compartment not declared free from infection with [pathogen X]

When importing, for *aquaculture, aquatic animals*, excluding *gametes* and *fertilised eggs,* of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with [pathogen X], the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider ~~applying~~ the *risk* mitigation measures in ~~either~~ points~~s~~ 1 and~~or~~and 2 below.~~:~~

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

~~Either~~

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.X.3. or other products authorised by the *Competent Authority*; and

c) the treatment of all transport water, equipment, effluent and waste materials to inactivate [pathogen X] in accordance with Chapters 4.4., 4.8. and 5.5.

~~Or~~

~~d) apply the requirements of Chapter 4.Z.~~

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

~~Either~~

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 [pathogen X].

b) in the *importing country*:

i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for [pathogen X] 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 [pathogen X], and sample and test for [pathogen X] in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.6. of the *Aquatic Manual;*

v) if [pathogen X] is not detected in the F-1 population, it may be defined as free from infection with [pathogen X] and may be released from *quarantine*;

vi) if [pathogen X] 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.

~~Or~~

~~c) apply the requirements of Chapter 4.Z.~~

[…]

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

Article 10.4.15.

Importation of aquatic animals, excluding gametes and fertilised eggs, 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*, excluding *gametes* and *fertilised eggs,* 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 ~~applying~~ the *risk* mitigation measures in ~~either~~ points ~~s~~ 1 and ~~or~~ ~~and~~ 2 below.~~:~~

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

~~Either~~

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~~

~~d) apply the requirements of Chapter 4.7.~~

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

~~Either~~

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 2.3.6. 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.

~~Or~~

~~c) apply the requirements of Chapter 4.Z.~~

[…]

Annex 44. Item 7.2. – Model Article 10.X.15. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Article 10.4.20. for Chapter 10.4. 'Infection with ISAV'

Model Article 10.X.15. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV', and Chapter 10.10. 'Infection with VHSV'

CHAPTER 10.X.

INFECTION WITH [PATHOGEN X]

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports these proposed Model Articles.

[…]

Article 10.X.15

Importation of gametes~~milt~~ and fertilised eggs of fish ~~disinfected eggs~~ for aquaculture from a country, zone or compartment not declared free from infection with [pathogen X]

When importing *gametes~~milt~~* or *fertilised eggs* of a species referred to in Articles 10.X.2., for *aquaculture* from a country, *zone* or *compartment* not declared free from infection with [pathogen X], the *Competent Authority* of the *importing country* should ensure that:

1) the consignment meets the requirements in Chapter 4.Z.; and

2) *fertilised eggs* have been disinfected using a method proven to inactivate *pathogenic agents*, for salmonid eggs in accordance with recommendations in Chapter 4.5.; and

3) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of [pathogen X] 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 are treated to ensure inactivation of [pathogen X] or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

The *Competent Authority* should consider internal measures, such as additional *disinfection* of the *fertilised eggs* upon arrival in the *importing country*.

The consignment should be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* certifying that the *gametes~~milt~~* and *fertilised eggs* fulfil the recommendations in Articles 4.Z.3. to 4.Z.7.

~~1) When importing disinfected eggs of the species referred to in Article 10.X.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from infection with [pathogen X], 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 [pathogen X];

b) the prevalence of infection with [pathogen X] 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.X.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from infection with [pathogen X], 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.

[…]

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

Article 10.4.20.

Importation of gametes~~milt~~ and fertilised eggs of fish ~~disinfected eggs~~ for aquaculture from a country, zone or compartment not declared free from infection with ISAV

When importing *gametes~~milt~~* or *fertilised eggs* of a species referred to in Articles 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 ensure that:

1) the consignment meets the requirements in Chapter 4.Z.; and

4) *fertilised eggs* have been disinfected in accordance with recommendations in Chapter 4.5.; and

5) 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

6) 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.

The *Competent Authority* should consider internal measures, such as additional *disinfection* of the *fertilised eggs* upon arrival in the *importing country*.

The consignment should be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* certifying that the *gametes~~milt~~* and *fertilised eggs* fulfil the recommendations in Articles 4.Z.3. to 4.Z.7.

~~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.~~

[…]

———————

Annex 45. Items 7.2. and 7.3. – Glossary

GLOSSARY

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed changes to the Glossary.

[...]

COLLECTION AND INCUBATION CENTRE

means a facility approved by the *Competent Authority* in conformity with the provisions of Chapter 4.Z. for holding broodstock, the collection of eggs, fertilisation and incubation, and the collection, processing, and storage of milt.

[...]

FERTILISED EGG

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

[...]

GAMETES

means the sperm (contained within seminal fluid or milt) or unfertilised eggs of aquatic animals that are held or transported separately prior to fertilisation.

[...]

ORNAMENTAL AQUATIC ANIMAL

means an *aquatic animal* that is intended for display, exhibition, competition, or to be kept as a pet.

[...]

Annex 46. Item 7.3. – Draft new Chapter 5.X. 'Movement of ornamental aquatic animals'

SECTION 5

TRADE MEASURES, IMPORTATION/EXPORTATION PROCEDURES AND HEALTH CERTIFICATION

CHAPTER 5.X.

MOVEMENT OF ORNAMENTAL AQUATIC ANIMALS

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed draft new Chapter.

Article 5.X.1.

Introduction

This chapter provides recommendations to address the *risk* of pathogen~~*disease*~~ transmission via the movement of *ornamental aquatic animals* to prevent entry into a country, *zone* or *compartment* that is free from the *pathogenic agents* of concern.

Ornamental aquatic animals may originate from the wild or from *aquaculture establishments*. Once they have entered the supply chain they may be epidemiologically separated from farmed or wild populations but can be diverted to other end uses for which they were not intended. This may provide a pathway for *disease* transmission and place other populations of *susceptible species* at *risk*.

International movement of *ornamental aquatic animals* is characterised by translocation of numerous individual animals comprised of many species of fish, crustaceans, molluscs and amphibians originating from diverse environments. Supply chains may involve the aggregation of animals from multiple sources and their dissemination through retail trade as pets, providing opportunities for *disease* transmission. These characteristics of the movement of *ornamental aquatic animals* may present challenges for managing *aquatic animal disease risks*.

Article 5.X.2.

Scope

This chapter provides recommendations for managing the pathogen~~*disease*~~ *risks* associated with movement of *ornamental aquatic animals*. The standards concerning trade in species that are susceptible to the *diseases* listed in Chapter 1.3., are set out in the disease-specific chapters. This Chapter provides additional guidance for managing *risk* associated with the movement of *ornamental aquatic animals* which are susceptible to *listed diseases* or other *diseases* identified as *hazards*. ~~that complement other provisions of the *Aquatic Code*, including the measures specified in the disease-specific chapters.~~

Article 5.X.3.

General principles

The general principles for the movement of *ornamental aquatic animals* that should be considered when developing *risk* mitigation measures are:

1) the legality~~eligibility~~ for the movement of a species (or a taxonomic group of species) should be determined considering existing regulatory measures in the importing country regarding ~~its conservation status (e.g. species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora), and~~ potential biodiversity and ecosystem impacts ~~in the *importing country* (e.g. potential to become an invasive alien species)~~, as described in Article 5.X.4.;

2) *ornamental aquatic animals* intended for international movement should be clinically healthy at the time of movement, not exposed to animals of a lower health status, and should not be from an establishment experiencing recent or ongoing *disease* or unexplained mortality, as described in Article 5.X.5.;

3) *risk management* measures for *listed diseases* should be in accordance with the provisions of the disease-specific chapters, as described in Article 5.X.6.;

4) *risk management* measures for non-listed *diseases*, or any measures for *listed diseases* exceeding those described in the disease-specific chapters, should be justified by *risk analysis*, as described in Article 5.X.7.;

5) any *risk management* measures should be the least restrictive measures required to mitigate the *disease* risks identified by a *risk assessment,* as described in Articles 5.X.8. to 5.X.11.;

6) measures should be taken to maintain the welfare of *ornamental aquatic animals* during transit, including as described in Article 5.X.12.

Article 5.X.4.

Eligibility for the international movement of ornamental aquatic animals

Prior to considering the *aquatic animal* health *risks* associated with the import of a species of *ornamental aquatic animal*, the *Competent Authority* of an *importing country* should determine that import of the species would be compliant with ~~consult~~ relevant national regulations and international obligations ~~to determine that the species is eligible for import~~. ~~Species~~ For example, species of *ornamental aquatic animal* may be subject to controls on international movement or trade due to their conservation status (e.g. listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or listed as an endangered species or preserved species by a *Competent Authority* or other authorities of an *importing country*). These controls may prohibit international movement or may necessitate additional import documentation.

Species of *ornamental aquatic animals* (or taxonomic groups of species) may also be identified as invasive by a *Competent Authority* or other authority of an *importing country*. Such species may be prohibited to be traded, owned or farmed due to the risks they present to biodiversity, ecosystems, industry, ~~or~~ public amenity or public health in the *importing country*.

Article 5.X.5.

General health status of ornamental aquatic animals

Aquaculture establishments holding or packaging *ornamental aquatic animals* for international movement should have suitable facilities and husbandry practices for maintaining the health status of all species held within the facility.

The *Competent Authority* of an *exporting country* should ensure that *aquaculture establishments* are under sufficient supervision to ensure that requirements of the *Competent Authority* of the *importing country* for *ornamental aquatic animals* can be met. The *Aquatic Animal Health Services* relevant to meeting *importing country* requirements should comply with the principles of Chapter 3.1.

If *aquaculture establishments* are required by the *Competent Authority* to maintain a *biosecurity plan,* or if this is required to meet *importing country* requirements, the *biosecurity plan* should be developed as described in Chapter 4.1.

Ornamental aquatic animals should not be moved or traded from an *aquaculture establishment* if they are exhibiting clinical signs of *disease* or experiencing unexplained mortalities.

Article 5.X.6.

Application of measures for listed diseases

Sanitary measures applied to manage the *risk* of transmission of *listed diseases* associated with movement of *ornamental aquatic animals* should be in accordance with the relevant disease-specific chapters. The *Competent Authority* of an *importing country* can only require disease-specific measures if it is free from the *disease* of concern, or if the *disease* of concern is under an official control programme, as described in Chapter 5.1.

When importing *ornamental aquatic animals* of *susceptible species* (as listed in Article X.X.2. of each disease-specific chapter), from a *free country*, *free zone* or *free compartment*, the *Competent Authority* of the *importing country* should require, in accordance with Article X.X.9. of the relevant disease-specific chapter, that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that the consignment originates from a *free country*, *free zone* or *free compartment*.

The *Competent Authority* of an *importing country* can only require *sanitary measures* for a *listed disease* more stringent than the standards of the *Aquatic Code* if those measures are supported by a *risk analysis* in accordance with Chapter 2.1.

Article 5.X.7.

Risk analysis

The *Competent Authority* of an *importing country* should use *risk analysis* to justify any *sanitary measures* for non-listed *diseases* associated with imported *ornamental aquatic animals*. *Risk analysis* should also be used to justify any *sanitary measures* for *listed diseases* if the measures are more stringent than the standards of the *Aquatic Code*. The *Competent Authority* of an *importing country* can only require pathogen-specific *sanitary measures* if the country is free from the *disease* of concern, or if the *disease* of concern is under an official control programme, as described in Chapter 5.1.

Risk analysis for the import of *ornamental aquatic animals* should be conducted as described in Chapter 2.1. In addition to the factors provided in Chapter 2.1, the *risk analysis* should take into account the following factors relevant to the assessment of likelihood of entry and exposure of *hazards* associated with *ornamental aquatic animals*.

Entry

1) The *disease* status of identified *hazards* within the country, *zone* or *compartment* of origin, including information on the prevalence of identified *hazards* within populations of *ornamental aquatic animals* or within their source populations (e.g. wild animals).

2) The *disease* prevention and control practices within the supply chain for *ornamental aquatic animal*s in the *exporting country*, and the quality of the *aquatic animal health services* supporting disease prevention and control.

3) The range of species that are susceptible to the specific *pathogenic agents* identified as *hazards* and the evidence to substantiate susceptibility in accordance with Chapter 1.5.

4) The suitability of environmental conditions (e.g. temperature, salinity) for the *hazard* at the place of origin of the *ornamental aquatic animals*.

5) The nature of supply chains and the degree of mixing or epidemiological separation of populations originating from sources with different health status.

Exposure

6) The presence of populations of *susceptible species* in the *importing country*.

7) The suitability of environmental conditions (e.g. temperature, salinity) for the *susceptible species* of imported *ornamental aquatic animals* in the *importing country*.

8) The suitability of environmental conditions (e.g. temperature, salinity) for the *hazard* in the *importing country.*

9) Intended end uses of the *ornamental aquatic animals* and the implications for exposure. For example:

   a) display in zoos or public aquariums – *ornamental aquatic animals* may be displayed in professionally managed facilities which may have veterinary oversight and *biosecurity* measures in place;

   b) exhibition or competition – *ornamental aquatic animals* may be moved internationally for short periods for participation in exhibitions or competitions, may be kept epidemiologically isolated, and then returned to the country of origin;

   c) pets – *ornamental aquatic animals* may be moved internationally in large numbers and widely distributed through retail trade for sale as pets.

10) Cultural practices that may influence exposure, including diversion from intended end-uses (e.g. deliberate release into waterways, use as bait).

11) Internal measures for disease prevention and control and to limit diversion to non-intended end uses.

Article 5.X.8.

Risk management

The standards of the *Aquatic Code* are the preferred choice of *sanitary measures* for *risk management* of *listed diseases* associated with *ornamental aquatic animals*.

To develop *sanitary measures* for non-listed *diseases*, or to justify measures for *listed diseases* that are more stringent than the standards of the *Aquatic Code*, the *Competent Authority* of an *importing country* should follow the recommendations for *risk management* as described in Chapter 2.1. The *sanitary measures* should also comply with the requirements of Section 5 of the *Aquatic Code*.

Sanitary measures for imported *ornamental aquatic animals* can be applied along the import pathway. The *Competent Authority* of the *importing country* should select the least restrictive measures required to mitigate the *disease risks* identified by a *risk assessment.* Options for *risk management* are provided in articles 5.X.9. to 5.X.11. and include those applied:

1) within the *exporting country,* as described in Article 5.X.9.;

2) at the *frontier post,* as described in Article 5.X.10.;

3) within the *importing country*, as described in Article 5.X.11.

Article 5.X.9.

Risk management measures in the exporting country

Where required by the *Competent Authority* of the *importing country* based on *risk analysis*, *risk management* measures can be applied within the *exporting country* to mitigate the *disease risks* associated with international movement of *ornamental aquatic animals* from a country, *zone* or *compartment* not declared free from *diseases* of concern. ~~The *Competent Authority* of the *importing country* should select the least restrictive measures required to mitigate the *disease risks* identified by a *risk assessment.*~~ *Risk management* measures may include:

1) registration or approval by a *Competent Authority* of *aquaculture establishments* that produce, hold or package *ornamental aquatic animals* for export. Registration or approval is a means for ensuring that any *aquaculture establishments* meet any necessary requirements for export of *ornamental aquatic animals* (e.g. general health requirements, *biosecurity*, record keeping);

2) confirmation that the exported *ornamental aquatic animals* are free from signs of *disease* or unexplained mortality at the place of origin (as described in point 2 of Article 5.X.7.) and meet general health requirements in accordance with Article X.X.5.;

3) pre-export *quarantine* in an *aquaculture establishment* (e.g. packaging facility) to ascertain the health status of the animals to be exported. The length of *quarantine* would be based on the *risk assessment* and may vary depending on the species and specific *diseases* of concern;

4) pre-export testing of consignments of *ornamental aquatic animals* to confirm they are free from *pathogenic agents* of concern;

5) systems for traceability and record keeping to ensure transparency of the health status of specific populations or consignments of *ornamental aquatic animals*;

6) appropriate packaging of *ornamental aquatic animals* to maintain their health status for the expected duration and conditions of the transport;

7) certification or provision of other documentation to verify that the *risk management* measures required by the *Competent Authority* of the *importing country* have been met.

Article 5.X.10.

Risk management measures at the border

Where required by the *Competent Authority* of the *importing country* based on *risk assessment*, *risk management* measures can be applied at the border to mitigate the *disease risks* associated with international movement of *ornamental aquatic animals* from a country, *zone* or *compartment* not declared free from *diseases* of concern. ~~The *Competent Authority* of the *importing country* should select the least restrictive measures required to mitigate the *disease risks* identified by a *risk assessment.* *Risk management* measures may include:

1) upon arrival at the *frontier post,* the *Competent Authority* of the *importing country* may perform an inspection of the containers, checking that the consignment matches information included on the accompanying certificate or other documentation. The inspection may include checking for damage to the containers, and observing the animals for abnormal behaviour and suspected clinical signs;

2) at border *quarantine* under the supervision of the *Competent Authority*. The length of *quarantine* would be based on the *risk assessment* and may vary depending on the species and specific *diseases* of concern. Effluent and waste materials from the *quarantine* facilities should~~may~~ be treated or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.;

3) at border testing under the supervision of the *Competent Authority*. Any testing requirements would be based on the *risk assessment*;

4) destruction (as described in Chapter 7.4.) and biosecure disposal of clinically affected animals. All water (including ice), equipment, containers and packaging material used in transport should~~may~~ be treated or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.

Article 5.X.11.

Risk management measures in the importing country

The *Competent Authority* of the *importing country* may apply internal *risk management* measures, including to address the *risks* associated with *ornamental aquatic animals* being used for non-intended purposes or being released into the wild. *Risk management* measures may include:

1) prohibiting the diversion of *ornamental aquatic animals* for an alternative end use (e.g. for *aquaculture*, *feed*, bait, research) or from being released into the wild;

2) notifying the *Competent Authority* of the *exporting country* of the detection of a *pathogenic agent* of concern in a consignment, in accordance with Chapter 5.3.;

3) traceability of imported *ornamental aquatic animals* to commercial establishments~~through the commercial supply chain~~.

Article 5.X.12.

Animal welfare during transport

Welfare of *ornamental aquatic animals* during international movement relies on the maintenance of environmental conditions appropriate to the biological characteristics of the species. The minimum requirements to maintain welfare will vary among different species.

Transport of *ornamental aquatic animals* in conditions that are not suited to their biological characteristics may increase vulnerability to infection and the development of clinical *disease*, leading to an increased likelihood of *disease* transmission and morbidity or mortality of animals not related to *disease*.

Transport of *ornamental aquatic animals* should follow protocols that are appropriate for maintaining the welfare of the species and life stage being transported (e.g. for packaging, water quality, temperature, stocking density, duration). Where existing protocols are not available, they may be developed by considering the factors provided in Chapter 7.2. *Welfare of farmed fish during transport* and should accommodate other requirements during transport, (e.g. the need for inspection and external container repackaging). The International Air Transport Association (IATA) regulations for the transport of live animals should also be taken into account.

Contingency plans should be developed that identify possible adverse welfare events that may occur during transport, the procedures for managing each event, the actions to be taken and the responsibilities of the parties involved.

Annex 47. Item 7.4. – Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the *Aquatic Code*

Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the WOAH Aquatic Animal Health Code

February 2024

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the recommendations.

Executive summary and recommendations

- Chapter 1.4. 'Aquatic animal disease surveillance' of the *Aquatic Code* sets out the principles for declaration of disease freedom via four different pathways: 1. Absence of susceptible species, 2. Historical freedom, 3. Targeted surveillance and 4. Returning to freedom.
- The disease-specific chapters of the *Aquatic Code* provide recommendations for periods of basic biosecurity conditions (BBC) for all four pathways and targeted surveillance (TS) for pathways 3 and 4. Following the adoption of the revised Chapter 1.4. in May 2022, the periods of BBC and TS remained under study pending analysis.
- This report details how recommended periods for BBC and TS have been developed by applying the relevant criteria included in Chapter 1.4. 'Aquatic Animal Disease Surveillance' of the *Aquatic Code*.
- If a pathogen is present, it may be detected via the early detection system or passive surveillance throughout the periods of the BBC and TS.
- Pathogen-specific information relevant to the likelihood of pathogen detection by either the early detection system/passive surveillance and by TS (i.e. seasonality of transmission, persistence in the environment, the rapidity of onset of clinical signs or mortality, and rate of spread) was extracted from the disease-specific chapters of the *Aquatic Manual*, and are summarised in the attachments.
- For each pathway, the relevant information was used to rank pathogens and the rankings used to recommend periods for BBC for each pathway, and for TS for pathways 3 and 4. For countries and zones, pathways 1 to 4 apply. For compartments, only pathways 3 and 4 apply.

BBC periods

- For pathway 1, the default minimum period for BBC is 6 months (defined in Chapter 1.4.). Only information on the persistence of the pathogen in the external environment was used for ranking. It is recommended that the period of BBC for pathogens ranked 1 or 2 is 6 months. For pathogens ranked 3, a period of one year is recommended. This pathway is not considered suitable for three pathogens because, as a result of their broad host range, demonstrating absence of susceptible species is not considered possible.
- For pathway 2, the default minimum period for BBC prior to declaring freedom is 10 years (defined in Chapter 1.4.). Only information on the likelihood that infection results in observable clinical signs and a noticeable increase in mortality was used to rank pathogens. For pathogens ranked 1 and 2, the

period for BBC prior to declaring freedom is recommended to be ten years. For pathogens ranked 3, a 15 year period for BBC prior to declaring freedom is recommended. For all declarations of freedom utilising pathway 2, the requirements of passive surveillance in article 1.4.8 must be met (e.g. conditions must be conducive for clinical expression of infection).

- For pathway 3, the default minimum period of BBC preceding TS for countries and zones is one year (defined in Chapter 1.4.). The duration of BBC preceding TS should be long enough for the design prevalence used in TS design to be reached, assuming the pathogen became established immediately prior to commencement of BBC. Hence, the rate of spread between populations is critical.
- Pathogens whose transmission only occurs during limited periods (determined primarily by water temperature) require a longer period of BBC to ensure high confidence that the design prevalence has been reached before TS begins.
- During the period of BBC, the pathogen, if present, may be detected through passive surveillance, which is more likely for pathogens that cause observable signs or mortality. As passive surveillance is a secondary form of evidence for pathway 3 (refer to Article 1.4.3. of the *Aquatic Code*), this factor was also used to make recommendations for the period of BBC for pathway 3 (see Table 3).

TS periods

- The default minimum period for TS for countries and zones is two years. For pathogens whose transmission rate is significantly determined by environmental conditions the prevalence may fall below the design prevalence at periods when environmental or biological conditions are not conducive to transmission.
- For pathogens whose transmission is significantly influenced by environmental factors and where infection does not consistently result in observable clinical signs or mortality, it is recommended that the period of TS is extended to three years (see Table 3).
- For compartments seeking freedom in accordance with pathway 3, a period of one year for BBC and TS is considered sufficient for all pathogens, as the conditions required to maintain a compartment will generate a high confidence that the pathogen will be detected irrespective of its characteristics.
- Chapter 1.4. of the *Aquatic Code* requires that countries, zone or compartments attempting to return to freedom via pathway 4 following an outbreak, review measures to prevent the introduction of the pathogenic agent and implement changes for as long as necessary to evaluate success. As the circumstances of each disease outbreak leading to a breakdown in disease freedom are unique, setting the period of BBC (preceding TS to regain freedom) on a pathogen basis is not considered appropriate.
- In principle the minimum period of TS under pathway 4, should be consistent with the requirements for pathway 3. However, guidance in *Aquatic Code* Chapter 1.4., allows for flexibility in applying periods of TS to regain a disease free status if justified by the circumstances of the outbreak.

Table 1. Recommendations for periods of BBC using Pathway 1. 'Absence of susceptible' species.

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
6 months	EHNV *G. salaris* IHNV ISAV KHV RSIV SVCV TiLV	AHPND *H. penai* IHHNV IMNV MrNV WSSV YHV1	AbHV *B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *X. californiensis*	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*
12 months	SAV	Crayfish plague		
Pathway not suitable	EUS VHSV		*P. olseni*	

Table 2. Recommendations for periods of BBC using Pathway 2. 'Historical freedom'.

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
10 years	EHNV EUS IHNV ISAV RSIV SAV SVCV TiLV VHSV	AHPND Crayfish plague *H. penai* IHHNV IMNV MrNV WSSV YHV1	AbHV *B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *P. olseni* *X. californiensis*	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*
15 years	*G. salaris* KHV			

Table 3. Recommendations for periods of BBC and TS for claims of freedom for countries and zones using Pathway 3. 'Targeted surveillance'.

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
BBC				

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
1 year	EHNV EUS IHNV ISAV RSIV SAV SVCV VHSV TiLV	AHPND Crayfish plague *H. penai* IHHNV IMNV MrNV WSSV YHV1	AbHV	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*
2 years	KHV *G. salaris*		*B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *P. olseni* *X. californiensis*	
TS				
2 years	*A. astacii* EHNV EUS IHNV ISAV RSIV SAV SVCV VHSV	AHPND Crayfish plague *H. penai* IHHNV IMNV MrNV WSSV YHV1	AbHV	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*
3 years	*G. salaris* KHV		*B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *P. olseni* *X. californiensis*	

Contents

List of tables

Abbreviations

BBC	basic biosecurity conditions
TS	targeted surveillance

Abbreviations for 'listed diseases' of fish

EHNV	Infection with epizootic haematopoietic necrosis virus
EUS	Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)
G. salaris	Infection with *Gyrodactylus salaris*
IHNV	Infection with infectious haematopoietic necrosis virus
ISAV	Infection with HPR-deleted or HPR0 infectious salmon anaemia virus
KHV	Infection with koi herpesvirus
RSIV	Infection with red sea bream iridovirus
SAV	Infection with salmon alphavirus
SVCV	Infection with spring viraemia of carp virus
TiLV	Infection with tilapia lake virus
VHSV	Infection with viral haemorrhagic septicaemia virus

Abbreviations for 'listed diseases' of molluscs

AbHV	Infection with abalone herpesvirus
B. ostreae	Infection with *Bonamia ostreae*
B. exitiosa	Infection with *Bonamia exitiosa*
M. refringens	Infection with *Marteilia refringens*
P. marinus	Infection with *Perkinsus marinus*
P. olseni	Infection with *Perkinsus olseni*
X. californiensis	Infection with *Xenohaliotis californiensis*

Abbreviations for 'listed diseases' of crustaceans

AHPND	Acute hepatopancreatic necrosis disease
crayfish plague	Infection with *Aphanomyces astaci* (crayfish plague)
DIV1	Infection with decapod iridescent virus 1
H. penaei	Infection with *Hepatobacter penaei* (necrotising hepatopancreatitis)
IHHNV	Infection with infectious hypodermal and haematopoietic necrosis virus
IMNV	Infection with infectious myonecrosis virus
MrNV	Infection with Macrobrachium rosenbergii nodavirus (white tail disease)
TSV	Infection with Taura syndrome virus
WSSV	Infection with white spot syndrome virus
YHV1	Infection with yellow head virus genotype 1

Abbreviations for 'listed diseases' of amphibians

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

Introduction

The World Organisation for Animal Health (WOAH) provides standards for Members to allow them to demonstrate freedom from specified pathogens at the country, zone or compartment level. The disease-specific chapters of the Aquatic Animal Health Code[1] (*Aquatic Code*) set default minimum periods for the duration of basic biosecurity conditions (BBC) before a declaration of freedom can be made by pathways 1, 2 and 3, and the period of targeted surveillance (TS) for pathway 3. Attachment 1 details the minimum periods for each listed pathogen and pathway stipulated in the disease-specific chapters before the adoption of the revised Chapter 1.4. 'Aquatic animal disease surveillance' in 2022. Since 2022, the default minimum periods have been under study.

This paper presents a rationale for determining, for each aquatic animal disease, the minimum periods of BBC for pathways 1, 2 and 3, and the duration of targeted surveillance for pathway 3, for declarations of freedom for a country, zone or compartment (only pathway 3 applies for compartments). In addition, the guidance for the BBC for a country, zone or compartment to return to freedom under pathway 4 is reviewed.

The duration of the minimum period of BBC required before declaration of freedom using pathway 1 (absence of susceptible species) should be long enough for any pathogen introduced by a fomite (e.g. via trade) before measures were implemented, to lose viability.

The duration of BBC before declaring freedom via pathway 2 should allow the early detection system (EDS) and passive surveillance to generate a high level of confidence that if present the pathogen would be detected (EDS and passive surveillance are components of basic biosecurity).

The design of the TS to demonstrate freedom (via pathway 3) will be largely based on the selected design prevalence (i.e. the minimum prevalence that will be detected with 95% confidence). Guidance on setting the design prevalence is provided in Chapter 1.4. of the *Aquatic Code*. At a zone and country level, the BBC needs to be in place long enough to generate a high level of certainty that the design prevalence would have been reached prior to the start of TS (assuming the pathogen is present before BBC were implemented). The duration of BBC (preceding TS) may need to be longer than the default minimum period (one year) if the pathogen: i) has a long lifecycle; ii) spreads only slowly within and between populations (e.g. requires a high infectious dose); iii) transmission only takes place during limited periods of the year (i.e. when water temperatures are permissive for replication); or iv) only remains viable for only short periods (<14 days) outside the host (survival outside the host correlates with likelihood of transmission).

For pathways 3 and 4, information from passive surveillance can be used as secondary evidence in demonstration of disease freedom. Therefore, in addition to the pathogen transmission (i.e. the rate at which the design prevalence is reached), the likelihood of detection during the period of BBC may also be used to determine the period of BBC. Infections which result in rapid onset of clinical disease or mortality following introduction to a naïve population, are more likely to be detected during the period of BBC compared with pathogens which cause low levels of clinical disease or mortality.

The default minimum period of TS specified in chapter 1.4. is two years for a country or zone and one year for compartments. The rationale for setting the minimum period of TS used in this paper, assumes that the design prevalence has been reached before TS starts. However, for many pathogens transmission, and therefore prevalence, is influenced by environmental factors. Unseasonably low water temperatures in the first year of sampling may result in the prevalence falling below the design prevalence. In addition, the likelihood that a sampled infected fish will test positive may be reduced if levels of infection are lower (e.g. due to a reduced exposure level). A longer sampling period increases the time before freedom is declared, which allows for further pathogen spread (i.e. a higher prevalence and geographic distribution), and thus making detection more likely. Secondly, if sites are sampled on multiple occasions, then the lifecycle of the pathogen becomes

[1] https://www.woah.org/en/what-we-do/standards/codes-and-manuals/aquatic-code-online-access/

relevant, as in the second year of sampling, the likelihood that the prevalence has increased above the design prevalence increases. Seasonality is the key factor driving variation in prevalence from year to year (i.e. the likelihood detecting the pathogen is strongly influenced by water temperature). As passive surveillance can be combined with active surveillance to demonstrate freedom, the likelihood that infection results in clinical signs or mortality detectable through passive surveillance is also considered in determining the minimum period of TS.

Terms of reference

1. Develop an approach to determine for each listed pathogen the minimum period of basic biosecurity conditions for demonstration of freedom at country or zone level via pathway 1 (absence of susceptible species) and pathway 2 (historical freedom) and preceding targeted surveillance for pathway 3 (targeted surveillance[2]).
2. Apply the method to WOAH listed aquatic animal diseases and recommend periods of BBC for pathway 1 and 2, and to precede targeted surveillance to demonstrate freedom at country and zone level (via pathway 3) for the disease-specific chapters of Aquatic Animal Health Code.
3. Review guidance for the minimum period of BBC for compartments seeking disease freedom under pathway 3 (TS)
4. Review the guidance for the BBC for countries, zones or compartments to regain freedom under pathway 4.

Method

Information on pathogen specific characteristics that influence i) the speed at which the design prevalence will be reached and ii) likelihood of early detection through passive surveillance, was extracted from the *Aquatic Manual* disease-specific chapters (summarised in Attachments 2-5). The characteristics are:

1. lifecycle;
2. rate of spread within and between populations (e.g. infectious dose);
3. period of the year during which transmission takes place (i.e. when water temperatures are permissive for replication);
4. persistence outside the host (in the environment);
5. likelihood of early detection (i.e. rapid onset of clinical disease/ mortality following introduction).

For pathway 1 (absence of susceptible species), only information on persistence outside the host in the environment was considered relevant to determining the BBC. This factor was used to rank (from 1-3) pathogens at host group level (i.e. fish, molluscs, crustaceans, amphibians). Recommendations for the duration of BBC for each pathogen are made.

For pathway 2 (historical freedom), only information on the likelihood of detection was considered relevant to determining the BBC. This factor was used to rank (from 1-3) pathogens at host group level (i.e. fish, molluscs, crustaceans, amphibians). Recommendations for the duration of BBC for each pathogen groups were made.

For the BBC of pathway 3, pathogens are ranked (from 1-3) at host group level based on all the characteristics assessed (see Table 4 for details). The rankings indicate the relative rate at which design prevalence will be reached and/or a higher likelihood of detection by passive surveillance.

[2] Described in Article 1.4.3. of the *Aquatic Code*

Table 4. Rankings used to assess the period of basic biosecurity conditions for pathway 3. 'Targeted surveillance'.

Rank 1.
• little or no seasonal variation in transmission • evidence of rapid onset of clinical signs/mortality following pathogen introduction • evidence of rapid spread between populations • persistence outside of host in the environment for > 14 days
Rank 2.
• seasonal variation in transmission, at least some evidence of low to negligible level of transmission during some period of the year • evidence of rapid onset of clinical signs/mortality following pathogen introduction • evidence of at least moderate rate of spread between populations • persistence outside of host in the environment for > 7 days
Rank 3.
• strong seasonal variation in transmission, good evidence of low to negligible level of transmission during some period of the year • slow onset of clinical signs/mortality following pathogen introduction AND / OR • slow spread between populations

For the duration of TS (pathway 3), the factors listed in Table 5 are compared between pathogens for each host group (i.e. fish, molluscs, crustaceans, amphibians) considering:

1. limited period of the year during which transmission occurs, that may vary between years due to environmental factors (e.g. water temperatures);
2. likelihood of early detection (i.e. rapid onset of clinical disease/ mortality following introduction).

For each category of host (i.e. fish, molluscs, crustaceans, amphibians), pathogens are ranked on the basis of the characteristics assessed (see Table 5 for details).

Table 5. Definitions of rankings used to determine the minimum period of targeted surveillance for pathway 3

Rank 1.
• little or no seasonal variation in transmission, • evidence of rapid onset of clinical signs/mortality following pathogen introduction
Rank 2.
• seasonal variation in transmission, at least some evidence of low to negligible level of transmission during some period of the year • evidence of rapid onset of clinical signs/mortality following pathogen introduction
Rank 3.
• strong seasonal variation in transmission, good evidence of low to negligible level of transmission during some period of the year • slow onset of clinical signs/ mortality following pathogen introduction

Results and Recommendations

Pathway 1: Assessment of duration of basic biosecurity conditions (absence of susceptible species)

The rankings of pathogens within host group are set out in Table 6.

Table 6. Summary rankings of pathogens to determine the minimum period of BBC for pathway 1. 'Absence of susceptible species'. Pathogens marked * are considered unsuitable for application of this pathway.

Ranking	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
1	KHV *G. salaris*	AHPND WSSV YHV1		
2	VHSV* IHNV SVCV RSIV ISAV EHNV TiLV	*H. penaei* IHHNV IMNV MrNV TSV	AbHV *B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *X. californiensis*	*B. dendrobatidis* *B. salamandrivorans* Ranavirus
3	EUS* SAV	crayfish plague	*P. olseni**	

Based on the analysis, it is recommended that for cases demonstrating freedom at a country or zone level, pathogens ranked 1 and 2 should retain the default minimum six month period of BBC. For pathogens ranked 3, it is recommended that the BBC is extended to 12 months.

This pathway is not considered suitable for pathogens with a broad host range and for which new susceptible species are expected to be determined with further research or spread of the pathogens to new geographic areas. For these species, demonstrating absence of susceptible species in a country or zone is not considered possible. Pathway 1 is thus unsuitable for three species - EUS, VHSV, and *P. olseni*. This recommendation is consistent with the provisions of the 2021 Aquatic Code (i.e. prior to the adoption of revised articles for declaration of freedom in the disease specific chapters in 2022). See Attachment 1.

Pathway 1 is not appropriate to demonstrate freedom at the compartment level as the Aquatic Code does not currently include provisions for compartment freedom via pathway 1.

Pathway 2: Assessment of duration of basic biosecurity conditions (historic freedom)

The rankings of pathogens by host group are set out in Table 7. All fish pathogens with the exception of KHV and *G. salaris* have a high likelihood of detection by the early detection systems or passive surveillance, and hence the default minimum period of ten years will generate a high likelihood of detection (for populations that meet the requirements of Article 1.4.8. and assuming an annual surveillance systems sensitivity of at least 30%). For *G. salaris* and KHV annual surveillance systems sensitivity may be less than 30% and therefore an extended period of 15 years is recommended.

All crustacean pathogens have a high or moderate likelihood of detection and the default minimum period of ten years can be recommended. It should be noted that for all pathogens the passive surveillance requirements of Article 1.4.8. must be met. For example, this pathway may be suitable for declarations of freedom from crayfish plague (*A. astaci*) in populations of susceptible species in which infection results in clinical signs and

observable levels of mortality (e.g. native European species). However, it may not be appropriate to declare freedom for species in which *A. astaci* causes subclinical infection (e.g. North American species of crayfish).

Many mollusc species only cause mortality in older animals and thus may not be detected for some years after introduction. If the pathogen is introduced shortly before the period of BBC starts, mortality will become apparent within the default minimum ten year time period. Hence a period of ten years for BBC can be recommended.

The ranking and recommendation for ISAV applied only to applications of disease freedom for the HPR deleted strain (not the HPR0 strain) where there are populations of Atlantic salmon in which infection will lead to clinical signs and an observable level of mortality. Pathway 2 is not considered appropriate to claim freedom from HPR0 ISAV for which clinical disease is not expected. Similarly claims of freedom from *B. dendrobatidis* and *B. salamondrivorans* need to provide evidence of the presence of susceptible species in which infection will cause mortality and clinical signs.

Table 7. Summary rankings of pathogens to determine the minimum period of BBC for pathway 2. 'Historic freedom'.

Ranking	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
1	SAV	AHPND Crayfish plague *H. penai* IHHNV IMNV MrNV WSSV YHV1	AbHV	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*
2	EHNV EUS IHNV ISAV HPR-deleted RSIV TiLV SVCV VHSV		*B. exitiosa* *B. ostreae* *M. refringens* *P. marinus* *P. olseni* *X. californiensis*	
3	KHV *G. salaris*			

It is recommended that pathogens ranked 1 and 2 retain the default minimum ten year period for BBC. For pathogens ranked 3, the minimum BBC period is extended to 15 years.

Pathway 2 should not be used to demonstrate freedom at compartment level.

Pathway 3: Assessment of duration of basic biosecurity conditions preceding targeted surveillance to demonstrate freedom

The current default minimum BBC period of one year is considered the minimum period. The results of the assessments for each pathogen (Attachments 2-5) are summarised in the following sections. The

requirements for passive surveillance described in Article 1.4.8. are a pre-requisite for application of this pathway.

Fish pathogens

Details summarised below can be found in Attachment 2.

- All the fish pathogens had direct lifecycles and therefore lifecycle information was uninformative and not used for ranking pathogens.
- Information in the *Aquatic Manual* chapters did not allow for levels of 'infectiousness' to be compared between pathogens; this criterion could not be used for ranking.
- Based on seasonality and persistence in the environment, only SAV achieved a ranking of 1.
- All pathogens with exception of KHV and *G. salaris*, had a high likelihood of rapid detection post-introduction by passive surveillance.
- The ranking and recommendation for ISAV applied only to applications of disease freedom for the HPR deleted strain. The HPR0 strain is not known to cause clinical disease and exists at very low prevalences in wild Atlantic salmon populations. Historical freedom is not considered a suitable pathway for HPR0 ISAV.

Crustacean pathogens

Details summarised below can be found in Attachment 3.

- All crustacean pathogens have simple direct lifecycles.
- Information on survival outside the host and on environmental factors affecting replication/transmission was not available for most pathogens.
- No basis was found to recommend different durations of BBC on pathogen characteristics.
- All pathogens have high rates of spread and high likelihood of detection by passive surveillance so the minimum period of one year can be applied to all crustacean pathogens.
- The ranking for *Aphanomyces astaci* (crayfish plague) applies to infection in populations of susceptible species in which infections leads to signs and mortality. Demonstration of freedom in populations of crayfish species which do not display clinical signs and experience mortality, cannot be used as evidence from passive surveillance to demonstrate disease freedom.

Molluscan pathogens

Details summarised below can be found in Attachment 4.

- Little information is available on environmental persistence of molluscan pathogens.
- All molluscan pathogens showed seasonality in prevalence/mortality indicating transmission was restricted or reduced for a period of the year (usually during winter months).
- Likelihood of early detection is low for all molluscan pathogens (except abalone herpesvirus) as onset of clinical signs/mortality occurs months to years after exposure.
- *Marteillia refringens* is an outlier, having an indirect lifecycle and the best evidence for restricted periods of transmission.

Amphibian pathogens

Details summarised below can be found in Attachment 5

- Little evidence of strong seasonal impact on the rate of transmission of *B. salamondrivorans* or *B. dendrobatidis.*
- Evidence of limited spread between infected populations leads *B. salamondrivorans* to be ranked lower than *B. dendrobatidis.*
- Ranavirus is listed as a genus. Rate of spread and transmission varies considerably between hosts and viral species (multiple), making ranking at genus level invalid.

The rankings are summarised in 8.

Table 8. Summary rankings of pathogens to determine minimum periods of basic biosecurity conditions for pathway 3. 'Targeted surveillance'.

Ranking	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
1	SAV	All	AbHV	*B. dendrobatidis*
2	EHNV EUS IHNV ISAV RSIV SVCV TILV VHSV			*B. salamondrivorans* (*Ranavirus**)
3	KHV *G. salaris*		*B. exitiosa* *B. ostreae* *P. marinus* *P. olseni* *M. refringens* *X. californiensis*	

*not assessed, given same ranking as EHNV which is a ranavirus

It is recommended that for pathogens ranked 1 and 2, the default minimum BBC period of one year is retained. For pathogens ranked 3, the period is extended to two years.

Compartments

The default minimum period of BBC is one year for compartments, zones and countries demonstrating freedom using pathway 3 (targeted surveillance). At a compartment level, a case can be made to apply a one year minimum period for all pathogens. Compartments are epidemiologically isolated and factors associated with spread between populations (assessed in this paper) are not relevant. In addition, the high level of management required by Competent Authorities authorising a compartment, should generate a very high likelihood of detection via passive surveillance (e.g. through monitoring of feed consumption and growth rates) even for infections with pathogens that result in few clinical signs or only low mortality. On this basis, the period of BBC (preceding TS) of one year can be adopted for all pathogens.

Pathway 3. Assessment of duration of targeted surveillance to demonstrate freedom

The results of the assessments can be found in Attachments 2-5, and summarised in the following sections.

Fish pathogens

Details summarised below can be found in Attachment 2.

- Based on seasonality and persistence in the environment, SAV is the only pathogen to rank 1.
- All pathogens, with exception of KHV and *G. salaris*, have a high likelihood of rapid detection following introduction into a naïve population by passive surveillance.

Crustacean pathogens

Details summarised below can be found in Attachment 3.

- Little evidence for seasonality of transmission of any pathogens.
- All pathogens have a high likelihood of rapid detection following introduction into a naïve population by passive surveillance.

Molluscan pathogens (Attachment 3)

Details summarised below can be found in Annex 4.

- All pathogens showed seasonality in prevalence/mortality indicating transmission was restricted or reduced for a period of year (usually during winter months).
- Likelihood of early detection is low for all molluscan pathogens (except abalone herpesvirus) as onset of clinical signs /mortality occurs months to years after exposure.
- *Marteillia refringens* is an outlier, having an indirect lifecycle, and the best evidence for seasonally restricted periods of transmission.

Amphibian pathogens

Details summarised below can be found in Attachment 5.

- Little evidence of strong seasonal impact on the rate of transmission of *B. salamondrivorans* or *B. dendrobatidis*
- Good evidence of rapid onset of mortality and morbidity in many (but not all) host species for *B. salamondrivorans* and *B. dendrobatidis*

Rankings for TS are summarised in Table 9.

Table 9. Summary rankings of pathogens to determine the minimum period of targeted surveillance for pathway 3. Targeted surveillance

Ranking	Fish	Crustacean	Molluscs	Amphibian
1	SAV	ALL	AbHV	*B. dendrobatidis* *B. salamondrivorans*
2	VHSV IHNV SVCV RSIV ISAV TiLV EUS EHNV			(*Ranavirus**)
3	KHV *G. salaris*		*B. exitiosa* *B. ostreae* *P. marinus* *P. olseni* *M. refringens* *X. californiensis*	

*not assessed, given same ranking as EHNV which is a ranavirus

It is recommended that for pathogens ranked 1 and 2, the minimum period for TS is two years and for pathogens ranked 3 it is three years.

Compartments

The current default minimum period for TS is one year for compartments for pathway 3. A case can be made to keep a one year period for TS for all pathogens. The high level of management required by Competent Authorities authorising a compartment, should generate a very high likelihood of detection via passive surveillance if the pathogen was present. On this basis, TS for a minimum period of one year is sufficient for all pathogens.

Pathway 4: returning to disease freedom

In Chapter 1.4. of the *Aquatic Code* a default minimum period for BBC before TS to regain freedom is not specified. Instead the guidance requires that 'the pathway of disease introduction should be investigated and basic biosecurity conditions should be reviewed and modified' and that 'mitigation measures should be implemented following eradication of the disease, and prior to commencement of any targeted surveillance'. As the circumstances of each disease outbreak leading to a breakdown in disease freedom are unique setting periods for BBC (preceding TS to regain freedom) on a pathogen basis is not required.

Chapter 1.4. of the *Aquatic Code* suggests that for 'a country or a zone, the default minimum period of surveillance to regain freedom is consistent with the requirements for pathway 3', and thus the periods of TS recommended in this paper can be used for pathway 4. However, it should be noted that guidance in Chapter 1.4. allows for earlier self-declarations of freedom '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'. As outbreaks leading to a breakdown in disease freedom will vary considerably in size and circumstance, flexibility in applying periods of TS to regain a disease free status is justified.

Discussion

Pathway 1. 'Absence of susceptible species'.

Based on the analysis in this paper, it is recommended a minimum period of 6 months for BBC before claiming freedom based on the absence of susceptible species is sufficient for most pathogens. However, for pathogens for which there is evidence of persistence in the environment for months, a minimum period of 12 months is recommended. The viability of pathogens in the environment (outside the host) will be influenced by environmental factors, which following guidance in Chapter 1.4. of the *Aquatic Code*, should be considered in any claim for disease freedom using pathway 1.

Pathway 2. 'Historical freedom'.

In editions of the *Aquatic Code* before revision of Chapter 1.4., a minimum period of ten years over which the pathogen had not been observed was required for all but a few diseases (see Attachment 1). Evidence that the pathogen has not been observed is only reliable if BBC (i.e. passive surveillance) have been implemented. A ten year period of BBC will generate a high likelihood of confidence that the pathogen is present for all but two fish diseases (KHV and *G. salaris*). Guidance in Chapter 1.4. is clear that pathway 2 can only be used if infection results in observable clinical signs. As well, in addition to meeting standards for duration of BBC set in the *Aquatic Manual* disease-specific chapters, evidence of the effectiveness of the passive surveillance component of BBC is required in any application for recognition of disease freedom.

Pathway 3. 'Targeted surveillance' (period of BBC).

The BBC period will only formally start once a Competent Authority is confident that the disease is absent (as a result of stamping-out or a long period of no detections). For pathogens with high rates of spread and high likelihood of detection (i.e. ranked 1 and 2), it is reasonable to assume that one year is a sufficient minimum period for the design prevalence to be reached (assuming introduction just preceding implementation of BBC) or detection through passive surveillance.

For pathogens ranked 3, a longer BBC may be required to allow either a second window for spread, or for clinical signs or mortality to occur. For example, infection with a number of molluscan diseases may only become apparent in older animals and thus a longer period is needed for detection during the period of BBC via passive surveillance. For pathogens ranked 3 with limited periods of transmission and low likelihood of detection by passive surveillance, the period of BBC should be extended to two years. All fish disease were ranked 1 or 2, except KHV and *G. salaris* (ranked 3), both of which had limited periods of transmission during some periods of the year and low likelihood of detection by passive surveillance. It is recommended that BBC be extended to 2 years for these pathogens.

Compared with fish diseases, less evidence is available to rank crustacean diseases. On the basis that they are all i) highly infectious and cause rapid onset of morbidity and mortality after introduction to a naïve population, and ii) observational evidence of rapid spread between population, all crustacean diseases met the criteria for a rank of 1. By contrast, for all the molluscan parasites seasonal variation in prevalence indicates water temperature dependent rates of transmission. Only abalone herpesvirus has a high likelihood of detection by passive surveillance within one year of introduction into a naïve population. It proposed that the BBC (preceding TS) is one years for abalone herpesvirus and 2 years for all the other pathogens.

It did not prove possible to assess ranavirus genus (due to the large variation in characteristics between the multiple host-pathogen combinations). Ranavirus was given the same ranking as EHNV (which is a ranavirus). Based primarily on observations on a low level of spread between populations, it is suggested that the BBC for *Batrachochytrium salamandrivorans* is at least 2 years. The largely observational evidence for *B. dendrobatidis* indicates higher rate of spread and rapid onset of clinical signs and a one year BBC is appropriate.

Pathways 3. 'Targeted surveillance' (duration of targeted surveillance).

It is suggested that for pathogens ranked 1 and 2 in this analysis, the minimum period of TS is two consecutive years (the default minimum period stipulated in Chapter 1.4. of the *Aquatic Code*). The design of the surveillance should follow guidance in Chapter 1.4. that requires surveillance to take place in consecutive years. Sampling should take place when conditions for pathogen detection is optimal, which may occur during a period of weeks or months during each year of the surveillance period. Whilst transmission for pathogens ranked 1 and 2 are not strongly seasonal, stochastic inter-annual variation in transmission (and therefore prevalence) justifies the default minimum period of two years for TS.

For pathogens ranked 3, three consecutive years of TS can be justified. This means that sampling is done at the time of year when likelihood of detection is highest in at least three consecutive years, on the basis that environmental conditions in the years one and two may result in a low likelihood of detection by either TS (sampling) or passive surveillance. It is therefore recommended that the minimum period of TS is three years for pathogens ranked 3.

Conditions making detection of the pathogen suboptimal may persist for more than two or three years. Therefore, it is important that Members follow guidance in Chapter 1.4. when making a case for disease freedom and provide evidence that sampling took place when conditions were optimal for pathogen detection.

Conclusion

The aim of this assessments is to provide a justification for the durations of the BBC and TS for the disease-specific chapters of the *Aquatic Code*. Therefore, the analysis was focused on pathogen characteristics and has not attempted to provide recommendations based on host and environment. Arguably, it may be problematic to assess the importance of pathogen characteristics without considering the host (for pathogens with multiple hosts) and environment (for pathogens with a wide geographic distribution). To some extent the rankings are based on the pathogen characteristics in the major hosts and on environmental conditions in the main areas where these hosts are found. Nevertheless, it is possible to cite specific examples where pathogen/host/environmental combinations for which the ranking is not appropriate. Therefore, it is important that the provisions of Chapter 1.4. requiring that passive surveillance is effective (as infection will cause observable clinical signs), and sampling is undertaken when conditions are optimal for detection and populations with higher likelihoods of infection are preferentially sampled.

It is important to recognise the lack of data, especially for environmental persistence for many of the pathogens, and especially those of molluscs and crustaceans. Ideally, quantitative assessments from observational epidemiological studies would be available to assess the rate of spread between populations. However, in general these data are not available and are not necessarily thoroughly reviewed in the disease-specific chapters of the *Aquatic Manual*.

Despite these possible criticisms and weaknesses in the available data, the analysis presented provides a sound evidence base to justify recommendations for duration of the BBC and TS that should be used when developing surveillance programmes to claim freedom from WOAH listed diseases as described in Chapter 1.4. 'Aquatic animal disease surveillance' of the *Aquatic Code*.

Attachments

Attachment 1. Summary of the previously recommended minimum periods of BBC and TS for all listed diseases and all pathways in the 2021 Aquatic Code (i.e. preceding the adoption of Chapter 1.4. in 2022). Periods for country freedom are shown. NA = not applicable (pathway not available).

	Epizootic haematopoietic necrosis disease	A. invadans (EUS)	Infection with *Gyrodactylus salaris*	ISA virus HPR0 and HPR deleted	ISA virus HPR deleted	Infection with salmonid alphavirus	Infectious haematopoietic necrosis	Koi herpesvirus disease	Red sea bream iridoviral disease	Spring viraemia of carp	Viral haemorrhagic septicaemia	Infection with abalone herpesvirus	Infection with *Bonamia ostreae*	Infection with *Bonamia exitiosa*	Infection with *Martelilia refringens*	Infection with *Perkinsus marinus*	Infection with *Perkinsus olseni*	Infection with *Xenohaliotis californiensis*	Acute hepatopancreatic necrosis disease	Crayfish plague (*Aphanomyces astaci*)	Infection with yellow head virus	Infectious hypodermal and haematopoietic necrosis	Infectious myonecrosis	Necrotising hepatopancreatitis	Taura syndrome	White spot disease	White tail disease	Infection with *Batrachochytrium dendrobatidis*	Infection with ranavirus	*Infection with Batrachochytrium salamandrivorans*
1. Absence of susc species	2	NA	2	2	NA	2	2	2	2	2	NA	2	2	2	3	3	NA	3	2	2	2	2	2	2	2	2	2	2	2
2. Historical freedom																													
-Not observed	10	10	10	NA	10	10	10	10	10	10	10	10	10	10	10	10	10	10	10	25	10	10	10	10	10	10	10	10	10
-Basic biosec conds	10	10	10	NA	10	10	10	10	10	10	10	2	2	2	3	3	3	3	2	10	2	2	2	2	2	2	2	10	10	10
3. Targeted surv																													
-Basic biosec conds	2	2	5	2	2	2	2	2	2	2	2	2	2	2	3	3	3	3	2	5	2	2	2	2	2	2	2	2	2	2
-Targeted surv	2	2	5	2	2	2	2	2	2	2	2	2	2	2	3	3	3	2	2	5	2	2	2	2	2	2	2	2	2	2
4. Return to freedom	2	2	5	2	2	2	2	2	2	2	2	2	2	2	3	3	3	2	2	5	2	2	2	2	2	2	2	2	2	2

Attachment 2. Fish pathogens: Assessment of duration of BBC preceding TS to demonstrate freedom (pathway 3).

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
VHSV	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Restricted (when water temp <14 C)	Moderate- Days to weeks	2
IHNV	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Restricted (when water temp <14 C)	Moderate- Days to weeks	2
SVCV	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Restricted (when water temp 11-17 C)	Moderate- Days to weeks	2
KHV	Simple-direct	High – very infectious, low minimum infectious dose Slow spread between populations when water temp <16 C	Low: Subclinical infection at low water temp	Restricted (when water temp <16 C)	Low - days	3
SAV	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Unrestricted (seasonal variation observed but outbreaks occur throughout the year)	High – weeks to months	1
EHNV	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Restricted (outbreaks occur at water temperatures between and 11-20 C)	Very high – months to years	2
RSIV	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Restricted to summer months (water temp >25 C)	unknown	2
ISAV (HPR deleted strain)	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Unrestricted with mortality peaks in early summer and winter	Low persistence – hours to days	2
TiLV	Simple - direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Outbreaks generally when water temp >22 C	unknown	2
A invadans (EUS)	Simple-direct	High (single spore sufficient for pathogen to establish)	High: Rapid onset clinical signs	Restricted 18-22 C.	Month-years (encysted form)	2

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
G. salaris	Simple-direct	High (single parasite sufficient for infestation to establish) Evidence of slow spread between wild populations	Low: Months to years to detect populations declines in wild *Salmo salar;* Clinical signs not apparent in rainbow trout	Rate of replication and spread low below 6.5 C (and on rainbow trout)	Hours to days on dead host; temperature dependent	3

LH = likelihood

Attachment 3. Crustacean pathogens: Assessment of duration of BBC preceding TS to demonstrate freedom (pathway 3).

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
AHPND	Simple-direct	100% prevalence achieved indicating high rate of spread	High: Rapid onset mortality	Unrestricted	9-18 d	1
A. astaci	Simple-direct	Very rapid spread in susceptible species crayfish, reaching 100% prevalence	High: Rapid onset mortality (in susc. spp.)	Unrestricted – Infection over wide temp range	Several weeks, spores 2 months	1
H. penaei	Simple-direct	Little some information but evidence of rapid spread in farmed P. vannaemi	High: Rapid onset mortality	Unrestricted – High rate of spread at high temp and salinity	No information available	1
IHHNV	Simple-direct	Very rapid spread in P. stylirostris; low in P. vannamei (may go undetected for months)	High; P stylirostric Low: P vannamei	Unrestricted – reduced replication at high temp	No information available	1
IMNV	Simple-direct	Little information	Medium : mortality following stress events in endemic areas	No information available	No information available	1
MrNV	Simple-direct	Rapid spread on introduction to naïve populations	High: Rapid onset mortality in juveniles	No information available	No information available	1
TSV	Simple-direct	Dependent of strain/spp susceptibility	High Rapid onset mortality Rapid onset mortality	No information available - (outbreaks more frequent when salinities are below 30 ppt	No information available	1
WSSV	Simple-direct	High rates of spread and mortality	High Rapid onset mortality	Outbreaks generally at water temp between 18-30 C.	3-4 d in pond water, 3-5 wks in sediment	1
YHV1	Simple-direct	Very rapid – 100% mortality with 3-5 d of clinical signs	High Rapid onset mortality	Little information – probably unrestricted	viable in aerated seawater for 3 d	1

LH = likelihood

Attachment 4. Molluscan pathogens : Assessment of duration of BBC preceding TS to demonstrate freedom (pathway 3).

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
abalone herpesvirus	Simple-direct	High – rapid rise in prevalence and onset of mortality in all age classes	High	Evidence of seasonal variation in transmission: Outbreaks at 16-19 C but impact of temp not established.	No information available	1
B. exitiosa	Simple-direct	Slow - spread in O chilensis, causing mortality of 80% over 2-3 years; lower prevalence /mortality in O. edulis	Low	Evidence of seasonal variation in transmission: Peak infection in O chilensis in autumn & winter; seasonality not established for infection in O. edulis	No information available	3
B. ostreae	Simple-direct	Slow – infection observed >3 mon after introduction – highest prevalence 2 yr old animals	Low	Evidence of seasonal variation in transmission: Peak infection in late winter/early spring	>7d in seawater	3
M. refringens	Indirect via intermediate host	Slow – prevalence peaks 1 yr post-introduction.	Low	Evidence of seasonal variation in transmission: When water temp > 17 C; higher transmission at high salinity	Up to 21 d	3
P. marinus	Simple-direct	Slow - prevalence highest in animals 1 yr post introduction; mortality observed 1-2 yr post introduction	Low	Evidence of seasonal variation in transmission: Peak transmission when water temp high	No information available	3
P. olseni	Simple-direct	Slow – mortality 1-2 yrs post introduction; low mortality	Low	Evidence of seasonal variation in transmission: Transmission low/ negligible when temp < 15 C.	Several months (spores)	3

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
X. californiensis	Simple-direct	Slow – prevalence increases with age (size); infection may persist months without signs (3-7 month pre-patent period) esp. at lower water temp	Medium	Evidence of seasonal variation in transmission: Transmission higher at elevated when water temp >15	Demonstrated but not quantified	3

LH = likelihood

Attachment 5. Amphibian pathogens: Assessment of duration of BBC preceding TS to demonstrate freedom (pathway 3).

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
B. dendrobatidis	Simple - direct	Very high: in susceptible species	High: Rapid onset mortality in susceptible populations (host species dependent)	Unrestricted: Transmission probably higher in cooler months	Suspected but not confirmed	1
B. salamondrivorans	Simple - direct	High within susceptible species in the invasive range; spread between populations is limited	High: Rapid onset mortality in susceptible populations (host species dependent)	Unrestricted:	Encysted spores viable for up to 31 d	2
Ranavirus	Simple - direct	Host species / viral species dependent	Host species / viral species dependent	Not known: Outbreaks area seasonal	Months	?

LH = likelihood

Annex 48. Item 7.5. – Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus'

CHAPTER 9.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed changes to this Chapter.

[…]

Article 9.9.2.

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.~~: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.~~

Family	Scientific name	Common name
Astacidae	*Austropotamobius pallipes*	white-clawed crayfish
	Pacifastacus leniusculus	signal crayfish
	Pontastacus leptodactylus	Danube crayfish
Calanidae	*Calanus pacificus californicus*	no common name
Cambaridae	*Faxonius limosus*	spinycheek crayfish
	Procambarus spp. (all species)	N/A
Cancridae	*Cancer pagurus*	edible crab
Nephropidae	*Homarus gammarus*	European lobster
	Nephrops norvegicus	Norway lobster
Nereididae	*Dendronereis sp.*	N/A
Paguridae	*Pagurus benedicti*	no common name
Palaemonidae	*Palaemon spp.* (all species)	N/A
Palinuridae	*Panulirus spp.* (all species)	N/A
Parastacidae	*Cherax quadricarinatus*	red claw crayfish
Penaeidae	all species	N/A
Polybiidae	*Liocarcinus depurator*	blue-leg swimcrab
	Necora puber	velvet swimcrab
Portunidae	all species	N/A
Varunidae	*Eriocheir sinensis*	Chinese mitten crab

[…]

Annex 49. Item 7.6. – Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *P. olseni*'

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed changes to this Chapter.

Article 11.6.1.

For the purposes of the *Aquatic Code*, infection with *Perkinsus olseni* means *infection* with the pathogenic agent *P. olseni* of the Family Perkinsidae.

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

Article 11.6.2.

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
Arcidae	*Anadara kagoshimensis*	half-crenated ark cockle
	Anadara trapezia	ark cockle
Cardiidae	*Tridacna crocea*	crocus giant clam
Haliotidae	*Haliotis laevigata*	greenlip abalone
	Haliotis rubra	blacklip abalone
Margaritidae	*Pinctada fucata*	Japanese pearl oyster
Mytilidae	*Mytilus galloprovincialis*	Mediterranean mussel
	Perna canaliculus	New Zealand mussel
Veneridae	*Austrovenus stutchburyi*	Stutchbury's venus clam
	Leukoma jedoensis	Jedo venus clam
	Paratapes undulatus	undulate venus clam
	Protapes gallus	rooster venus clam
	Proteopitar patagonicus	no common name
	Ruditapes decussatus	grooved carpet shell

Family	Scientific name	Common name
	Ruditapes philippinarum	Japanese carpet clam

~~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*, *Barbatianovaczelandiae*, *Macomonaliliana*, *Paphies australis* and *Crassostrea ariakensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

[…]

Annex 60. Item 10.1.1. – Sections 2.2.1. and 2.2.2. of Chapter 2.2.8. 'Infection with white spot syndrome virus'

CHAPTER 2.2.8.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed changes to this Chapter.

[…]

2.2. Host factors

2.2.1. Susceptible host species

Species that fulfil the criteria for listing as susceptible to infection with WSSV according to Chapter 1.5. of the *Aquatic Animal Health Code* (*Aquatic Code*) are:

Family	Scientific name	Common name
Astacidae	*Austropotamobius pallipes*	white-clawed crayfish
	Pacifastacus leniusculus	signal crayfish
	Pontastacus leptodactylus	Danube crayfish
Calanidae	*Calanus pacificus californicus*	no common name
Cambaridae	*Faxonius limosus*	spinycheek crayfish
	Procambarus spp. (all species)	N/A
Cancridae	*Cancer pagurus*	edible crab
Nephropidae	*Homarus gammarus*	European lobster
	Nephrops norvegicus	Norway lobster
Nereididae	*Dendronereis sp.*	N/A
Paguridae	*Pagurus benedicti*	no common name
Palaemonidae	*Palaemon spp.* (all species)	N/A
Palinuridae	*Panulirus spp.* (all species)	N/A
Parastacidae	*Cherax quadricarinatus*	red claw crayfish
Penaeidae	all species	N/A
Polybiidae	*Liocarcinus depurator*	blue-leg swimcrab
	Necora puber	velvet swimcrab

Portunidae	all species	N/A
Varunidae	*Eriocheir sinensis*	Chinese mitten crab

~~Of all the species that have been tested to date, no decapod (order Decapoda) crustacean from marine, brackish or freshwater sources has been reported to be refractory to infection with WSSV (Flegel, 1997; Lightner, 1996; Lo & Kou, 1998; Maeda *et al.*, 2000; Stentiford *et al.*, 2009).~~

~~[**Note:** an assessment of species that meet the criteria for listing as susceptible to infection with WSSV in accordance with Chapter 1.5. has not yet been completed]~~

2.2.2. Species with incomplete evidence for susceptibility

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with WSSV according to Chapter 1.5. of the *Aquatic Code* are:

Family	Scientific name	Common name
Carcinidae	*Carcinus maenas*	green crab
Ergasilidae	*Ergasilus manicatus*	no common name
Gecarcinucidae	*Spiralothelphusa hydrodroma*	no common name
	Vela pulvinata	no common name
Grapsidae	*Metopograpsus sp.*	N/A
Macrophthalmidae	*Macrophthalmus (Mareotis) japonicus*	no common name
Ocypodidae	*Leptuca pugilator*	Atlantic sand fiddler
Palaemonidae	*Macrobrachium idella*	slender river prawn
	Macrobrachium lamarrei	Kuncho river prawn
	Macrobrachium nipponense	Oriental river prawn
	Macrobrachium rosenbergii	giant river prawn
Scyllaridae	*Scyllarus arctus*	lesser slipper lobster
Sergestidae	*Acetes sp.*	N/A
Sesarmidae	*Sesarma sp.*	N/A
Varunidae	*Helice tientsinensis*	N/A
Veneridae	*Meretrix lusoria*	Japanese hard clam

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated:

Family	Scientific name	Common name
Alpheidae	*Alpheus brevicristatus*	teppo snapping shrimp
	Alpheus digitalis	forceps snapping shrimp
	Alpheus japonicus	Japanese snapping shrimp
	Alpheus lobidens	brownbar snapping shrimp
Artemiidae	*Artemia salina*	brine shrimp
	Artemia sp.	N/A

	Nitokra sp.	N/A
Astacidae	*Astacus astacus*	noble crayfish
Balanidae	*Belanus sp.*	N/A
Brachionidae	*Brachionus plicatilis*	no common name
	Brachionus urceolaris	no common name
Calappidae	*Calappa lophos*	common box crab
	Calappa philargius	spectacled box crab
Cambaridae	*Faxonius punctimanus*	spothand crayfish
Crangonidae	*Crangon affinis*	Japanese sand shrimp
Cyclopidae	*Apocyclops royi*	no common name
Diogenidae	*Diogenes nitidimanus*	no common name
Dorippidae	*Paradorippe granulata*	granulated mask crab
Epialtidae	*Doclea muricata*	no common name
Eunicidae	*Marphysa gravelyi*	polychaete worm
Euphausiidae	*Euphausia pacifica*	Isada krill
Galenidae	*Halimede ochtodes*	no common name
Grapsidae	*Grapsus albolineatus*	no common name
	Metopograpsus messor	no common name
Hippolytidae	*Latreutes anoplonyx*	medusa shrimp
	Latreutes planirostris	flatnose shrimp
Leucosiidae	*Philyra syndactyla*	no common name
Lithodidae	*Lithodes maja*	stone king crab
Macrophthalmidae	*Macrophthalmus (Macrophthalmus) sulcatus*	no common name
Matutidae	*Ashtoret miersii*	no common name
	Matuta planipes	flower moon crab
Menippidae	*Menippe rumphii*	maroon stone crab
Ocypodidae	*Gelasimus vocans*	orange fiddler crab
	Leptuca panacea	gulf sand fiddler
	Leptuca spinicarpa	spined fiddler
	Minuca longisignalis	gulf marsh fiddler
	Minuca minax	redjointed fiddler
	Minuca rapax	mudflat fiddler
Ostreidae	*Magallana gigas*	Pacific oyster
Paguridae	*Pagurus angustus*	no common name
Parthenopidae	*Parthenope prensor*	no common name
Pasiphaeidae	*Leptochela gracilis*	lesser glass shrimp
Sergestidae	*Acetes chinensis*	northern mauxia shrimp

Sesarmidae	*Armases cinereum*	squareback marsh crab
	Circulium rotundatum	no common name
Solenoceridae	*Solenocera crassicornis*	coastal mud shrimp
Squillidae	*Squilla mantis*	spottail mantis squillid
Thiaridae	*Melanoides tuberculata*	red-rim melania
Upogebiidae	*Austinogebia edulis*	no common name
Varunidae	*Chhapgarus intermedius*	no common name
	Cyrtograpsus angulatus	no common name
	Helice tridens	no common name
	Neohelice granulata	no common name
Xanthidae	*Atergatis integerrimus*	red egg crab
	Demania splendida	no common name
	Liagore rubronaculata	no common name

~~All life stages are potentially susceptible, from eggs to broodstock (Lightner, 1996; Venegas *et al.*, 1999). WSSV genetic material has been detected in reproductive organs (Lo *et al.*, 1997), but susceptibility of the gametes to WSSV infection has not been determined definitively.~~

[…]

Annex 61. Item 10.2.1. – Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *P. olseni*'

CHAPTER 2.4.6.

INFECTION WITH *PERKINSUS OLSENI*

Norway	**Category:** General **Proposed amended text:** not relevant **Rationale:** Norway supports the proposed changes to this Chapter.

[…]

2.2. Host factors

2.2.1. Susceptible host species

Species that fulfil the criteria for listing as susceptible to infection with *Perkinsus olseni* according to Chapter 1.5. of the *Aquatic Animal Health Code* (*Aquatic Code*) are:

Family	Scientific name	Common name
Arcidae	*Anadara kagoshimensis*	half-crenated ark cockle
	Anadara trapezia	ark cockle
Cardiidae	*Tridacna crocea*	crocus giant clam
Haliotidae	*Haliotis laevigata*	greenlip abalone
	Haliotis rubra	blacklip abalone
Margaritidae	*Pinctada fucata*	Japanese pearl oyster
Mytilidae	*Mytilus galloprovincialis*	Mediterranean mussel
	Perna canaliculus	New Zealand mussel
Veneridae	*Austrovenus stutchburyi*	Stutchbury's venus clam
	Leukoma jedoensis	Jedo venus clam
	Paratapes undulatus	undulate venus clam
	Protapes gallus	rooster venus clam
	Proteopitar patagonicus	no common name
	Ruditapes decussatus	grooved carpet shell
	Ruditapes philippinarum	Japanese carpet clam

~~*Perkinsus olseni* has an extremely wide host range. Known hosts include the clams *Anadara trapezia*, *Austrovenus stutchburyi*, *Ruditapes decussatus*, *R. philippinarum*, *Tridacna maxima*, *T. crocea*, *Protothaca jedoensis* and *Pitar rostrata*~~

~~(Cremonte *et al.*, 2005; Goggin & Lester, 1995; Park *et al.*, 2006; Sheppard & Phillips, 2008; Villalba *et al.*, 2004;); oysters *Crassostrea gigas*, *C. ariakensis*, and *C. sikamea* (Villalba *et al.*, 2004); pearl oysters *Pinctada margaritifera, P. martensii*, and *P. fucata* (Goggin & Lester, 1995; Sanil *et al.*, 2010); abalone *Haliotis rubra, H. laevigata, H. scalaris,* and *H. cyclobates* (Goggin & Lester, 1995). Other bivalve and gastropod species might be susceptible to this parasite, especially in the known geographical range. Members of the families Arcidae, Malleidae, Isognomonidae, Chamidae and Veneridae are particularly susceptible, and their selective sampling may reveal the presence of *P. olseni* when only light infections occur in other families in the same habitat.~~

2.2.2. ~~Susceptible stages of the host~~ Species with incomplete evidence for susceptibility

~~All stages after settlement are susceptible.~~

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with *P. olseni* according to Chapter 1.5. of the *Aquatic Code* are:

Family	Scientific name	Common name
Cardiidae	*Cerastoderma edule*	common edible cockle
Mytilidae	*Mytilus chilensis*	Chilean mussel
Ostreidae	*Crassostrea gasar*	gasar cupped oyster
	Ostrea angasi	Australian mud oyster
Pectinidae	*Pecten novaezelandiae*	New Zealand scallop
Psammobiidae	*Hiatula acuta*	no common name
Veneridae	*Venerupis corrugata*	corrugated venus clam

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated:

Family	Scientific name	Common name
Cardiidae	*Cerastoderma glaucum*	olive green cockle
Chamidae	*Chama pacifica*	reflexed jewel box
Haliotidae	*Haliotis diversicolor*	small abalone
Isognomonidae	*Isognomon alatus*	flat tree oyster
	Isognomon sp.	N/A
Margaritidae	*Pinctada imbricata*	Atlantic pearl oyster
Ostreidae	*Crassostrea rhizophorae*	mangrove cupped oyster
	Dendostrea frons	Frons oyster
	Magallana [syn. *Crassostrea*] *gigas*	Pacific oyster
	Magallana [syn. *Crassostrea*] *hongkongensis*	no common name
	Saccostrea sp.	N/A
Pectinidae	*Mimachlamys crassicostata*	noble scallop
Pharidae	*Sinonovacula constricta*	constricted tagelus clam
Veneridae	*Meretrix lyrata*	lyrate hard clam

Family	Scientific name	Common name
	Polititapes aureus	golden carpet shell
	Venus verrucosa	warty venus clam

[…]