Report of the Meeting of WOAH Aquatic Animal Health Standards Commission

Original: English (EN)

18 to 25 September 2024

Introduction and Member contribution

This report presents the work of the WOAH Aquatic Animal Health Standards Commission (hereinafter 'the Aquatic Animals Commission') who met in Paris, France from 18 to 25 September 2024.

The Aquatic Animals Commission wished to thank the following Members for providing written comments for the WOAH *Aquatic Animal Health Code* (hereinafter 'the *Aquatic Code*') and WOAH *Manual of Diagnostic Tests for Aquatic Animals* (hereinafter 'the *Aquatic Manual*'): Australia, Canada, Chile, China (People's Rep. of), Chinese Taipei, Japan, Mexico, New Caledonia, Norway, Singapore, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), the Members of the WOAH Americas Region (the Americas) and the Member States of the European Union (EU). The Commission also wished to acknowledge the valuable advice and contributions from numerous experts of the WOAH scientific network.

The Aquatic Animals Commission reviewed all comments that were submitted prior to the deadline and were supported by a rationale. The Commission thanked Members that submitted their comments following the Guide for WOAH Members and International Organisations on submitting comments during the process for the elaboration of WOAH International Standards. The Commission wished to highlight that comments received on texts circulated with this report that are not in line with this Guide will not be considered or published. The Commission made amendments to draft texts, where relevant, in the usual manner by 'double underline' and 'strikethrough'. In relevant annexes, amendments proposed at this meeting are highlighted in yellow to distinguish them from those made previously.

As communicated in the Commission's September 2023 report the Director General agreed to progressively implement a process to improve the transparency of the WOAH process for the elaboration of Standards for better documentation and traceability of the process.

The first step in this process was the publication on the Delegates' website (in April 2024) of comments submitted by WOAH Members and partners and that were considered by the Commission at its February 2024 meeting. Comments were uploaded onto the Delegate's website at the same time as the publication of the Commission's report. Comments were published in the language that they were submitted.

The next step in this process is the publication of comments considered by the Commission together with the Commission responses in a specific annex for information only (refer to Annex 3). In this annex, comments considered are published in the language in which they were submitted. Commission responses are presented in English, French or Spanish according to the language version. Comments and Commission responses are embedded in the English version of the text that was circulated for comment in February 2024. The background text is presented only in English for all three language versions (En, Sp and Fr) due to resource constraints. Please note that the texts for comment are presented in Annexes 4 to 11 and 13 to 25.

Annexes

Annex 3 is presented for information only, and presents the comments considered and the Commission's responses.

Texts in Annexes 4 to 11 and 13 to 25 are presented for comment.

Text in Annex 12 is presented for information.

How to submit comments

The Aquatic Animals Commission strongly encourages WOAH Members and International Organisations with a WOAH Cooperation Agreement to participate in the development of WOAH International Standards by submitting comments on relevant texts of this report.

Engagement of Members and International Organisations in the standard-setting process through the submission of comments is critical to ensure that standards are science based and take into consideration the different contexts among Members and stakeholders and can be implemented. To ensure that comments are considered, they should be submitted by the requested deadline and in the format described in the Guide for WOAH Members and International Organisations on submitting comments during the process for the elaboration of WOAH International Standards (Guide) and the Standard Operating Procedure for WOAH Members and International Organisations to submit comments during the process for the elaboration of WOAH International Standards (SOP) available on the Delegate's website and the WOAH public website.

Comments that are not correctly formatted as described in the Guide and SOP will not be considered by the Commission. Any questions on the requirements for formatting and submission of comments should be sent to AAC.Secretariat@woah.org

The Aquatic Animals Commission wished to highlight that when a Commission discussion is based on the input of an *ad hoc* Group, Members are encouraged to review the relevant *ad hoc* Group report together with the report of the Commission. *Ad hoc* Group reports are available on the dedicated webpages on the WOAH website at https://www.woah.org/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/

Deadline for comments

Comments on relevant texts in this report must be received by 6 January 2025 to be considered by the Aquatic Animals Commission.

Where to send comments

All comments should be sent to AAC.Secretariat@woah.org

Date of the next meeting

The Aquatic Animals Commission noted the dates for its next meeting: 12 to 19 February 2025.

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List of Annexes

1. Meetings with the Director General and the Deputy Director General - International Standards and Science

1.1. WOAH Director General

Dr Emmanuelle Soubeyran, the newly elected Director General of WOAH, together with Dr Montserrat Arroyo, WOAH Deputy Director General for International Standards and Science (DDG-ISS) met with the Aquatic Animals Commission on 18 September 2024.

Dr Soubeyran congratulated the Commission members on their election for the new term and expressed her confidence in their collective efforts moving forward. She highlighted the importance of aquatic animal health and WOAH's commitment to work in this area.

Dr Soubeyran outlined her vision for enhancing the Organisation, focusing on innovation, strategic development and increasing the visibility of WOAH's work, including the contributions of the Specialist Commissions. She emphasised the importance of visibility as a tool to effectively raise relevant issues and influence decision-makers. Dr Soubeyran also highlighted innovation in the development of standards as key steps in modernising processes, specifically through digitalisation and prioritisation based on the Member's needs.

She further stressed the importance of the work of the Specialists Commissions and the impact of work on WOAH Members. Thus she emphasised the need to foster collaboration and dialogue between the Specialist Commissions, Members, WOAH Regional Representations, experts, the private sector and academia, to promote innovative approaches to the Organisation's work.

Dr Soubeyran stressed WOAH's activities to improve transparency through the publication of Members comments. Further she reminded the Commission about the digitisation of the WOAH standards in the form of the WOAH Standards Online Navigation Tool to provide users with streamlined access and navigation. Inclusion and member involvement were also highlighted as essential elements of WOAH's governance. Dr Soubeyran shared plans to increase Member participation in the standard-setting processes and shared that upcoming Regional Commission Conferences will include dedicated sessions for Members to share priorities for standard setting work items. In closing, Dr Soubeyran reaffirmed WOAH's commitment to transparency, credibility and inclusivity in all its operations.

The Commission expressed their appreciation for her updates and wished her success in her term as Director General.

1.2. WOAH Deputy Director General, International Standards and Science

Dr Arroyo highlighted the significance of a new term and noted that a new President and the inclusion of a new member to the Commission brings an opportunity to evaluate and enhance the work of this Commission. She stressed the importance of inclusivity, transparency, and continuity in each of the Commissions' work. Dr Arroyo reminded the Commission that it is composed of international experts with a geographic balance. She emphasised that a global perspective is needed and that they are all tasked with making sure that WOAH standards are both practical and inclusive for implementation by all Members.

She acknowledged the considerable workload of the Commission and stressed the importance of continuity in the work from the previous Commission.

Addressing the role of WOAH Reference Centres and Collaborating Centres, Dr Arroyo underscored their importance and value for the organisation. She also stressed the need for them to offer consistent support to both the Members and the organisation, ensuring a uniform level of assistance across the network.

In conclusion, Dr Arroyo wished the Commission success in its new term. The Commissions expressed their gratitude for the support provided by the WOAH Secretariat.

Following Dr Arroyo's address, Dr Gillian Mylrea, Head of the Standards Department, conducted an induction session given this was the start of a new term of Specialist Commissions. This was the final session of the Specialist Commission induction programme which also included induction sessions for new Commission members, the Presidents, and Commission members and Secretariats, to meet and discuss information relevant to this new term.

2. Adoption of the agenda

The draft agenda was adopted by the Aquatic Animals Commission. The agenda and the list of participants are attached as Annex 1 and Annex 2 respectively.

3. Cooperation with the Terrestrial Animal Health Standards Commission

The Bureaus of the Aquatic Animals Commission and the Terrestrial Animals Health Standards Commission met on 19 September 2024, chaired by the WOAH DDG-ISS. The purpose of the meeting was to share information and ensure a harmonised approach for the revision of horizontal chapters. Both Commissions had committed to convene Bureau meetings at least annually to ensure enhanced coordination. The Bureaus discussed issues of common interest which are reported below.

The Bureaus discussed issues of mutual interest notably:

- the approach taken by both Commissions in the planning and progress of their work programmes and prioritisation of items,
- ongoing work on Glossary definitions to consider harmonisation between the *Terrestrial Code* and the *Aquatic Code* if relevant,
- the Aquatic Animals Commission's work on Chapter 4.3. 'Application of Compartmentalisation' in the *Aquatic Code,*
- the plan for a revision of Chapter 4.4. 'Zoning and Compartmentalisation' and development of a new chapter on the implementation of zoning in the *Terrestrial Code*,
- both Commissions work being undertaken on emergency management standards, and
- the potential work on AMR related chapters following the adoption of the revised *Terrestrial Code* Chapter 6.10.

The Bureaus discussed and highlighted the importance of the User's Guide, emphasising the need for it to support better understanding and interpretation of the Codes, and agreed to make continuous updates to align with ongoing revisions of the chapters and other relevant works. The Bureaus also discussed that it could be good to develop an introductory chapter for Section 5 of the two Codes, to provide clarity on its objectives and how the chapters should be used.

The Bureaus agreed that the planned work on e-certification, including a review of Chapters 5.1. 'General obligations related to certification' and 5.2. 'Certification procedures' for both the *Terrestrial Code and Aquatic Code* (see item 7.1.4.) should be done as a joint work. This work will ensure harmonisation and consistency between these chapters in the two Codes.

4. Aquatic Animal Health Strategy

The Aquatic Animals Commission was informed of the key milestones and achievements of the WOAH Aquatic Animal Health Strategy since the last update in February 2024, new activities underway, communication initiatives and key priorities. The Commission was informed about planned activities including the development of a WOAH Aquatic Animal Diseases Field Guide Phone Application, the review of the scientific basis of welfare standards for farmed fish in the *Aquatic Code*, accessibility of the standards and training materials for self-

declaration. The Commission confirmed their support for continued work on Strategy activities which impact the standards.

In addition, the Commission was informed about a global workshop scheduled for 20-22 February 2025 linked to Activities 4.5. 'Identify the highest-priority research areas' and 4.3. 'Engage WOAH scientific networks' of the Strategy. The aim of the workshop is to identify high-priority research areas that will provide lasting benefit for the global management of aquatic animal diseases, in particular those that will have an impact on WOAH International Standards in aquatic animal health. The event will be co-organised by WOAH Headquarters, STAR-IDAZ International Research Consortium on Animal Health, and the Commission to optimise resources and foster interdisciplinary collaboration for impactful outcomes. The involvement of STAR-IDAZ, the workshop's outcomes are expected to engage funders and industry representatives promoting long-term partnerships to improve tangible results for aquatic animal health. A scientific committee is being created to design the agenda and validate the workshop's outcomes. It will include members from WOAH Reference Centres, STAR-IDAZ, and the Commission to provide guidance and ensure the objectives are met.

5. Work programme and priorities

5.1. Comments received on the Work Programme

Comments were received from Canada, Norway and the EU.

The Aquatic Animals Commission noted comments expressing support of the Commission's work programme. Comments proposing new work are addressed in sections 7.2. and 9.1. of this report; comments on work items discussed in this meeting are addressed in the corresponding items of this report.

The Commission's responses to comments received are presented in Annex 3.

The Commission reminded Members that the work programme outlines the current and planned work to be undertaken. The Commission strongly encouraged Members to continue to provide feedback as to whether they agree with the topics being proposed, as well as their level of prioritisation.

Texts for comment

The updated work programme is presented as Annex 4 for comments.

5.2. Overview of the Work Programme

The Commission considered areas of focus for its three-year term by reviewing the status of existing work and proposed new work, and prioritised work after considering factors including the expected improvement of the standards, benefit to Members, Member comments, activities of the WOAH Aquatic Animal Health Strategy, capacity constraints, Headquarters' comments and progress on the previous Commission's work plan.

Sections 5.2.1 to 5.2.4. below provide a brief update of the status of some key area of work.

5.2.1. Section 4. 'Disease prevention and control' of the *Aquatic Code*

At its October 2015 meeting, the Aquatic Animals Commission developed and circulated a proposed restructure of Section 4. 'Disease prevention and control'. At that time the Commission's proposed changes included the addition of new chapters, and reorganisation and revision of existing chapters.

At its September 2024 meeting, the Commission reviewed the work on Section 4 to date and determined that the revision of Chapters 4.X. 'Application of compartmentalisation' and 4.7. 'Fallowing in aquaculture' and the development of new Chapter 4.X. 'Application of zoning' should

continue to be included its work programme. The revision of these chapters would complete the planned work on Section 4 which has been ongoing since 2015.

The table below shows the original proposed revisions and restructure (October 2015 report, Annex 8, page 37) and the progress of this work to date.

Proposed restructure of Section 4. 'Disease prevention and control' (October 2015)			
Chapter number (as in 2015 *Aquatic Code*)	Comments	New Chapter (as proposed in 2015)	**Status - September 2024**
N/A	Introduction to the chapters in this section.	Ch. 4.1. 'Introduction to disease prevention and control'	Redundant - Scope covered in current Ch. 4.1. 'Biosecurity for aquaculture establishments'.
Ch. 4.1. 'Zoning and compartmentalisation'	Requires revision to improve readability and clarity on the general principles for establishing zones and compartments.	Ch. 4.2. 'Zoning and compartmentalisation' (revised Chapter 4.1.)	Yet to commence - To be replaced by new Ch. 4.X. 'Application of zoning'.
N/A	Develop a new chapter specific to the application of zoning to provide clearer guidance on establishing zones for trade and disease control purposes. Would integrate with other chapters.	Ch. 4.3. 'Application of zoning' (new chapter)	Yet to commence - Development of a new Ch. 4.X. 'Application of zoning' in current work programme (see item 7.1.1.).
Ch. 4.2. 'Application of compartmentalisation'	Requires revision to improve readability and clarity and to improve guidance for establishing compartments for trade purposes. Would integrate with other chapters e.g. biosecurity, disinfection.	Ch. 4.4. 'Application of compartmentalisation' (revised Chapter 4.2.)	In progress - Development of a revised Ch. 4.X. 'Application of compartmentalisation' in current work programme (see item 7.1.2.).
N/A	Develop a new chapter on principles of aquaculture biosecurity. Would cover key approaches to biosecurity planning such as risk analysis and identification of transmission pathways. Would integrate with other chapters e.g. disinfection, compartmentalisation.	Ch. 4.5. 'Aquaculture biosecurity' (new chapter)	Complete - A new Ch. 4.1. 'Biosecurity for aquaculture establishments' was adopted in 2021.
Ch. 4.3. 'General recommendations on disinfection'	Currently under revision to provide more detailed recommendations on the principles of disinfection.	Ch. 4.6. 'Disinfection of aquaculture establishments and equipment' (revised Ch. 4.3. under development)	Complete - A revised Ch. 4.4. 'Disinfection of aquaculture establishments and equipment' was adopted in 2017.
Ch. 4.4. 'Recommendations for surface disinfection of salmonid eggs'	New chapter adopted in 2015. If amended in the future consider changes suggested at Oct 2015 AAC meeting.	Ch. 4.7. 'Recommendations for surface disinfection of salmonid eggs'	Complete - Ch. 4.5. 'Recommendations for surface disinfection of salmonid eggs' was amended in 2017.

Proposed restructure of Section 4. 'Disease prevention and control' (October 2015)			
Chapter number (as in 2015 *Aquatic Code*)	Comments	New Chapter (as proposed in 2015)	**Status - September 2024**
Ch. 4.5. 'Contingency planning'	Requires substantial revision to provide adequate guidance on the principles of contingency planning and emergency response. Required to support articles in each disease-specific chapter on returning to freedom following an outbreak. Would integrate with other chapters e.g. biosecurity, disinfection.	Ch. 4.10. 'Emergency disease preparedness' (new chapter)	In progress - New Ch. 4.X. 'Emergency disease preparedness' and new Ch. 4.Y. 'Disease outbreak management' to be proposed for adoption in 2025. Ch. 4.6. 'Contingency planning' is proposed to be removed (see item 6.1.).
Ch. 4.6. 'Fallowing'	Delete this chapter and integrate relevant information in the proposed new chapter on biosecurity.	To be included in proposed new Ch. 4.4. 'Aquaculture biosecurity'	Yet to commence - Revision of Ch. 4.7. 'Fallowing in aquaculture' in current work programme (see item 7.1.3.).
Ch. 4.7 'Handling, disposal and treatment of aquatic animal waste'	May require some revision to integrate with other new and revised chapters in this section (e.g. emergency disease preparedness, disinfection) and ensure recommendations are sound.	Ch. 4.8. 'Handling, disposal and treatment of aquatic animal waste'	Review to follow completion of other chapters - Revised Ch. 4.8. 'Handling, disposal and treatment of aquatic animal waste' adopted in 2010.
Ch. 4.8. 'Control of pathogenic agents in aquatic animal feed'	Recently revised and adopted (2015). Would integrate with other chapters e.g. biosecurity.	Ch. 4.9. 'Control of pathogenic agents in aquatic animal feed'	Review to follow completion of other chapters - Ch. 4.9. 'Control of pathogenic agents in aquatic animal feed' was first adopted in 2008 and amended in 2015.
N/A	N/A	N/A	In progress - New Ch. 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' to be proposed for adoption in 2025 (see item 6.2.)

The Commission reviewed the work on Section 4 to date and determined that revision of the current *Aquatic Code* Chapters 4.2., 4.3. and 4.6. should be included in the work programme. The revision of these chapters would complete the planned work on Section 4 which had been ongoing since 2015.

5.2.2. Trade

The Aquatic Animals Commission considered that the usability of the *Aquatic Code* for trade purposes should be reviewed including both the texts and the logical ordering of texts. The Commission agreed to develop a plan for the review of all relevant texts, including Section 5. 'Trade measures', importation/exportation procedures and health certification together with other relevant texts from other sections, as well as relevant proposed new texts. This work would be complimentary to work discussed with the Terrestrial Animal Health Standards Commission during the Bureaus meeting (see item 3). The Commission agreed to discuss this further at its February 2025 meeting and will share its proposal with Members once finalised.

5.2.3. Susceptible species

Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogenic agent' of the *Aquatic Code*, provides criteria for determining which host species are listed as susceptible in Article X.X.2. of each disease-specific chapter in the *Aquatic Code*.

Assessments for all of the WOAH listed diseases in the *Aquatic Code* are being undertaken progressively by dedicated *ad hoc* Groups. Based on assessments undertaken, the revised list of susceptible species in the relevant Article X.X.2. of the *Aquatic Code* and Section 2.2.1. of the *Aquatic Manual* are circulated for comment and then presented for adoption. Species that have some evidence of susceptibility, but insufficient evidence to demonstrate susceptibility in accordance with the criteria of chapter 1.5, are included in Section 2.2.2 of the relevant disease-specific chapter of the *Aquatic Manual*.

Assessments have now been completed for all fish and mollusc diseases (11 and 7 listed diseases respectively) as well as all crustacean diseases except infection with *Aphanomyces astaci* (crayfish plague) which will be conducted in 2025 (9 of 10 listed diseases). Assessments for the amphibian listed diseases (3 listed diseases) will start in 2025. (see item 7.1.7.)

5.2.4. Aquatic Manual reformat

The Aquatic Animals Commission has continued the process of progressively reformatting and reviewing each disease-specific chapter of the *Aquatic Manual* into a new template. As of September 2024, only five of 31 disease-specific chapters are yet to be reformatted and comprehensively revised.

The WOAH Aquatic Animal Health Code

6. *Aquatic Code* Items for Member comments

6.1. Draft new Chapter 4.X. 'Emergency disease preparedness' and draft new Chapter 4.Y. 'Disease outbreak management'

Background

At its September 2022 meeting, the Aquatic Animals Commission discussed the work of the *ad hoc* Group on Emergency Disease Preparedness and Disease Outbreak Management for Aquatic Animals, which met twice during 2021-2022, and agreed to continue the work on the development of a draft new Chapter 4.X. 'Emergency disease preparedness' and draft new Chapter 4.Y. 'Disease outbreak management'.

At its September 2023 meeting, the Commission finalised work on these two draft new chapters and noted that these two chapters are closely connected. Chapter 4.X. outlines the essential elements of an emergency disease preparedness framework which encompasses all the elements that will enable the Competent Authority to activate an efficient response to a disease outbreak. Chapter 4.Y. describes the specific actions which are necessary to operationalise the framework in the event of a disease outbreak.

At its February 2024 meeting the Commission considered comments received and noted that Members were generally supportive of the proposed changes.

The draft new chapters have been circulated twice for comment.

Previous Commission reports where this item was discussed

September 2023 report (Item 6.6., page 12); February 2024 report (Item 7.1., page 21).

September 2024 meeting

Comments were received from Australia, Canada, China (People's Rep. of), Mexico, New Caledonia, Norway, Singapore, the UK, the USA and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the draft new Chapter 4.X. 'Emergency disease preparedness', and the draft new Chapter 4.Y. 'Disease outbreak management', while proposing suggestions for clarity and some proposals for content to consider.

The Commission's responses to comments received are presented in Annex 3.

In Article 4.X.4.'General Principles' the Commission agreed to add a new point 2 covering the principle that case definitions for suspect and confirmed cases should be established for important aquatic animal diseases within the emergency disease preparedness framework. This addition was in response to a comment 4.Y.4_7 provided for Chapter 4.Y. (see Annex 3).

The Commission noted that Chapter 4.6. 'Contingency planning' would become obsolete once the draft new Chapters 4.X. and 4.Y. are adopted. The Commission therefore proposed that Chapter 4.6. be proposed for deletion at the 92nd General Session in May 2025.

Texts for comment

The draft new Chapter 4.X. 'Emergency disease preparedness' and draft new Chapter 4.Y. 'Disease outbreak management', are presented as Annex 5 and Annex 6, respectively, for comments.

6.2. Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'

Background

At its September 2023 meeting, the Aquatic Animals Commission reviewed the draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' which had been developed in collaboration with industry, with the purpose to provide recommendations for safe trade in milt and fertilised eggs of fish from areas which have not been declared free from infection with a listed disease.

To take into account the provisions in the draft new Chapter 4.Z., the Commission revised model Articles 10.X.10. and 10.X.15. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Articles 10.4.15. and 10.4.20. for Chapter 10.4. 'Infection with ISAV'. The Commission also proposed a new definition for 'collection and incubation centre' to the Glossary of the *Aquatic Code* to ensure a common understanding of this term given the importance of its use in the draft new Chapter 4.Z.

At its February 2024 meeting the Commission considered comments received and noted that Members were generally supportive of the proposed changes. The Commission agreed that it would ask industry experts to draft a new article providing guidance on the biosecurity in the collection and incubation centre.

The Commission further considered the integration of the draft new Chapter 4.Z. into the disease-specific chapters and made an assessment of the suitability of the provisions of draft new Chapter 4.Z. for listed diseases of fish to determine the suitability of including the model Article 10.X.15. (10.4.20. for ISAV) in each of the relevant fish disease-specific chapters. As a result of this assessment, the Commission agreed to only apply the model Article 10.X.15. to 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'.

In relation to the glossary terms, the Commission proposed to change the glossary term 'egg' to 'fertilised egg' and proposed to amend the glossary term 'gametes'.

The draft new chapter, model articles and new and revised glossary terms have been circulated twice for comment.

Previous Commission reports where this item was discussed

September 2023 report (Item 6.7., page 12); February 2024 report (Item 6.7., page 27).

September 2024 meeting

Comments were received from Canada, Chile, China (People's Rep. of), Norway, Thailand, the UK, the USA, and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish', while proposing suggestions for clarity and some proposals for content to consider.

The Commission's responses to comments received are presented in Annex 3.

The Commission agreed to add a new article to Chapter 4.Z. providing guidance on the biosecurity in the collection and incubation centre.

The Commission agreed that the February 2024 proposed changes to model Article 10.X.10. (and 10.4.15.) suggested that the risk mitigation measures outlined in this article were not an option for the importation of gametes and fertilised eggs. As this was not the intent of these amendments, the Commission agreed to revert to the original amendments presented in its September 2023 report.

The Commission also agreed to insert 'In this article, all statements referring to infection with ISAV includes HPR-deleted ISAV and HPR0 ISAV.', as the first paragraph to Article 10.4.20. of Chapter 10.4. 'Infection with infectious salmon anaemia virus' to align with the other articles of the chapter.

Texts for comment

The draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' is presented as Annex 7 for comments.

The revised 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' are presented as Annex 8 for comments.

The revised 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' are presented as Annex 9 for comments.

The new glossary term for 'collection and incubation centre' and revised glossary terms for 'fertilised eggs' and 'gametes' are presented as Annex 10 for comments.

6.3. Draft new Chapter 5.X. 'Movement of ornamental aquatic animals'

Background

At its September 2023, the Aquatic Animals Commission reviewed a draft new Chapter 5.X. 'Movement of ornamental aquatic animals', which it had developed taking into account input from Aquatic Animal Focal Point seminars where the proposed need, purpose and scope of this chapter had been discussed.

Chapter 5.X. provides recommendations for managing the disease risks associated with movement of ornamental aquatic animals and complements other provisions of the *Aquatic Code*, including the measures specified in the disease-specific chapters.

The Commission added a new definition for 'ornamental aquatic animal' to the glossary of the *Aquatic Code* to ensure a common understanding of this term within the *Aquatic Code* given the importance of its use in the draft new Chapter 5.X. At its February 2024 meeting, the Commission reviewed comments received and noted that Members were generally supportive of the new draft Chapter 5.X. with some proposed edits.

The draft new chapter and new glossary term have been circulated twice for comment.

Previous Commission reports where this item was discussed

September 2023 report (Item 6.7., page 12).; February 2024 report (Item 7.3., page 33).

September 2024 meeting

Comments were received from Australia, Canada, Chile, Mexico, Norway, the USA, the Americas and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the draft new Chapter 5.X. 'Movement of ornamental aquatic animals', while proposing suggestions for clarity and content to consider.

The Commission's responses to comments received are presented in Annex 3.

On review of Chapter 5.X. the Commission removed the latter portion of the first sentence in Article 5.X.1. for consistency with Article 5.X.2. As well, in the last paragraph of Article 5.X.12. the Commission changed 'contingency plan' to 'plan' to address welfare impacts, as contingency plan is a Glossary definition and does not include welfare.

Texts for comment

The draft new Chapter 5.X. 'Movement of ornamental aquatic animals', is presented as Annex 11 for comments.

The new glossary term for 'ornamental aquatic animal' is presented as Annex 10 for comments.

6.4. Assessment of default periods in Articles X.X.4. – X.X.8. for disease-specific chapters

Background

The revised Chapter 1.4. 'Aquatic animal disease surveillance' of the *Aquatic Code* was adopted in May 2022 and provides guidance for the declaration of disease freedom via four different pathways, including: 1. absence of susceptible species; 2. historical freedom; 3. targeted surveillance; and 4. returning to freedom. Chapter 1.4. specifies default minimum periods of basic biosecurity conditions (BBC) for all four pathways and targeted surveillance (TS) for pathways 3 and 4. The disease-specific chapters in the *Aquatic Code* provide more specific recommendations for these periods of BBC and TS. The Commission agreed to review the BBC and TS periods in the disease-specific chapters pending assessments against criteria included in Chapter 1.4.

At its February 2024 meeting, the Aquatic Animals Commission considered the assessments prepared at the request of the Commission by a Collaborating Centre expert, and presented the assessments for Member comment.

The assessments of the default periods in Articles X.X.4. – X.X.8. are presented in 'Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the *Aquatic Code*' which was circulated for comment in its February 2024 report.

Previous Commission reports where this item was discussed

February 2024 (Item 7.4., page 36).

September 2024 meeting

Comments were received from Canada, Chinese Taipei, Japan, Mexico, New Caledonia, Norway, Singapore, Thailand and the EU.

The Aquatic Animals Commission considered comments received and updated the assessment document 'Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the *Aquatic Code*'. The Commission added 'infection with decapod iridescent virus 1' and 'infection with *Megalocytivirus pagrus 1*' to the assessment as these diseases were not included in the version circulated in February 2024. The Commission also explained in the document that 'infection with infectious salmon anaemia virus' (ISAV) in the *Aquatic Code* applies to two categories of disease status: freedom from ISAV (including HPR0 and HPR-deleted) and HPR-deleted ISAV. Recommendations in the assessment were updated to clarify the default periods relative to these two categories for ISAV.

The Commission's responses to comments received are presented in Annex 3.

During the review of the assessment document, the Commission noted that the inclusion of some pathways for certain diseases should not have been included (e.g. pathway 2 for ISAV (including HPR0 and HPR-deleted)). The Commission made these changes in the assessment document and suggested modifications in the relevant articles in the disease-specific chapters.

After reviewing the articles for default periods, the Commission agreed to update point 2c in Article X.X.7. of disease-specific chapters to reflect the Glossary term 'pathogenic agent'. The Commission also agreed that point 2a in Article X.X.5. be updated to reflect that conditions conducive to clinical expression of disease are described in Article 1.4.8. of Chapter 1.4., and to remove the reference to the *Aquatic Manual.*

After reviewing the articles for default periods in Chapter 10.4. 'Infection with infectious salmon anaemia virus', in Article 10.4.5. the Commission noted that the introductory sentence indicating the article included HPR0 ISAV needed to be added. Further, the Commission noted that Article 10.4.6. incorrectly referenced HPR0 ISAV and amended this article to reflect HPR-deleted ISAV.

The recommendations for periods of basic biosecurity conditions and targeted surveillance were applied to Articles X.X.5. to X.X.7. (and 10.4.5. to 10.4.10.) for all disease-specific chapters. The recommendations were not applied to Chapter 10.8. 'Infection with red sea bream iridovirus' as this will be replaced with a new Chapter 10.X. 'Infection with *Megalocytivirus pagrus 1*'.

Texts for comment

The revised document 'Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the *Aquatic Code*', is presented as Annex 12 for information.

The revised Articles X.X.5. to X.X.7. (and 10.4.5. to 10.4.10.) for all disease-specific chapters, are presented as Annex 13 for comments.

6.5. Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus'

6.5.1. Application of Article 1.5.9. of Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'

The Aquatic Animals Commission wished to remind Members that the aim of the *Aquatic Code* is to prevent the spread of aquatic animal diseases and to assure the sanitary safety of international trade in aquatic animals. If the criteria outlined in Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' are not applied for diseases with a proven broad host range (e.g. infection with WSSV) this would result in a substantial reduction in the list of susceptible species for these diseases. As a consequence, the *Aquatic Code* measures for these diseases would not apply to many species that are likely to be susceptible. The Commission noted that this circumstance would be contrary to the purposes of the *Aquatic Code* and could lead to the spread of listed diseases. The Commission encouraged Members to refer to Item 1.5., page 6, of its February 2018 report for a more comprehensive explanation of this approach.

The Commission noted that the desired outcome of applying the criteria in Article 1.5.9. is an appropriate level of risk management while also facilitating trade.

To ensure a balanced risk based approach the Commission took the following considerations into account when applying the criteria in Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher':

- evidence that any species within a taxonomic group are non-susceptible,
- the proportion of species within a taxonomic group that have been determined to be susceptible,
- the breadth of taxonomic representation of susceptible species within the taxonomic group (e.g. evidence of susceptibility found across multiple genera within a family),
- additional evidence of susceptibility to confirm an approach (e.g. other species in a taxonomic group have some, but incomplete evidence of susceptibility),
- whether susceptible species occur across distantly related taxa,
- other phylogenetic information (e.g. where some clades within a taxa show evidence of susceptibility and other clades do not have available evidence susceptibility),
- pathogen related factors (e.g. the taxonomic grouping contains multiple genotypes with different evidence of susceptibility),
- the range of suitable environmental conditions for different species within a taxonomic group compared to the permissible conditions for the pathogen, and
- relevance of species for trade of aquatic animal commodities.

The Commission utilised these considerations when reviewing the evidence of susceptibility for each disease. This approach ensured there was sufficient evidence available to support the listing of susceptible species at a taxonomic ranking of Genus or higher.

6.5.2. Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus'

Background

The *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases met in November 2023 to continue its work to apply the criteria in Chapter 1.5. 'Criteria for listing

species as susceptible to infection with a specific pathogen'. At this meeting the *ad hoc* Group conducted the assessments for susceptibility of crustacean species to infection with white spot syndrome virus (WSSV). This assessment is an update of a previous assessment completed in 2016.

At its February 2024 meeting, the Aquatic Animals Commission considered the *ad hoc* Group report on Susceptibility of Crustacean Species to Infection with WSSV. The Commission agreed to apply Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' and to amend the list of susceptible species in Article 9.9.2. in line with the recommendations of the *ad hoc* Group. The Commission applied this to the list of species found to be susceptible to infection with WSSV and determined that Penaeidae and Portunidae should be listed at the family level and that *Procambarus*, *Palaemon* and *Panulirus* should be listed at the genus level.

Relevant sections of Chapter 2.2.8. Infection with white spot syndrome virus, in the *Aquatic Manual* were also amended in line with the recommendations of the *ad hoc* Group (see Item 8.1.1.).

The amended Article 9.9.2. of Chapter 9.2. has been circulated once for comment.

Previous Commission reports where this item was discussed

February 2024 (Item 7.5., page 39).

September 2024 meeting

Comments were received from Canada, China (People's Rep. of), Chinese Taipei, Norway, Thailand and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to Article 9.9.2. of Chapter 9.2. 'Infection with white spot syndrome virus', while proposing suggestions for clarity and some proposals for content to consider.

The Commission's responses to comments received are presented in Annex 3.

The Commission reviewed its application of Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' for 'infection with WSSV' (that had been provided for comment in its February 2024 meeting report) using the considerations outlined in Item 6.5.1.

The Commission agreed to keep Penaeidae and Portunidae listed at the family level as several species and genera were found to be susceptible in each family. For several additional species of each family there is also incomplete evidence of susceptibility.

The Commission agreed to keep *Panulirus spp.* listed at the genus level as there are a low number of species in this genus, providing a good proportion of species with evidence of susceptibility. Also, there are other *Panulirus spp.* showing incomplete evidence of susceptibility.

The Commission agreed to list *Procambarus spp.* and *Palaemon spp.* at the species level instead of at the genus level as both genera have a large number of species with only a few species represented in the assessments for susceptibility.

In response to a comment received that suggested there is evidence to list Oriental river prawn (*Macrobrachium nipponense*) as a susceptible species, the Commission requested that the *ad hoc* Group review its assessments for this species.

The ad hoc Group reviewed the publication provided (Tong *et al*., 2023; Cho *et al*., 2017 & 2021) and re-assessed the susceptibility of Oriental river prawn against the criteria in Chapter 1.5. The revised assessment is presented in the table below.

Re-assessment of Oriental river prawn (*Macrobrachium nipponense*):

Stage 1: Route of infection	Stage 2: Pathogen Identification	Stage 3: Evidence of Infection				Outcome	Year Assessed	References
		A	B	C	D			
E (per os)	qPCR	YES	NO	YES	YES	1	2023	Tong *et al*., 2023
E (per os)	PCR	YES	NO	YES	YES	2	2016	Yun *et al*., 2014
E (per os)	qPCR	ND	NO	NO	NO	3	2023	Cho *et al*., 2017
E (per os)	NO	ND	NO	NO	NO	NS	2023	Cho *et al*., 2021

The *ad hoc* Group concluded that Oriental river prawn meets the criteria to be listed as a susceptible species.

The Commission reviewed the revised assessment and agreed to add Oriental river prawn (*Macrobrachium nipponense*) to Article 9.9.2. of Chapter 9.9. 'Infection with WSSV' of the *Aquatic Code* and Section 2.2.1. of Chapter 2.2.8. 'Infection with WSSV' of the *Aquatic Manual*, and to remove this species from Section 2.2.2. 'Species with incomplete evidence for susceptibility' of Chapter 2.2.8. 'Infection with WSSV' in the *Aquatic Manual*.

The Commission encouraged Members to refer to the *ad hoc* Group's November 2023 report available on the WOAH website for details of the assessment conducted by the *ad hoc* Group.

Texts for comment

The revised Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus', is presented as Annex 14 for comments.

6.6. Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)'

Background

The *ad hoc* Group on Susceptibility of Fish Species to Infection with WOAH Listed Diseases met virtually during January and April 2024 to continue its work to apply the criteria in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'. The *ad hoc* Group conducted the assessments for susceptibility of fish species to infection with *Aphanomyces invadans* (epizootic ulcerative syndrome).

September 2024 Meeting

The Aquatic Animals Commission considered the *ad hoc* Group report on Susceptibility of Fish Species to Infection with *A. invadans* and commended its members for their comprehensive work.

The Commission agreed to amend the list of susceptible species in Article 10.2.2. of Chapter 10.2. 'Infection with *A. invadans* (epizootic ulcerative syndrome)' in line with the recommendations of the *ad hoc* Group. Also following the recommendations of the *ad hoc* Group, the Commission agreed to apply Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' to the list of susceptible species. The Commission used the additional considerations outlined in Item 6.5.1. to guide the application of Article 1.5.9. to the susceptible species for infection with *A. invadans*.

The Commission noted that infection with *A. invadans* has been identified in epizootics impacting multiple species and in which pathogen identification was not confirmed through molecular testing. Often, in these cases pathogen identification was not confirmed due to lack of availability of molecular testing or it was not considered necessary at the time given the clinical picture. As a result, the evidence of susceptibility of species to *A. invadans* is likely underestimates the full host range of this disease. The Commission took this into consideration when applying Article 1.5.9.

The Commission agreed that *Micropterus spp.* should be listed at the species level rather than the genus level. The assessment found two species of *Micropterus* susceptible which was not considered a large enough representation given the number of species in the genus.

The Commission agreed that *Labeo spp.* should be listed at the species level rather than the genus level. The assessment found two species of *Labeo* susceptible which was not considered a large enough taxonomic representation given the number of species in the genus.

The Commission agreed that *Channa spp.* should be listed at the genus level as multiple species of this genus were found to be susceptible to *A. invadans.* Additionally, many species were found to have incomplete evidence of susceptibility which provided confirmation.

The application of the criteria from Article 1.5.9. is shown in the table below. In the table it is highlighted grey to indicate whether susceptible species considered at species or genus level; see Item 6.5.1. for further information on Article 1.5.9. and considerations for application of this article:

Family	Genus	Species
Alosidae	*Alosa*	*Alosa sapidissima*
	Brevoortia	*Brevoortia tyrannus*
Anabantidae	*Anabas*	*Anabas testudineus*
Bagridae	*Mystus*	*Mystus cavasius*
Centrarchidae	*Lepomis*	*Lepomis macrochirus*
	Micropterus	*Micropterus dolomieu*
		Micropterus salmoides
Channidae	*Channa*	*Channa marulius*
		Channa punctatus
		Channa striata
Cichlidae	*Etroplus*	*Etroplus suratensis*
Clariidae	*Clarias*	*Clarias gariepinus*
Cyprinidae	*Cirrhinus*	*Cirrhinus mrigala*
	Dawkinsia	*Dawkinsia filamentosa*
	Enteromius	*Enteromius paludinosus*
	Labeo	*Labeo catla*
		Labeo rohita
	Pethia	*Pethia conchonius*
Gobiidae	*Glossogobius*	*Glossogobius giuris*
Ictaluridae	*Ictalurus*	*Ictalurus punctatus*
Mastacembelidae	*Mastacembelus*	*Mastacembelus armatus*
Mugilidae	*Mugil*	*Mugil cephalus*
Osphronemidae	*Trichogaster*	*Trichogaster fasciata*
Siluridae	*Wallago*	*Wallago attu*
Sparidae	*Archosargus*	*Archosargus probatocephalus*
Xenocyprididae	*Hypophthalmichthys*	*Hypophthalmichthys nobilis*

Relevant sections of Chapter 2.3.1. 'Infection with *A. invadans* (epizootic ulcerative syndrome)' in the *Aquatic Manual* were also amended in line with the recommendations of the *ad hoc* Group (see item 8.2.1.).

The Commission encouraged Members to refer to the *ad hoc* Group's April 2024 report available on the WOAH Website for details of the assessment conducted by the *ad hoc* Group.

The Commission also amended Article 10.2.1. to ensure consistency with the approach taken in other fish disease-specific chapters.

Texts for comment

The revised Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)', are presented as Annex 15 for comment.

6.7. Articles 10.4.11. and 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia virus'

September 2024 meeting

The Aquatic Animals Commission noted that there were some discrepancies in Articles 10.4.11. and 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia virus' in the English, Spanish and French versions of the *Aquatic Code*.

English version

In the second paragraph of Article 10.4.12., the Commission agreed to change both instances of 'HPR0' to 'HPR-deleted' to align with the scope of this article.

French and Spanish versions

In the first paragraph to Article 10.4.11. of both the French and Spanish versions, the Commission agreed to insert 'In this article, all statements referring to a country, zone or compartment free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV', at the start of this paragraph

In the first paragraph to Article 10.4.12. of both the French and Spanish versions, the Commission agreed to insert 'In this article, all statements referring to a country, zone or compartment free from infection with HPR-deleted ISAV, but not necessarily free from infection with HPR0 ISAV', at the start of this paragraph.

These additions align with what is currently in the English version.

Texts for comment

The revised Articles 10.4.11. and 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia virus', are presented as Annex 16 for comment.

6.8. Draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus 1*'

Background

At the 91st General Session in May 2024, the revised Article 1.3.1. of Chapter 1.3. 'Diseases listed by WOAH', was adopted to change the listing of 'infection with red sea bream iridovirus' to 'infection with *Megalocytivirus pagrus 1*'. Infection with *Megalocytivirus pagrus 1* includes infection with the genogroups, red sea bream iridovirus (RSIV), infectious spleen and kidney necrosis virus (ISKNV) and turbot reddish body iridovirus (TRBIV).

September 2024 meeting

The Aquatic Animals Commission drafted a new Chapter 10.X. 'Infection with *M. pagrus 1*' based on the model for disease-specific chapters.

The Commission noted that Chapter 10.8. 'Infection with red sea bream iridovirus' would become obsolete once the draft new Chapter 10.X. was adopted. The Commission therefore proposed that Chapter 10.8. be proposed for deletion at the 92nd General Session in May 2025.

Article 10.X.1.

The Commission agreed to add an additional sentence to Article 10.X.1. to allow for the notification of infection with *M. pagrus 1* at the genogroup level as requested by Members in comments on the listing of the disease and at the 91st General Session in May 2024.

Article 10.X.2.

The Commission agreed to apply Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' to list the susceptible species in Article 10.X.2. in line with the recommendations of the *ad hoc* Group (November 2022 report). The Commission used the additional considerations outlined in Item 6.5.1. to guide the application of Article 1.5.9. to the susceptible species for infection with *M. pagrus 1*.

Although at least one species was assessed as susceptible in three or more genera in each of the following families, Carangidae, Cichlidae and Osphronemidae, the Commission agreed not to list any of these at the family level. These families are made up of numerous genera and species and the assessments identified only a few representative species from these taxa. As a result, the Commission concluded that the Carangidae, Cichlidae and Osphronemidae should not be listed as susceptible at the family level.

The Commission agreed to list *Seriola spp.*,*Trachinotus spp.*, *Pterophyllum spp.*, *Oplegnathus spp.* and *Trichopodus spp.* at the genus level as the assessments provided proportional representation of susceptible species in these taxa. The Commission also agreed to list *Epinephelus spp.* at the genus level as eight species in this genus were assessed to be susceptible, five other species were found to have incomplete evidence of susceptibility and many *Epinephelus spp.* are traded globally.

The Commission agreed to list *Lethrinus spp.*, *Poecilia spp.* and *Xiphophorus spp.* at the genus level given the representation of species within each of these genera and the supporting evidence provided by species with incomplete evidence for susceptibility.

The application of the criteria from Article 1.5.9. is shown in the table below. In the table it is highlighted grey to indicate whether susceptible species considered at species or genus level; see Item 6.5.1. for further information on Article 1.5.9. and considerations for application of this article:

Family	Genus	Species
Apogonidae	*Pterapogon*	*Pterapogon kauderni*
Butidae	*Oxyeleotris*	*Oxyeleotris marmorata*
Carangidae	*Pseudocaranx*	*Pseudocaranx dentex*
	Seriola	*Seriola dumerili*
		Seriola lalandi
		Seriola quinqueradiata
		Seriola quinqueradiata x Seriola lalandi
	Trachinotus	*Trachinotus blochii*
		Trachinotus carolinus
	Trachurus	*Trachurus japonicus*
Centrarchidae	*Lepomis*	*Lepomis macrochirus*
Cichlidae	*Astronotus*	*Astronotus ocellatus*
	Etroplus	*Etroplus suratensis*
	Oreochromis	*Oreochromis niloticus*
	Pterophyllum	*Pterophyllum altum*
		Pterophyllum scalare
Cyprinidae	*Epalzeorhynchos*	*Epalzeorhynchos frenatum*
Danionidae	*Danio*	*Danio rerio*
Ephippidae	*Platax*	*Platax orbicularis*

Family	Genus	Species
Girellidae	*Girella*	*Girella punctata*
Haemulidae	*Parapristipoma*	*Parapristipoma trilineatum*
	Plectorhinchu	*Plectorhinchus cinctus*
Latidae	*Lates*	*Lates calcarifer*
Lethrinidae	*Lethrinus*	*Lethrinus haematopterus*
		Lethrinus nebulosus
Mugilidae	*Mugil*	*Mugil cephalus*
Nothobranchiidae	*Aphyosemion*	*Aphyosemion gardneri*
Oplegnathidae	*Oplegnathus*	*Oplegnathus fasciatus*
		Oplegnathus punctatus
Osphronemidae	*Macropodus*	*Macropodus opercularis*
	Osphronemus	*Osphronemus goramy*
	Trichogaster	*Trichogaster lalius*
	Trichopodus	*Trichopodus leerii*
		Trichopodus microlepis
Paralichthyidae	*Paralichthys*	*Paralichthys olivaceus*
Percichthyidae	*Maccullochella*	*Maccullochella peelii*
Pleuronectidae	*Verasper*	*Verasper variegatus*
Poeciliidae	*Poecilia*	*Poecilia latipinna*
		Poecilia reticulata
	Xiphophorus	*Xiphophorus hellerii*
		Xiphophorus maculatus
Procatopodidae	*Poropanchax*	*Poropanchax normani*
Rachycentridae	*Rachycentron*	*Rachycentron canadum*
Sciaenidae	*Larimichthys*	*Larimichthys crocea*
	Sciaenops	*Sciaenops ocellatus*
Scombridae	*Scomber*	*Scomber japonicus*
	Scomberomorus	*Scomberomorus niphonius*
	Thunnus	*Thunnus orientalis*
Scophthalmidae	*Scophthalmus*	*Scophthalmus maximus*
Serranidae	*Epinephelus*	*Epinephelus akaara*
		Epinephelus awoara
		Epinephelus bruneus
		Epinephelus coioides
		Epinephelus fuscoguttatus
		Epinephelus fuscoguttatus ♀ × ♂*E. lanceolatus*
		Epinephelus malabaricus
		Epinephelus septemfasciatus
Sinipercidae	*Siniperca*	*Siniperca chuatsi*
Sparidae	*Acanthopagrus*	*Acanthopagrus schlegelii*
	Dentex	*Dentex tumifrons*
	Pagrus	*Pagrus major*
Stromateidae	*Pampus*	*Pampus argenteus*
Synanceiidae	*Inimicus*	*Inimicus japonicus*
Tetraodontidae	*Takifugu*	*Takifugu rubripes*

Article 10.X.3.

The Commission agreed to use the time-temperature combination assessed for the RSIV genogroup for *M. pagrus 1*, as per the 'Safe commodity assessments for listed aquatic animal diseases (2023)'. The

close taxonomic relatedness between the ISKNV genogroup, and other megalocytiviruses including TRBIV genogroup deomonstrates that the heat inactivation data for RSIV and ISKNV can also be used for *M. pagrus 1*.

Articles 10.X.5. to 10.X.7.

The Commission agreed to revise Articles 10.X.5. to 10.X.7. based on the 'Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the *Aquatic Code*' (see Item 6.4.).

Article 10.X.14.

The Commission agreed to use the same list of 'aquatic animal products' (i.e. fish fillets or steaks (chilled)) assessed for the RSIV genogroup for *M. pagrus 1* as per the 'Safe commodity assessments for OIE listed aquatic animal diseases (2016)'. Fish fillets or steaks (chilled) are prepared and packaged for retail trade for human consumption in a way that removes tissues (i.e. internal organs, gills and skin) where the pathogenic agent may be found.

Texts for comment

The draft new Chapter 10.X. 'Infection with *M. pagrus 1*', is presented as Annex 17 for comment.

6.9. Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *Perkinsus olseni*'

Background

The *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases met in June and November/December 2023 to continue its work to apply the criteria in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'. The *ad hoc* Group conducted the assessments for susceptibility of mollusc species to infection with *Perkinsus olseni*.

At its February 2024 meeting, the Aquatic Animals Commission considered the *ad hoc* Group report on Susceptibility of Mollusc Species to Infection with *P. olseni* and agreed to amend the list of susceptible species in Article 11.6.2. in line with the recommendations of the *ad hoc* Group.

Relevant sections of Chapter 2.4.6. 'Infection with *P. olseni*' in the *Aquatic Manual* were also amended in line with the recommendations of the *ad hoc* Group (see Item 8.3.3.).

The amended Articles 11.6.1. and 11.6.2. of Chapter 11.6. have been circulated once for comment.

Previous Commission reports where this item was discussed

February 2024 (Item 7.6., page 40).

September 2024 meeting

Comments were received from Canada, China (People's Rep. of), Chinese Taipei, Norway and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *Perkinsus olseni*', while proposing suggestions for clarity and some proposals for content to consider.

The Commission's responses to comments received are presented in Annex 3.

The Commission reviewed its application of Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' for 'infection with *P. olseni*' using the considerations outlined in Item 6.5.1.

The Commission agreed that *Anadara spp.* and *Haliotis spp.* should be listed at the species level as these genera are made up of numerous species and the assessments only identified a few species. Therefore, taxonomic representation is not considered sufficient.

The Commission agreed that the species belonging to the family Veneridae should be listed at the species level as this family is made of a large number of genera with a significant number of species. Therefore the seven species identified as susceptible is not considered a sufficient taxonomic representation to list at the family level.

As a result, the Commission concluded that the criteria in Article 1.5.9. should not be applied to any of the genera or families of susceptible species for infection with *P. olseni*.

The Commission encouraged Members to refer to the *ad hoc* Group's December 2023 report available on the WOAH Website for details of the assessment conducted by the *ad hoc* Group.

Texts for comment

The revised Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *P. olseni*', are presented as Annex 18 for comments.

6.10. Articles 11.7.1. and 11.7.2. of Chapter 11.7. 'Infection with *Xenohaliotis californiensis*'

Background

The *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases met in June 2024 to continue its work to apply the criteria in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'. The *ad hoc* Group conducted the assessments for susceptibility of mollusc species to infection with *Xenohaliotis californiensis*.

September 2024 Meeting

The Aquatic Animals Commission considered the *ad hoc* Group report on Susceptibility of Mollusc Species to Infection with *X. californiensis* and commended its members for their comprehensive work.

The Commission agreed to amend the list of susceptible species in Article 11.7.2. of Chapter 11.7. 'Infection with *X. californiensis*' in line with the recommendations of the *ad hoc* Group, i.e.

- Six species currently listed in Article 11.7.2. as susceptible to infection with *X. californiensis*, black abalone (*Haliotis cracherodii*), green abalone (*Haliotis fulgens*), red abalone (*Haliotis rufescens*), tuberculate abalone (*Haliotis tuberculata*) and white abalone (*Haliotis sorenseni*) were assessed to meet the criteria for listing as susceptible to infection with *X. californiensis*, and are therefore proposed to remain in Article 11.7.2.

- Four new susceptible species, Japanese abalone (*Haliotis discus discus*), small abalone (*Haliotis diversicolor*), pinto abalone (*Haliotis kamtschatkana*) and hybrid red and Japanese abalone (*Haliotis rufescens* X *Haliotis discus hannai* hybrid) were assessed to meet the criteria for listing as susceptible to infection with *X. californiensis* and are therefore proposed to be added to Article 11.7.2.

- One species currently included in Article 11.7.2. as susceptible to infection with *X. californiensis*, *Haliotis discus hannai* was assessed to not meet the criteria for listing as susceptible to infection with *X. californiensis*. Flat abalone (*Haliotis walallensis*), which is also currently listed in Article 11.7.2. was not assessed due to a lack of publications related to this species. Both of these species are therefore proposed to be removed from Article 11.7.2.

Relevant sections of Chapter 2.4.7. 'Infection with *X. californiensis*' in the *Aquatic Manual* were also amended in line with the recommendations of the *ad hoc* Group (see Item 8.3.4.).

The Commission encouraged Members to refer to the *ad hoc* Group's June 2024 report available on the WOAH Website for details of the assessment conducted by the *ad hoc* Group.

The Commission also amended Article 11.7.1. to ensure consistency with the approach taken in other mollusc disease-specific chapters.

Texts for comment

The revised Articles 11.7.1. and 11.7.2. of Chapter 11.7. 'Infection with *X. californiensis*', are presented as Annex 19 for comment.

6.11. Emerging diseases

A standing agenda item for each meeting of the Aquatic Animals Commission is to review scientific information on emerging diseases to determine whether a disease should be considered as an emerging disease by Members or whether any other actions are warranted. The Commission also considered information from other sources such as Members, experts and Reference Centres.

The Commission reminded Members that 'emerging disease' is a defined term in the Glossary of the Aquatic Code and that should the Commission determine that a disease meets the WOAH definition for an emerging disease then Members should report it in accordance with Article 1.1.4 of the Aquatic Code.

The Commission reiterated that the purpose of identifying and reporting emerging diseases is to:

- bring global attention to the disease,
- disseminate information regarding the disease,
- determine the importance of the disease in terms of impact to aquaculture production and trade,
- prevent spreading within countries and regions and
- be proactive to avoid global spread.

The Commission also encouraged Members to investigate mortality and morbidity events linked to any emerging disease, emphasising that a better understanding of the pathogenic agent is essential for efforts to control its possible spread. The Commission also highlighted the role that WOAH collaborating centres could play in enhancing the understanding of emerging diseases.

The Commission also encouraged Members to provide information to the Commission on their experiences with emerging diseases and impacts, in particular the impact of these diseases to aquaculture production and trade so that the Commission can consider this information when reviewing emerging diseases.

6.11.1. Infection with covert mortality nodavirus (CMNV)

Background

At its September 2022 meeting, the Aquatic Animals Commission considered scientific information available on infection with covert mortality nodavirus (CMNV) and agreed that infection with CMNV meets the definition of an emerging disease and should be reported to WOAH in accordance with Article 1.1.4. of the *Aquatic Code*.

At its February 2023 and September 2023 meetings, the Commission reviewed scientific information and agreed that infection with CMNV continued to meet the definition of an 'emerging disease' and should therefore be reported to WOAH in accordance with Article 1.1.4. of the *Aquatic*

Code. The Commission encouraged Members to investigate mortality and morbidity events in the range of aquatic animal species affected.

Previous Commission reports where this item was discussed

September 2022 report (Item 6.2.2., page 13); February 2023 report (Item 9.1.2., page 26); September 2023 report (Item 7.1.1., page 19).

September 2024 meeting

The Aquatic Animals Commission noted that there have been no notifications of infection with CMNV in WAHIS by Members since the Commission considered it an emerging disease in September 2022. The Commission reiterated that new detections of infection with CMNV should be reported to WOAH as an emerging disease, in accordance with Article 1.1.4. of the *Aquatic Code*.

The Commission requested Members share information with WOAH regarding the impact of infection with CMNV on their aquaculture production to determine the impact of this disease globally, as well as any other relevant information. In the absence of additional information the Commission may consider that the definition of an emerging disease is no longer met and that infection with CMNV should no longer be considered as an emerging disease.

The Commission wished to inform Members that a technical disease card for infection with CMNV is available on the WOAH website at: https://www.woah.org/en/document/infection-with-covert-mortality-nodavirus-cmnv_technical-disease-card/.

6.11.2. Infection with Enterocytozoon hepatopenaei (EHP)

Background

At its September 2021 meeting, the Aquatic Animals Commission considered scientific information available on infection with *Enterocytozoon hepatopenaei* (EHP) and agreed that infection with EHP meets the definition of an emerging disease and should be reported to WOAH in accordance with Article 1.1.4. of the *Aquatic Code*.

At its February 2022 and September 2023 meetings, the Commission reviewed scientific information and agreed that infection with EHP continues to meet the definition of an 'emerging disease' and should therefore be reported to WOAH in accordance with Article 1.1.4. of the *Aquatic Code*. The Commission encouraged Members to investigate mortality and morbidity events in the range of aquatic animal species affected.

Previous Commission reports where this item was discussed

September 2021 report (Item 5.2.1.2., page 28); February 2022 report Part B (Item 2.2.1.2., page 8); September 2023 report (Item 7.1.2., page 20).

September 2024 meeting

The Aquatic Animals Commission noted that there have been no notifications of infection with EHP in WAHIS by Members since the Commission considered it an emerging disease in September 2021. The Commission reiterated that new detections of infection with EHP should be reported to WOAH as an emerging disease, in accordance with Article 1.1.4. of the *Aquatic Code*.

The Commission requested Members share information regarding the impact of EHP on their shrimp production to determine the impact of this disease globally, as well as any other relevant information. In the absence of additional information the Commission may consider that the

definition of an emerging disease is no longer met and that infection with EHP should no longer be considered as an emerging disease.

The Commission reviewed new scientific evidence for infection with EHP and updated the technical disease card accordingly.

The Commission wished to inform Members that a technical disease card for EHP is available on the WOAH website at: https://www.woah.org/en/document/infection-with-enterocytozoon-hepatopenaei/.

7. *Aquatic Code* Items for Member Information

7.1. *Aquatic Code* Ongoing work items

7.1.1. Chapter 4.2. 'Zoning and compartmentalisation'

September 2024

The Aquatic Animals Commission agreed that Chapter 4.2. 'Zoning and compartmentalisation' will be revised following the revision of Chapter 4.3. 'Application of compartmentalisation'.

7.1.2. Chapter 4.3. 'Application of compartmentalisation'

Background

At its September 2023 meeting, the Aquatic Animals Commission agreed to develop a discussion paper to engage Members on issues relevant to the revision of Chapter 4.3. 'Application of compartmentalisation'. The Commission highlighted that compartmentalisation provides an opportunity to trade disease-free aquatic animal commodities from zones or countries that are not declared free from the diseases of concern.

The discussion paper was informed by Member responses to a short questionnaire provided in the Commission's September 2022 meeting report, as well as feedback from Focal Point workshops. The paper proposed a range of purposes for applying compartments, high-level principles to guide their application and the concept of dependent and independent compartments. Together these proposals were intended to increase clarity on the application of compartments for effective risk management, while also broadening the range of circumstances where they might be applied.

At its February 2024 meeting, the Commission considered comments and responses received and noted that responses were generally supportive of the proposed approach to the revision of Chapter 4.3. The Commission proposed preferred approaches to the drafting of the revised Chapter 4.3. and circulated these in the final version of the discussion paper.

Previous Commission reports where this item was discussed

September 2023 report (Item 6.5., page 11); February 2024 (Item 8.1., page 41).

September 2024 meeting

The Aquatic Animals Commission agreed to use the final version of the discussion paper circulated in the February 2024 report to guide the revision of Chapter 4.3. 'Application of compartmentalisation'. The drafting of the revised chapter is underway and will be ready for the Commission's consideration at its next meeting. The revised chapter will be circulated for comments in the February 2025 meeting report.

7.1.3. Chapter 4.7. 'Fallowing in aquaculture'

September 2024 meeting

The Aquatic Animals Commission noted that Chapter 4.7. 'Fallowing in aquaculture', required a review following the drafting of draft new Chapters 4.X. 'Emergency disease preparedness' and 4.Y. 'Disease outbreak management'. The Commission agreed to review Chapter 4.7. for its consideration at its February 2025 meeting.

7.1.4. Revision of chapters on certification procedures (Chapters 5.2. and 5.11.)

Background

In September 2022, the Secretariat updated the Aquatic Animals Commission on the activities that WOAH had recently implemented to gain a better understating of e-certification practices implemented by Members, including the completion of a WTO Standards and Trade Development Facility project on electronic veterinary certification. The Secretariat also informed the Commission of the relevant work of other international organisations on e-certification and Single Window. They noted that the implementation of e-certification for aquatic animals and aquatic animal products was still limited, while the use of electronic phytosanitary certificates was well-established in many countries. The Secretariat reported that in 2021 Codex adopted revised 'Guidelines for design, production, issuance and use of generic official certificates (CXG 38-2011)', specifically related to transitioning to paperless certification.

The Secretariat proposed that the Aquatic Animals Commission together with the Terrestrial Animal Health Standards Commission include joint work to revise relevant standards in the *Aquatic Code* and *Terrestrial Code* to ensure alignment of standards for e-certification between Codex and WOAH. The Aquatic Animals Commission agreed to revise Chapter 5.2. 'Certification procedures', of the *Aquatic Code* to address e-certification in more detail and where relevant to align with the Codex Guidelines. The Commission was informed that WOAH would also develop reference data models for the WOAH model certificates for international trade in live aquatic animals and aquatic animal products. These model certificates will align with reference data models for food products that are included in the Codex Guidelines. The Commission agreed to include the revision of Chapter 5.2. in its work programme, and to undertake this work in collaboration with the Terrestrial Animal Health Standards Commission, to address jointly the corresponding Chapter 5.2. in the *Terrestrial Code*.

In June 2024, the Secretariat convened an expert consultation group on data models and data standards to create data models and standards for the model health certificates in the *Terrestrial Code* and the *Aquatic Code*, as well as a guidance document on how to use these standards. Completion of this work is anticipated in November 2024.

September 2024 meeting

The Secretariat updated the Aquatic Animals Commission on progress relating to the creation of WOAH data models and data standards for electronic certificates to meet the criteria currently included in Chapter 5.10. 'Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin' of the *Terrestrial Code* and Chapter 5.11. 'Model health certificates for international trade in live aquatic animals and aquatic animal products' of the *Aquatic Code*. WOAH has convened an expert group on data models and standards and their work should be complete by the end of 2024.

The Commission reviewed the draft Terms of Reference for an *ad hoc* Group to update relevant chapters of the *Terrestrial* and *Aquatic Codes* regarding certification procedures. The Commission clarified that the *ad hoc* Group should be convened to update Chapter 5.1. 'General obligations related to certification' and Chapter 5.2. 'Certification procedures' of both *Terrestrial* and *Aquatic Codes*, as appropriate, to incorporate electronic certification, including references to the newly

developed electronic data models and standards. The *ad hoc* Group should also consider the Codex 'Guidelines for design, production, issuance and use of generic official certificates' (CXG 38-2001) and update the *Codes* for consistency, as appropriate. The Commission also requested that the *ad hoc* Group review model health certificates for both *Codes* to determine if updates need to be made to those documents. The *ad hoc* Group should also review existing Glossary definitions of both *Codes* and propose revisions or new definitions, if relevant. The Commission proposed modifications to the draft Terms of Reference to reflect these priorities.

The Commission requested the Secretariat to report back on progress at its next meeting.

7.1.5. Section 7 'Welfare of farmed fish'

September 2024

The Aquatic Animals Commission were updated on Activity 1.3. 'Review the scientific basis of existing animal welfare standards' of the WOAH Aquatic Animal Health Strategy. The Commission agreed that a review of the scientific basis for welfare of farmed fish should be completed to ensure that the recommendations in the *Aquatic Code* are scientifically sound and meet the needs of Members. The review is to be completed by a provider identified through a procurement process. When this process is complete and the review of the scientific basis received, the Commission will utilise this information to inform a revision of Section 7 'Welfare of farmed fish'.

7.1.6. Assessments of susceptible species

Diseases of crustaceans

The Commission was informed that the *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases is planning to meet in early 2025 to progress its work assessing species susceptible to infection with *Aphanomyces astaci* (crayfish plague).

Diseases of amphibians

The Commission was informed that the selection of members for the *ad hoc* Group on Susceptibility of Amphibian Species to Infection with WOAH Listed Diseases is ongoing and the *ad hoc* Group's first meeting is planned for 2025. This *ad hoc* Group will assess susceptible species to all three amphibian listed diseases.

7.2. *Aquatic Code* New work items

7.2.1. Chapter 6.2. 'Principles for responsible and prudent use of antimicrobial agents in aquatic animals'

Background

The AMR Working Group (AMRWG) conducted the revision of Chapter 6.10 'Responsible and prudent use of antimicrobial agents in veterinary medicine' of the *Terrestrial Code* and the revised Chapter 6.10., was adopted at the 91st General Session in May 2024 to include the expansion of the environmental sector component and the inclusion of non-food producing animals (i.e. companion and leisure animals) considering a One Health approach.

At its February 2024 meeting, the AMRWG concluded that there was a need to revise chapters on the responsible use of antimicrobials in aquatic animals in the *Aquatic Code*.

September 2024 meeting

The Aquatics Animal Commission agreed that Chapter 6.2. 'Principles for responsible and prudent use of antimicrobial agents in aquatic animals' of the *Aquatic Code* no longer aligned with the newly

adopted Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine' of the *Terrestrial Code*. The Commission concluded that a revision of the chapters on the responsible use of antimicrobials in aquatic animals within the *Aquatic Code* should be added to the Commission's work programme.

The Commission requested that WOAH in collaboration with Reference Centre experts conduct a gap analysis between the newly adopted Chapter 6.10. of the *Terrestrial Code* and the chapters in Section 6 of the *Aquatic Code* to inform the revision of relevant chapters of the *Aquatic Code*.

The Commission requested the Secretariat to report back at its next meeting.

The WOAH Manual of Diagnostic Tests for Aquatic Animals

The Aquatic Animals Commission has commenced the process of progressively reformatting the disease-specific chapters of the *Aquatic Manual* into a new template. As the reformatted and updated chapters have substantial changes, at its meeting in September 2019, the Commission agreed that only clean versions of the revised chapters would be provided in its report. Subsequent changes made to these initial revisions following Member comments would be indicated in the usual style (i.e. ~~strikethrough for deletions~~ and double underline for additions).

A software-generated document that compares the adopted version of a chapter and the proposed new text can be created. This comparison document is not included in the Commission's report, but will be available upon request from the Secretariat of the Aquatic Animals Commission (AAC.Secretariat@WOAH.org).

8. *Aquatic Manual* Items for Member comments

8.1. Section 2.2. 'Diseases of crustaceans'

8.1.1. Sections 2.2.1. and 2.2.2. of Chapter 2.2.8. 'Infection with white spot syndrome virus'

Background

The *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases met in November 2023 to continue its work to apply the criteria in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'. At this meeting the *ad hoc* Group conducted the assessments for susceptibility of crustacean species to infection with white spot syndrome virus (WSSV). This assessment is an update of a previous assessment completed in 2016.

At its February 2024 meeting, the Aquatic Animals Commission considered the *ad hoc* Group report on Susceptibility of Crustacean Species to Infection with WSSV. The Commission agreed to apply Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' and to amend the list of susceptible species in Section 2.2.1. in line with the recommendations of the *ad hoc* Group. The Commission applied this to the list of species found to be susceptible to infection with WSSV and determined that Penaeidae and Portunidae should be listed at the family level and that *Procambarus*, *Palaemon* and *Panulirus* should be listed at the genus level.

The amended Sections 2.2.1. and 2.2.2. of Chapter 2.2.8. have been circulated once for comment.

Previous Commission reports where this item was discussed

February 2024 (Item 10.1.1., page 54).

September 2024 meeting

Comments were received from Canada, China (People's Rep. of), Chinese Taipei, Norway, Thailand and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the proposed amendments. The Commission re-assessed the application of Article 1.5.9. to the list of susceptible species in Section 2.2.1. as described in Item 6.5.2.

The Commission's responses to comments received are presented in Annex 3.

In response to a comment received that suggested there is evidence to list Oriental river prawn (*Macrobrachium nipponense*) as a susceptible species, the Commission requested that the *ad hoc* Group review its assessments for this species. Following this revised assessment, the Commission agreed to add Oriental river prawn to Article 9.9.2. of Chapter 9.9. 'Infection with WSSV' of the *Aquatic Code* and Section 2.2.1. of Chapter 2.2.8. 'Infection with WSSV' of the *Aquatic Manual*, and to remove this species from Section 2.2.2. 'Species with incomplete evidence for susceptibility' of Chapter 2.2.8. 'Infection with WSSV' in the *Aquatic Manual* (see Item 6.5.2.).

Texts for comment

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.2.8. 'Infection with white spot syndrome virus', are presented as Annex 20 for comments.

8.2. Section 2.3. 'Diseases of fish'

8.2.1. Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)'

Background

The *ad hoc* Group on Susceptibility of Fish Species to Infection with WOAH Listed Diseases met virtually during January and April 2024 to continue its work to apply the criteria in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'. The *ad hoc* Group conducted the assessments for susceptibility of fish species to infection with *Aphanomyces invadans* (epizootic ulcerative syndrome).

September 2024 meeting

The Aquatic Animals Commission amended Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)', in line with the recommendations of the *ad hoc* Group on Susceptibility of Fish Species to Infection with WOAH Listed Diseases (see Item 6.6.). The Commission applied Article 1.5.9. to the list of susceptible species in Section 2.2.1. as described in item 6.6.

Texts for comment

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *A. invadans* (epizootic ulcerative syndrome)' are presented as Annex 21 for comments.

8.3. Section 2.4. 'Diseases of molluscs'

8.3.1. Chapter 2.4.2. 'Infection with *Bonamia exitiosa*'

September 2024 meeting

The Aquatic Animals Commission reviewed Chapter 2.4.2. 'Infection with *Bonamia exitiosa*', which had been updated by the WOAH Reference Laboratory expert and reformatted using the new disease-specific chapter template.

The main amendments include:

Section/paragraph	Change
1. Scope	Amended the scope to align with the *Aquatic Code*. Moved most of the text to Section 2.1.1. 'Aetiological agent'.
Table 4.1.	Completed Table 4.1. and aligned with the case definitions in Section 6.
4.4. 'Nucleic acid amplification'	Completed the tables of PCR primer and probe sequences and cycling parameters and removed the details of the PCR methods.
6. 'Corroborative diagnostic criteria'	Revised definitions of suspect and confirmed case in apparently healthy and clinically affected animals.
6.3.1. 'For presumptive diagnosis of clinically affected animals' and 6.3.2. 'For surveillance of apparently healthy animals'	Completed the tables in these two sections.
7. References	Updated the references.

Texts for comment

The revised Chapter 2.4.2. 'Infection with *Bonamia exitiosa'*, is presented as Annex 22 for comments.

8.3.2. Chapter 2.4.3. 'Infection with *Bonamia ostreae*'

September 2024 meeting

The Aquatic Animals Commission reviewed Chapter 2.4.3. 'Infection with *Bonamia ostreae*', which had been updated by the WOAH Reference Laboratory expert and reformatted using the new disease-specific chapter template.

The main amendments include:

Section/paragraph	Change
1. Scope	Amended the scope to align with the *Aquatic Code*. Moved most of the text to Section 2.1.1. 'Aetiological agent'.
Table 4.1.	Completed Table 4.1. and aligned with the case definitions in Section 6.
4.4. 'Nucleic acid amplification'	Completed the tables of PCR primer and probe sequences and cycling parameters and removed the details of the PCR methods.
6. 'Corroborative diagnostic criteria'	Revised definitions of suspect and confirmed case in apparently healthy and clinically affected animals.
6.3.1. 'For presumptive diagnosis of clinically affected animals' and 6.3.2. 'For surveillance of apparently healthy animals'	Completed the tables in these two sections.
7. References	Updated the references.

Texts for comment

The revised Chapter 2.4.3. 'Infection with *Bonamia ostreae'*, is presented as Annex 23 for comments.

8.3.3. Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *Perkinsus olseni*'

Background

At its February 2024 meeting, the Aquatic Animals Commission amended Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *P. olseni*' in line with the recommendations from the *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases.

Previous Commission reports where this item was discussed

February 2024 (Item 10.2.1., page 55).

September 2024 meeting

Comments were received from Canada, China (People's Rep. of), Chinese Taipei, Norway and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the proposed amendments.

The Commission's responses to comments received are presented in Annex 3.

Texts for comment

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *Perkinsus olseni*', are presented as Annex 24 for comments.

8.3.4. Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*'

Background

The *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases met in June 2024 to continue its work to apply the criteria in Chapter 1.5. 'Criteria for listing as susceptible to infection with a specific pathogen'. The *Ad hoc* Group conducted the assessments for susceptibility of mollusc species to infection with *Xenohaliotis californiensis*.

September 2024 meeting

The Aquatic Animals Commission amended Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *X. californiensis*' in line with recommendations of the *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases (see Item 6.10.).

Texts for comment

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*', are presented as Annex 25 for comments.

9. *Aquatic Manual* Items for Member information

9.1. *Aquatic Manual* New work items

9.1.1. Chapter 2.2.5. 'Infection with infectious hypodermal and haematopoietic necrosis virus'

September 2024

A Member requested the Aquatic Animals Commission provide guidance on an issue with the specificity of the molecular methods given in Chapter 2.2.5. 'Infection with infectious hypodermal and haematopoietic necrosis virus (IHHNV)'. The lack of specificity can make it difficult to clearly differentiate between IHHNV genetic sequences and endogenous viral elements (EVEs) within the genome of *P. monodon* and *P. vannamei* shrimp. The Aquatic Animals Commission consulted the two WOAH Reference Laboratory experts for IHHNV and requested that they work together to provide a recommendation on how to address this issue. The Commission will review the proposal at the next meeting in February 2025.

9.1.2. Draft new Chapter 2.3.Y. 'Infection with *Megalocytivirus pagrus 1*'

Background

Following the listing change of 'infection with red sea bream iridovirus' to 'infection with *Megalocytivirus pagrus 1'* at the 91st General Session in May 2024, a new disease-specific chapter for the *Aquatic Manual* needs to be developed to reflect this change.

September 2024 meeting

Following the adoption of *Megalocytivirus pagrus* 1 as a WOAH listed disease of aquatic animals, the *Aquatic Manual* chapter needs to be updated to include validated diagnostic methods that are inclusive for viruses within all three genogroups: red sea bream iridovirus (RSIV), infectious spleen and kidney necrosis virus (ISKNV) and turbot reddish body iridovirus (TRBIV). To advance this task, the Aquatic Animals Commission proposed convening an electronic *ad hoc* Group charged with evaluating diagnostic methods for inclusion in the *Aquatic Manual* chapter.

After consulting with Reference Laboratory experts, the following approach was recommended: 1) review of the available literature on detection methods for *Megalocytivirus pagrus* 1 and establishing an initial short-list of the most appropriate methods of detection of all three genogroups; 2) use of this information to develop a technical disease card to provide preliminary guidance on diagnostic methods for Members (for February 2025 meeting); 3) evaluation of the short-listed assays through an inter-laboratory comparison test to determine their performance and inclusivity; 4) preparation of an *Aquatic Manual* chapter (for circulation to Members in the Commission's September 2025 report).

The Commission approved the Terms of Reference and proposed membership of the *ad hoc* Group.

10. Reference centres or change of experts

10.1. Evaluation of applications for Reference Centres for aquatic animal health issues or change of experts

The Aquatic Animals Commission recommended acceptance of the following application for WOAH Reference Centre status:

WOAH *Reference Laboratory for Infection with decapod iridescent virus 1*
Division of Maricultural Organism Disease control and Molecular Pathology Yellow Sea Fisheries

Research Institute (YSFRI), Chinese Academy of Fishery Sciences, CHINA (PEOPLE'S REP. OF)
Tel: (+86.532) 8582-3062 ext 802
E-mail: qiuliang@ysfri.ac.cn
Website: http://www.ysfri.ac.cn/jgsz/kyxt/yzswjbkzyfzblxyjs.htm
Designated expert: Dr Liang Qiu

10.2. Assessment of Reference Centres Annual Reports

The Aquatic Animals Commission reviewed the performance of the aquatic WOAH Reference Centres (all 37 Reference Laboratories and all four Collaborating Centres) by an in-depth analysis of the annual reports of activities in 2023 to ensure that each Reference Centre is fulfilling the Terms of Reference (ToRs) to the benefit of WOAH Members and performance criterion iii) of the Procedures for Designation of WOAH Reference Laboratories (https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3) and Collaborating Centres (https://www.woah.org/en/what-we-offer/expertise-network/collaborating-centres/#ui-id-3).

The Commission acknowledged the high level of performance demonstrated by the Reference Centre network, particularly their contributions to the *Aquatic Manual* and *Aquatic Code* and their participation in various *ad hoc* Groups. These efforts are highly valued by WOAH and its Members. The Commission also recognised the diverse challenges faced by some Reference Centres, noting that national circumstances can impact their ability to fully meet all the terms of reference (ToR). The Commission remains committed to supporting the work of these Centres while recognising the importance of ongoing collaboration within the network.

The Commission identified seven Reference Laboratories that were not fully complying with key ToR, primarily due to a stronger focus on national activities and challenges related to bio risk management systems. The Reference Laboratories concerned would be informed of the outcome of the review and asked to provide an explanation of their situation and possible reasons for the lack of adherence to the ToR. To support improvement, the Commission recommends that these Reference Laboratories review and implement the guidelines outlined in Chapter 1.1.4 of the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* to enhance their compliance.

The Commission encourages greater engagement from Reference Centres with WOAH Standards and promotes proactive involvement from the network in providing support and expertise to WOAH Members. For certain listed diseases, there is more than one designated WOAH Reference Laboratory, and the Commission encourages increased collaboration between these laboratories. The discussion also addressed the recently established network of aquatic Collaborating Centres, recognising their valuable contributions in recent months. The Commission emphasised the importance of sustaining and strengthening these efforts through regular and structured meetings to enhance coordination and impact.

Finally, the Commission expressed its appreciation to all aquatic WOAH Reference Centres for their timely submission of annual reports and their continued adherence to the ToRs. The Commission noted the significant contributions that had been made by Reference Centres and wished to thank designated experts for leading these valuable contributions to the WOAH mission. The Commission expressed its on-going appreciation for the enthusiastic support and expert advice given to the WOAH by the Reference Centres. In particular, the Commission is grateful for the ongoing support and essential contributions of Reference Laboratory experts for revision of the disease-specific chapters of the *Aquatic Manual.*

10.3. Update on the procedure to evaluate Centres at the end of their 5-year mandate

Collaborating Centres are designated for a period of 5 years, during which they are required to adhere to a 5-year workplan submitted at the start of their designation. A template was developed by the Biological Standards Commission for a Collaborating Centre self-assessment of their activities over the past 5 years in relation to the original 5-year work plan. This report should be submitted to the Commission to provide evidence of the Centre's impacts and achievements, as well as its contributions.

The Centres will be required to submit both their regular annual reports and the 5-year self-assessment. Both documents will be evaluated by the Commission.

Those Collaborating Centres for which the 5-year workplans will end in December 2024 were contacted by letter in August 2024, with the expectation that the self-assessment reports covering their 5-year workplans be submitted by November 2024. During the February meeting, the Aquatic Animals Commission will evaluate these reports (self-evaluations). Those Centres for which the annual and final reports are accepted will be notified that their designation is eligible for renewal, at which point they will be asked to submit a new 5-year workplan. Those Collaborating Centres for which the performance is deemed unsatisfactory will have a 6-month appeal period, after which their designation will be re-evaluated at the September Commission meeting. This last evaluation may result in their removal from the list of Collaborating Centres.

10.4. Update on increasing the visibility of the Collaborating Centres

During the Bureaus meeting in February 2024, the Aquatic Animals Commission and the Biological Standards Commission discussed strategies to enhance the visibility of Collaborating Centres. It was proposed that Centres be asked to submit three to five bullet points summarising the services they provide. These points will be included in each Centre's profile on the WOAH website under a link entitled "How can we help you?"

Centres concluding their 5-year work plan this year were requested to incorporate their bullet points into the template provided for the final report. Centres not completing their work plan in 2024 will be contacted separately to submit this information

10.5. Twinning projects

As of September 2024, 96 projects have been completed and 14 projects are underway. Three projects are pending funding identification before starting. Fourteen WOAH Reference Laboratories and four WOAH Collaborating Centres have been designated as a result of laboratory twinning projects.

The Aquatic Animals Commission reviewed a twinning project application between Italy and Saudi Arabia. The aim of the project is to improve the diagnosis of marine aquaculture diseases with a focus on emerging viral, bacterial and parasitic fish diseases. The Commission noted that the proposal had been improved since first version reviewed in February 2024. The Commission approved the project, and strongly encourages the project partners to prioritise activities because of the large number of pathogens and species included in the twinning project

The evaluation of WOAH Laboratory Twinning Programme is nearing its conclusion. In the scope of the evaluation, a workshop was held from 27 to 28 June 2024 at WOAH Headquarters to collect feedback from Programme stakeholders about the key themes emerging from the programme evaluation. The Commission will be informed of the findings at the February 2025 meeting. The main outputs of this process will be a new twinning guide, a post-project evaluation tool and the evaluation report.

11. Updates from WOAH Headquarters

11.1. WOAH *ad hoc* Group on emergency management

The Aquatic Animals Commission received an update on the work to develop standards for the *Terrestrial Code* on emergency management. The Commission was reminded that at the 89th General Session of the World Assembly of WOAH Delegates, Resolution No.28 was adopted following a Technical Item on emergency management, which recommended that WOAH ensures its International Standards further integrate emergency management. In June 2024 an *ad hoc* Group met to develop standards on emergency management for the *Terrestrial Code*, and a member of the Commission participated as an observer to ensure alignment, as relevant, given work on emergency preparedness and response under development for the *Aquatic Code*. The *ad hoc* Group recommended the

development of a chapter on emergency management for the *Terrestrial Code* and provided an outline for this potential chapter.

The Commission noted the progress on this work and requested that when developing the new chapter the Code Commission consider, as relevant, the draft new Chapters 4.X. 'Emergency disease preparedness' and 4.Y. 'Disease outbreak management' of the *Aquatic Code* which are circulated for comment as part of this report (refer to Item 6.1.).

The Commission requested that the Secretariat continue to report on the progress of this work.

11.2. Guidelines for monitoring antimicrobial usage in aquatic animals

The Aquatic Animals Commission was informed that an Electronic Expert Group under the Secretariat of the Antimicrobial Resistance and Veterinary Products Department, is working on the development of Guidelines for antimicrobial usage (AMU) monitoring in aquaculture at field level. These Guidelines are intended to offer methodologies on AMU monitoring, addressed specifically to aquaculture, to Members worldwide considering various capacity levels. The Guidelines have gone through a expert peer review and are expected to be published in the first quarter of 2025.

11.3. WOAH activities on substandard and falsified veterinary products

The Aquatic Animals Commission was updated about the main activities and plans of the WOAH Substandard and Falsified Veterinary Products Programme, which were developed following the outcomes of the second Global WOAH Conference on AMR in 2018.

This programme includes the development of a reporting system of falsified or substandard veterinary products in the animal sector which are illegally circulating within and between countries. The Commission was informed that while some Members are voluntarily reporting, others have suggested that more guidance should be provided within the WOAH standards. The Commission's opinion was sought on the relevance and pertinence to further develop standards on this topic, such as definitions for substandard and falsified veterinary products, as well as further clarifications on expectations around reporting and its modality. The Commission was informed that this topic would also be discussed with the other Specialist Commissions, in order to consider the best approach going forward.

The Commission highlighted that a significant issue in aquatic animal health is the lack of available veterinary products labelled for use in aquatic animals which may compound issues around substandard and falsified veterinary medical products. Further, the Commission stressed that before developing new standards, the scope and objective should be well defined.

The Aquatic Animals Commission highlighted the need to address this topic in coordination with the Biological Standards Commission and Terrestrial Animal Health Standards Commission and agreed to follow up the discussion with more concrete proposals at the next meeting in February 2025.

11.4. WOAH Standards Online Navigation Tool

The Aquatic Animals Commission was updated on the progress of the WOAH Standards Online Navigation Tool project, which is an innovative project aimed at providing users with streamlined access and navigation of WOAH standards.

The project will deliver two new user interfaces, on the WOAH website:

- Navigation and search tool; this interface will provide a guided navigation experience that will allow users to navigate through the WOAH International Standards.

- Recommendations for safe international trade, by commodity; this interface will enable users to easily visualise recommendations for safe international trade by commodity through a comprehensive filtering system for the *Aquatic Code* and *Terrestrial Code*, respectively.

The Commission was informed that the project was progressing well with most of the external features already completed, as well as the digitalisation of the content of four WOAH standards. The Commission was also informed that the project was at the final stages of the development of the 'internal' interface for the management of standards, which will enable WOAH staff to efficiently manage and update WOAH standards, following the adoption of new or revised text at the WOAH General Assembly.

The Commission praised the project team for progress of the project and reiterated its importance for Members.

11.5. WOAH Science System

The Aquatic Animals Commission reviewed the document 'The Science System of the World Organisation for Animal Health' which was shared for their information. The Commission noted that the document shows how research information flows from researchers to WOAH, where it is evaluated, and then how it is incorporated into policy changes, if applicable. The Commission appreciated the information regarding the role of Working Groups, Specialist Commissions, *ad hoc* Groups, Reference Laboratories and Collaborating Centres to ensure that WOAH is using the most relevant scientific information to inform policy decisions.

11.6. WAHIAD activities and WAHIS platform updates

The Aquatic Animals Commission appreciated the information provided on the key developments of the WAHIS platform for 2024, including the launch of the optimised six-monthly report and new annual report modules, as well as enhancements to WAHIS dashboards, mapping functionalities and the WAHIS Reference Tables. The Commission also noted the implementation of a new standardised approach for reporting and verifying disease cases, ensuring that diseases are reported as absent only if minimum control measures are in place.

11.7. Self-declaration of freedom from listed aquatic animal diseases

The Aquatic Animals Commission was briefed by the WOAH Status Department on the self-declarations published by WOAH on aquatic animal disease freedom and the interest of Members in publishing such dossiers. The Commission provided guidance on certain topics (i.e. level of biosecurity and shared water bodies, etc.) for WOAH to consider when revising self-declarations of aquatic animal health status. The Commission confirmed its interest to continue monitoring the publication of self-declarations and updating the procedures to ensure they remain aligned with the *Aquatic Code*.

11.8. WOAH Observatory

The Aquatic Animals Commission met with WOAH Observatory to discuss the potential for the Observatory to monitor the implementation and impact of the standards in the *Aquatic Code*. This discussion followed the new listing of 'infection with *Megalocytivirus pagrus 1*' at the 91st General Session in May 2024 where it was suggested by the Commission's President at the time that the Observatory could monitor its implementation. The Commission and the Observatory also discussed opportunities, potential risks and impacts on trade of the standards and listing a disease.

The Commission agreed to provide the Observatory with additional information on the areas within the standards that could be monitored through the Observatory and to continue this discussion at its February 2025 meeting.

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…/Annexes

Annex 1. Item 2. – Adopted Agenda

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

14 to 21 February 2024

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1. Meeting with the Director General and Deputy Director General
2. Adoption of the agenda
3. Cooperation with other specialist commissions
   - 3.1. Aquatic Animals Commission and Terrestrial Animal Health Standards Commission Bureaus meeting
4. Work programme of the Aquatic Animals Commission
   - 4.1. Proposed work
     - 4.1.1. Antimicrobial resistance
5. Aquatic Animal Health Strategy
   - 5.1. Status report on the implementation of the Aquatic Animal Health Strategy
6. *Aquatic Code*
   - 6.1. Items for Member comment
     - 6.1.1. Draft new Chapter 4.X. 'Emergency disease preparedness'
     - 6.1.2. Draft new Chapter 4.Y. Disease outbreak management
     - 6.1.3. Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'
       - 6.1.3.1. Model Article 10.X.10. for Chapter 10.5. 'infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection VHSV' and Article 10.4.15. for Chapter 10.4. 'Infection with ISAV'
       - 6.1.3.2. 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'
     - 6.1.4. Draft new Chapter 5.X. 'Movement of ornamental aquatic animals'
     - 6.1.5. Articles 5.1.2. and 5.1.4. of Chapter 5.1. 'General obligations related to certification'
     - 6.1.6. Default periods in Articles X.X.5. to X.X.7. for disease-specific chapters
     - 6.1.7. Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus'
     - 6.1.8. Article 10.2.2. of Chapter 10.2. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)'
     - 6.1.9. Chapter 10.8. 'Infection with *Megalocytivirus pagrus 1*'
     - 6.1.10. Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *Perkinsus olseni'*
     - 6.1.11. Articles 11.7.1. and 11.7.2. of Chapter 11.7. 'Infection with *Xenohaliotis Californiensis*'
   - 6.2. Items for consideration
     - 6.2.1. Chapter 4.3. Application of compartmentalisation
     - 6.2.2. Assessment of default periods in Articles X.X.5.-X.X.7. for disease-specific chapters
     - 6.2.3. Consideration of emerging diseases
       - 6.2.3.1. Covert mortality nodavirus (CMNV) in zebrafish
       - 6.2.3.2. Infection with *Enterocytozoon hepatopenaei*
       - 6.2.3.3. Other diseases

7. *Aquatic Manual*
   - 7.1. Items for Member comment
     - 7.1.1. Section 1.1. ‘Introductory chapters’
       - 7.1.1.1. Chapter 1.2. ‘Validation of diagnostic assays for infectious diseases of aquatic animals’
     - 7.1.2. Section 2.2. ‘Diseases of crustaceans’
       - 7.1.2.1. Section 2.2.1. and 2.2.2. of Chapter 2.2.8. ‘Infection with white spot syndrome virus’
     - 7.1.3. Section 2.3. ‘Diseases of fish’
       - 7.1.3.1. Section 2.2.1. and 2.2.2. of Chapter 2.3.1. ‘Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)’
       - 7.1.3.2. Chapter 2.3.9. ‘Infection with spring viraemia of carp virus’
       - 7.1.3.3. Draft new Chapter 2.3.X. ‘Infection with tilapia lake virus’
       - 7.1.3.4. Draft new Chapter 2.3.Y. ‘Infection with *Megalocytivirus pagrus 1*’
     - 7.1.4. Section 2.4. Diseases of molluscs
       - 7.1.4.1. Chapter 2.4.2. ‘Infection with *Bonamia exitosa*’
       - 7.1.4.2. Chapter 2.4.3. ‘Infection with *Bonamia ostreae*’
       - 7.1.4.3. Chapter 2.4.6. ‘Infection with *Perkinsus olseni*’
       - 7.1.4.4. Section 2.2.1. and 2.2.2. of Chapter 2.4.6. ‘Infection with *Perkinsus olseni’*
       - 7.1.4.5. Section 2.2.1. and 2.2.2. of Chapter 2.4.7. ‘Infection with *Xenohaliotis californiensis*’
   - 7.2. Items for consideration
8. *Ad hoc* groups
   - 8.1. Report of the a*d hoc G*roup on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases
   - 8.2. Report of the a*d hoc G*roup on Susceptibility of Fish species to Infection with WOAH Listed Diseases
   - 8.3. Report of the a*d hoc G*roup on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases
9. Reference centres or change of experts
   - 9.1. Evaluation of applications for Reference Centres for aquatic animal health issues or change of experts
   - 9.2. Assessment of Reference Centres Annual Reports
   - 9.3. Twinning projects
   - 9.4. Reference Centre Reporting System Evolution
10. Other issues
    - 10.1. For decision
      - 10.1.1. Review of aquatic self-declaration and the Aquatic Animals Commission’s role
      - 10.1.2. WOAH Observatory proposed case study for *Megalocytivirus pagrus 1*
    - 10.2. For discussion
      - 10.2.1. Communication on the work of the Aquatic Animals Commission
    - 10.3. For information
      - 10.3.1. Publication of Member comments, including Guidance for commenting
      - 10.3.2. Standards Online Navigation Tool update
      - 10.3.3. Monitoring antimicrobial usage in aquaculture paper update
      - 10.3.4. Substandard and falsified veterinary medical products
      - 10.3.5. *ad hoc Group* on emergency management

10.3.6. WOAH Science System

10.3.7. WAHIAD and WAHIS update

11. Meeting review
12. Next meeting: 12 – 19 February 2025

Annex 2. Item 2. – List of Participants

MEETING OF THE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

18 to 25 Septmeber 2024

MEMBERS OF THE COMMISSION

Dr Alicia Gallardo Lagno
(President)
Senior advisor Antimicrobial Stewardship in Aquaculture Centre,
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La Pintana,
CHILE

Dr Ingo Ernst
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Director Aquatic Pest and Health Policy,
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OTHER PARTICIPANTS

WOAH HEADQUARTERS

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Head of Department
Standards Department

Dr Mariana Delgado
Scientific Secretariat Officer
Science Department

Dr Kathleen Frisch
Scientific Coordinator for Aquatic Animal Health
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Dr Patricia Kelly
Scientific Coordinator for Aquatic Animal Health
Standards Department

Ms Sara Linnane
Senior Scientific Officer
International Standards
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Annex 3 (for information) – Aquatic Animals Commission's responses to comments considered

February 2024 Work Plan

General comments

Reference	Comment	Aquatic Animals Commission Response
General_1	**Category**: general The Member welcomes the opportunity to comment on revisions suggested for Annexes 40 to 49 and 60 to 61 in the WOAH Aquatic Animal Health Standards Commission (herein referred to as Aquatic Animals Commission) report February 2024 to be considered at the next meeting of the Aquatic Animals Commission, which will be held in September 2024. The Member would like to congratulate the Aquatic Animals Commission for their excellent work and commitment to the continuous improvement of the Aquatic Animal Health Standards.	Noted.
General_2	**Category:** general The Member supports the amendments made to the chapters presented for comments.	Noted.
General_3	**Category:** general The Member thanks the AAC for their continued work on these standards. Please find our comments and queries embedded in the annexes as requested.	Noted.
General_4	**Category:** general The Members would like to commend WOAH for its work and thank in particular the Aquatic Animals Commission for having taken into consideration EU comments on the Aquatic Code and the Aquatic Manual submitted previously. A number of general comments on this report of the February 2024 meeting of the Aquatic Animals Commission as well as the intended positions of the EU on the draft Aquatic Code and Manual chapters proposed for adoption at the 91st WOAH General Session are inserted in the text below, while specific comments are inserted in the text of the respective annexes to the report. The Members would like to stress once again its continued commitment to participate in the work of WOAH and to offer all technical support needed by the Aquatic Animals Commission and WOAH ad hoc groups for future work on the Aquatic Code and Manual.	Noted.

Comments on the work plan

Reference	Comment	Aquatic Animals Commission Response
Work.Plan_1	**Category:** general The Member appreciates the commitment of WOAH and the AAHSC to increasing transparency in the commenting process. The Member thanks the Specialist Commission Secretariats for the guidance provided to Members for submission of comments as it has assisted in formalising the internal commenting processes as well as submission of comments to WOAH. The Member is supportive of the transparency initiative and the step-wise approach to publication of comments and evolution of Commission reporting to support Members in tracking responses of the Commission to submitted comments. The Member would request additional information be provided to Members on the timing of implementation of the step wise approach for publication of Member comments.	Noted. The information regarding the timing of implementation of the step-wise approach for publication of comments is addressed in the September 2024 report.
Work.Plan_2	**Category:** general The Member would like to commend the Aquatic Animal Health Standards Commission for its work. The Member 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. The Member would particularly like to thank the Aquatic Animals Commission for continuing to engage the Member's 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.	Noted.
Work.Plan_3	**Category:** general The Members supports the work plan and priorities	Noted.
Work.Plan_4	**Comment submitted for February 2024 meeting** **Category:** general Aquatic Manual: Chapter 2.2.4. Infection with IHHNV The Member wishes to bring an issue to the awareness of the Commission that we have experienced when applying the standards for confirmation of a suspect case of IHHNV in apparently healthy populations of *P. vannamei*. The standards for molecular testing methods and amplicon sequencing (described in Section 4.4.1 and 4.4.2. of Chapter 2.2.4. Infection with IHHNV) are challenging for users to clearly differentiate between true infectious IHHNV genetic sequences and Endogenous Viral Elements (EVEs) in *P. monodon* and *P. vannamei* shrimp. When testing apparently healthy populations where disease prevalence and infection titres are expected to be very low, it is challenging to confirm a suspect case using the published case definition (as described in Section 6.1.2). We are outlining the challenges we have experienced for the AAC: Most of the PCR assays listed by WOAH in Section 4.4.1 and 4.4.2. of Chapter 2.2.4. have the potential to detect EVEs in *P. monodon*. There is one publicly reported genome of *P. vannamei* (LOC113800262). In-silico analyses, performed in the Member's national reference laboratories, show that most of the methods can detect known EVEs in the genome of *P. vannamei* also (see table below).	Item has been added to the Work Programme (see item 9.1.1. of the September 2024 report).

Assay included in Tables 4.4.1.1. and 4.4.2.1.	Comparison to *P. monodon* full genome (including EVEs)	Comparison to *P. vannamei* full genome (including EVEs)	Interpretation of genotyping using the assay, based on current knowledge and known EVEs
Tang & Lightner (2001), primers 1608F 1688R with probe	100% match *Penaeus monodon* uncharacterized LOC119575654*	100% match *Penaeus vannamei* uncharacterized LOC113800262	Sequences obtained with these primers would not help discriminate the EVEs in these two shrimp specimens by comparison to extant IHHNV
Tang et al (2007), 389F and 389R	99% match (384/389) Same LOCI as above	100% match Same LOCI as above	Sequences obtained with these primers would not help discriminate the EVEs in these two shrimp specimens by comparison to extant IHHNV
Nunan (2000), 77012F and 77353R	95% match *Penaeus monodon* uncharacterized LOC119575654	70% homology *Penaeus vannamei* uncharacterized LOC113820177	Genotyping would distinguish the EVEs found in the two shrimp genomes, from extant IHHNV
Tang et al (2000), 392F and 392R	91% match or less in the previous loci and known EVEs	98% but only over a short fragment of 138 bp	Genotyping would distinguish the EVEs found in the two genomes, from extant IHHNV, and primers would not be able to amplify the EVEs in the *P. vannamei* genome examined.

Tang et al (2007), 309F and 309R	99.6% match for the same loci as above	99% match in loci 113800262, but missing the 3'end region.	Genotyping would distinguish the EVEs found in the two genomes but with very few differences, compared to extant IHHNV, and primers would not be able to amplify the EVEs in the *P. vannamei* genome examined.	

(2) The Aquatic Manual Chapter 2.2.4. recommends confirmation by a method that does not detect EVEs (typically another PCR for testing of apparently healthy populations), followed by sequence comparisons to distinguish between EVEs and infectious IHHNV. However, most of the PCRs to be used in confirmation step also have potential to detect EVEs, which does not increase the necessary confidence in test results.

(3) There is continuous risk on specificity of PCR/real-time PCR assays, given that EVEs differ in animal populations and EVEs sequences are likely to change overtime in various shrimp populations. This also makes sequence comparisons difficult, which is recommended in the Aquatic Manual, to distinguish between sequences of EVEs and that of true infectious IHHNV.

(4) When testing apparently healthy populations with low prevalence and infection titres, there is additional challenge that results from various PCRs do not always match due to differing sensitivities of these assays.

As this is new information and important for Members to be aware of when performing diagnostic testing for IHHNV, the Member is requesting that the Commission:

Modify the footnote associated with Tables 4.4.1.1. and 4.4.2.1. to:

*NOTE – these methods will amplify EVEs within the genome of P. monodon and P.vannamei. Positive results in this species must be confirmed by a method that does not react with IHHNV EVEs

2) Consider including additional guidance on which follow up PCR assays and how many different assays should be performed to confidently rule out that detected sequences are not EVEs.

3) Provide clarity on sequence comparisons, what is the percentage of similarity/differences (cut-off values) to distinguish between sequences of EVEs and true infectious IHHNV, given that there is variability in these sequences and sequences are likely to evolve in future.

The Member has noted that development of test methods that ensure active infection is detected, as opposed to presence of non-infectious genetic material, especially for testing of apparently healthy populations for which other available assays are not fit for purpose, would be

	beneficial for inclusion within the Aquatic Manual. However we recognise that currently this is a research gap that will hopefully be addressed in the future.	

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)
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	–

Aquatic Code			
Chapter/Subject	**Status**		
	February 2024	**May GS 2024**	**September 2024**
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
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
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)

Aquatic Manual			
Chapter/Subject	**Status**		
	February 2024	**May GS 2024**	**September 2024**
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)

Draft new Chapter 4.X. 'Emergency disease preparedness'

Reference	Comment	Aquatic Animals Commission Response
4.X._1	**Category**: general The Member acknowledges the ad hoc group's hard work for drafting this entire new chapter. However, early articles of the chapter, Articles 4.X.1 to 3. Purpose, Scope and Introduction 4.X.3. appear to contain repetitive information. Some text in the Introduction article describes the scope of this chapter. Some background text under introduction is not essential for guiding member countries to develop the framework for emergency disease preparedness. As substantial editing of these three articles to make the text more succinct may be beneficial, the Member has provided suggested editing to these three articles under specific comments.	Noted, the editorial suggestions for Articles 4.X.1. to 4.X.3. to improve readability have been taken into account where possible.
4.X_2	**Category**: general The Member supports the proposed chapter and has inserted some comments within the chapter.	Noted
4.X_3	**Category:** general **Rationale:** The current draft only introduces the emergency disease preparedness at the national level, but does not cover the regional and compartment levels. It is suggested to add the specific requirements for the emergency disease preparedness at the regional and compartment levels to form a three-level emergency disease preparedness management system, so as to make the standard more targeted and operable.	The recommendations set out in the draft Chapter 4.X. can apply at the level of country, zone or compartment. When each Member draws up their own Emergency Disease Preparedness framework, they should take into account which level (or combination of levels) is important in their country. The essential elements that should apply at any of those levels are set out in the draft chapter and should be taken into account by the 'Competent Authority'.
4.X_4	**Category:** general **Rationale:** The Member supports the proposed changes to this Chapter.	Noted
4.X_5	**Category:** general Now that there are definitions for "Competent Authority" vs. "Veterinary Authority", we feel there may be areas of this chapter where the authority currently referenced is not in alignment with the glossary definitions as we understand them. Additionally, we do not see reference to the importance of developing case definitions for pathogens of concern prior to a disease outbreak. It is unclear if this information should be added to this section of Chapter 4.X. or if it will be addressed elsewhere in the chapter. If case definitions are not mentioned elsewhere, then we recommend adding them under Article 4.X.4. of this chapter.	In response to a similar comment concerning glossary definitions in the February 2024 report, the Commission highlighted that the 'Veterinary Authority' is a 'Competent Authority'. The definition of a 'Competent Authority' recognises that, in many countries, more than one governmental authority is responsible for implementing standards of the *Aquatic Code*. The term 'Competent Authority' is intended to apply to any governmental authority with some responsibility for the implementation of some WOAH standards. Depending on the administrative structures of a country, the Competent Authority may be a national or a regional governmental authority.

		The term 'Veterinary Authority' distinguishes the role of a single 'Competent Authority' that has responsibility for communicating with WOAH and an overarching responsibility for implementation of WOAH standards. The position of the Commission remains unchanged concerning these glossary definitions, and considers their use in Chapter 4.X. to be appropriate. Concerning the importance of developing case definitions for diseases of concern, this point has been taken into account with the addition of a new point 2 in Article 4.X.4.
4.X_6	**Category:** general The Members thank the Aquatic Animals Commission and in general supports this new chapter. However, the Members would like to reiterate comments that were not accepted before.	Noted

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.X.

EMERGENCY DISEASE PREPAREDNESS

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.1._1	**Category:** Revision **Proposed amended text:** 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. **Rationale:** The Member proposes that the addition of the text "and emerging" is unnecessary and does not need to be specified in this sentence. Reference to emerging diseases is included in the text	Agreed with removing the addition of 'emerging' in the first sentence because the following sentence adequately explains that important aquatic animal diseases include emerging diseases.

	of the sentence that follows which adequately explains emerging diseases are important.	
4.X.1._2	**Category**: deletion **Proposed amended text:** Décrire les éléments essentiels d'un cadre pour la préparation aux situations d'urgence sanitaire, qu'une *Autorité compétente* doit élaborer en accord avec les priorités et les ressources des pays afin de veiller à ce que les *foyers* de *maladies* importantes ~~et de *maladies émergentes*~~ des *animaux aquatiques* puissent être rapidement identifiés et gérés efficacement, et qui permettra de guider un pays, une *zone* ou un *compartiment* sur une voie appropriée conduisant au rétablissement." **Rationale:** Article 4.X.1. Dans le premier alinéa, il est précisé que ce chapitre concerne les foyers de maladies importantes et de maladies émergentes des animaux aquatiques. Cependant, dans le second alinéa, il est précisé qu'une maladie importante est une maladie listée au chapitre 1.3, ou une maladie émergente ou une autre maladie. Il semble donc inutile de parler de maladie émergente au premier alinéa.	Agreed, see response for comment 4.X.1._1.
4.X.1._3	**Category**: addition **Proposed amended text**: To describe the essential elements of an emergency disease preparedness framework which a *Competent Authority* *and/or Veterinary 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. **Rationale:** It is unclear if the responsible authority should be the *Competent Authority*, the *Veterinary Authority,* or both. We recommend including either both or just the "Veterinary Authority" for this activity.	Did not agree, see response for comment 4.X._5.

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*.

Reference	Comment	Aquatic Animals Commission Response
4.X.1._4	**Category**: editorial **Proposed amended text**: An important *aquatic animal disease* is one which has been identified by the *Competent Authority* to be subject to emergency disease preparedness measures 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*. **Rationale:** Editorial to make it clear that the disease(s) are identified for emergency preparedness purposes.	Agreed with the addition to make it clear that an important disease in this context is one that has been identified for emergency preparedness purposes.
4.X.1._5	**Category**: change **Proposed amended text**: An important *aquatic animal disease* is one which has been identified by the ~~*Competent Authority*~~ *Veterinary Authority* in accordance with Article 4.X.6. Such *diseases* may be listed in	Did not agree, see response for comment 4.X._5.

	Chapter 1.3., or they may be *emerging diseases* or other *aquatic animal diseases.* **Rationale:** It is unclear if the responsible authority should be the *Competent Authority*, the *Veterinary Authority*, or both. We recommend "Veterinary Authority" for this activity.	

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.2._1	**Category**: editorial **Proposed amended text**: ~~This chapter describes recommendations for the development of an emergency disease preparedness framework.~~ This recommended framework encompasses all the elements that will enable the Competent Authority to activate an efficient response to a disease outbreak, ~~thereby minimising~~ to minimise the impact on aquatic animal populations, trade, the economy and the financial resources that are required to manage the disease outbreak~~s~~. The specific actions which are necessary to operationalise the framework in the event of a disease outbreak are described in Chapter 4.Y. **Rationale:** Editorial. Repetitive.	Editorial changes were made to the text which reflect the proposal to improve clarity.
4.X.2._2	**Category**: change **Proposed amended text**: 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*~~ *Veterinary Authority* to activate an efficient response to a *disease outbreak*, …	Did not agree, see response for comment 4.X._5.

Article 4.X.3.

Introduction

Aquatic animal diseases 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.

Reference	Comment	Aquatic Animals Commission Response

4.X.3._1	**Category**: editorial **Proposed amended text**: ~~*Aquatic animal diseases* 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 aquatic animal disease ~~those~~ emergencies. **Rationale:** Editorial. Known context and unessential text.	Agreed with removing the first sentence because it is unnecessary text as the context of spread of aquatic animal diseases is known.

When developing the framework, it is of fundamental importance to ensure that the *aquatic animal diseases* 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 *diseases* that is developed after conducting a *risk analysis* as described in 4.X.6., may include *aquatic animal diseases* which are listed in Chapter 1.3., as well as other *diseases* which have been identified as being of importance to the country, *zone* or *compartment*.

Reference	Comment	Aquatic Animals Commission Response
4.X.3._2	**Category**: editorial **Proposed amended text**: When developing the framework, it is of fundamental importance to ensure that important diseases that are subject to emergency preparedness measures ~~the aquatic animal diseases 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 diseases that is developed after conducting a risk analysis as described in 4.X.6., may include aquatic animal diseases which are listed in Chapter 1.3., as well as other diseases which have been identified as being of importance to the country, zone or compartment.~~ **Rationale:** The definition, "diseases subject to emergency measures" should be used. The original text "important to a country, zone or compartment" is confusing. The second sentence is repetitive, it has already mentioned at the purpose article. The second sentence is repetitive and suggest deletion.	Did not agree to text on diseases subject to emergency preparedness measures as this clarification was included in Article 4.X.1. Did not agree to remove the reference to country, zone or compartment as it provides information on what constitutes an important disease and where the recommendations of Chapter 4.X. apply. Did not agree to remove the final sentence regarding the list of important diseases. It is not considered repetitive as this sentence goes beyond what is stated in Article 4.X.1. due to the link to Article 4.X.6. 'Risk analysis'. It also further clarifies that the list of important disease can apply at the level of country, zone or compartment.
4.X.3._3	**Category**: deletion **Proposed amended text** Lors de l'élaboration du cadre, il est essentiel de veiller à ce que les *maladies* des *animaux aquatiques* d'importance pour un pays, une *zone* ou un *compartiment* soient identifiées à l'avance (c'est-à-dire en temps de paix) par l'*Autorité compétente* et que leur contrôle à venir s'appuie sur des mesures législatives et financières appropriées. ~~La liste officielle des *maladies* importantes, qui est établie après avoir procédé à une *analyse des risques*, telle qu'elle est décrite à l'article 4.X.6., peut comprendre des *maladies* des *animaux aquatiques* qui figurent dans la liste du chapitre 1.3., ainsi que d'autres *maladies* qui ont été identifiées~~	Did not agree, see response for comment 4.X.3._2.

	~~comme étant importantes pour le pays, la *zone* ou le *compartiment* concerné.~~ **Rationale:** Article 4.X.3. A la fin du second alinéa, il est précisé que la liste officielle des *maladies* importantes, qui est établie après avoir procédé à une analyse des risques, telle qu'elle est décrite à l'article 4.X.6., peut comprendre des maladies des animaux aquatiques qui figurent dans la liste du chapitre 1.3., ainsi que d'autres maladies qui ont été identifiées comme étant importantes pour le pays, la zone ou le compartiment concerné. Or ces éléments sont déjà précisés à l'article 4.X.1. Proposition de les supprimer.	
4.X.3._4	**Category**: deletion **Proposed amended text**: The statutory list of important *diseases* ~~that is developed after conducting a *risk analysis* as described in 4.X.6.,~~ may include *aquatic animal diseases* which are listed in Chapter 1.3., as well as other *diseases* which have been identified as being of importance to the country, *zone* or *compartment*. **Rationale:** The Members reiterate the following suggestions concerning the final sentence of the above paragraph of Article 4.X.3., to account for situations where a disease may become important to a country, not only as a result of risk analysis, which could be a lengthy procedure but as a result of other considerations. For example, a disease might be listed in the national statutory list because it is listed by WOAH based on listing criteria, without conducting a risk analysis. Limiting the scope of the list of important diseases subject to disease preparedness to those where a risk analysis has already been conducted may hamper proper disease control.	Did not agree to remove reference to conducting a risk analysis. However, a sentence was added to broaden the scope of how diseases may be included in the list of important diseases. This addition takes into account situations where a disease may be included in the list of important diseases due to other national considerations without completing a risk analysis.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.3._5	**Category**: editorial **Proposed amended text**: The Competent Authority should consider whether the contingency plan and recovery plan ~~elements of~~ within 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 is most suitable taking into account disease characteristics, ~~best meets their needs, taking into account aquatic animal diseases that are listed in their country,~~ the relevant susceptible species, and the types of production.	Did not agree to remove the third paragraph as the text is intended to introduce concepts which are elaborated in Article 4.X.7. The text was amended to improve clarity.

	Rationale: The whole 3rd para could be deleted, this text is repeated at Article 4.X.7.	
4.X.3._6	**Category**: change **Proposed amended text**: *Aquatic animal diseases* 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*~~ *Authorities* 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 diseases* which are important to a country, *zone* or *compartment*, are identified in advance (i.e. in peacetime) by the *Competent* ~~*Authority*~~ *Authorities*, and that their future control is supported by adequate legislative and funding measures. The statutory list of important *diseases* that is developed after conducting a *risk analysis* as described in 4.X.6., may include *aquatic animal diseases* which are listed in Chapter 1.3., as well as other *diseases* which have been identified as being of importance to the country, *zone* or *compartment*. Also in peacetime, the *Competent* ~~*Authority*~~ *Authorities* 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*~~ *Authorities* 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. **Rationale:** We recommend changing "Competent Authority" to "Competent Authorities" since some members have more than 1 agency/group involved in the oversight of these activities.	Did not agree to change 'Competent Authority' to 'Competent Authorities'. As indicated in the first paragraph recommendations in Chapter 4.X. apply to 'a Competent Authority' and the text uses the singular as the provisions are intended to apply to each Competent Authority that is involved in emergency preparedness individually. However, the use of the singular does not prohibit multiple Competent Authorities being involved in the emergency preparedness but instead indicates each Authorities individual responsibility. As such, it is not considered necessary to indicate the plural in this section of text. Usage of 'Competent Authority' was reviewed through the text. It was only amended to indicate the plural when referencing communication or collaboration between Competent Authorities.

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*.

Reference	Comment	Aquatic Animals Commission Response
4.X.4._1	**Category**: change **Proposed amended text**: Emergency *disease* preparedness is a core function of the ~~*Competent Authority*~~ *Veterinary Authority*. The various elements	Did not agree, see response for comment 4.X._5.

	that are necessary to ensure that the ~~*Competent Authority*~~ *Veterinary 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*. **Rationale:** It is unclear if the responsible authority should be the *Competent Authority,* the *Veterinary Authority*, or both. We recommend changing "Competent Authority" to "Veterinary Authority" for this activity.	

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.4._2	**Category:** Revision **Proposed amended text:** 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~~. **Rationale:** While the Member that industry stakeholders need to be involved in emergency disease preparedness, we deem that the inclusion of 'and relevant industry stakeholders' in addition to Aquatic Animal Health Services has the potential to create inconsistency within the Code and misinterpretation between the use of the definition within this Chapter and other usages of the definition within the Code. The Member requests removal of the wording 'and relevant industry stakeholders' throughout this chapter. If the Aquatic Animals Commission deems that the definition is not sufficiently clear for Members, that industry stakeholders are included within the Aquatic Animal Health Services as non-governmental individuals or organisations, this change should be made throughout the Code to avoid misinterpretation elsewhere. The Member also notes that the Commission has indicated that revision of Chapter 3.1. Quality of Aquatic animal Health Services should be considered for inclusion within the workplan and would suggest that this level of clarification would be better suited for inclusion within that Chapter.	Did not agree with removing the inclusion of relevant industry stakeholders in addition to Aquatic Animal Health Services. Whilst the definition of Aquatic Animal Health Services clearly includes non-governmental individuals or organisations, for the avoidance of doubt, and given the importance of the active participation of industry stakeholders in emergency disease preparedness, the Commission agreed that the explicit mention of those stakeholders in relevant Articles, is justified.

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.;

Reference	Comment	Aquatic Animals Commission Response
4.X.4._3	**Category**: change **Proposed amended text**:	Did not agree, see response for comment 4.X.3_6.

	legal provisions and funding should be available to allow ~~a~~ *Competent ~~Authority~~ Authorities* 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.; **Rationale:** We recommend changing "Competent Authority" to "Competent Authorities" since some members have more than 1 agency/group involved in the oversight of these activities.	

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;

Reference	Comment	Aquatic Animals Commission Response
4.X.4._4	**Category**: editorial **Proposed amended text**: 2) *risk analysis* should be used in advance of, during and after a *disease outbreak* as described in Article 4.X.6. **Rationale:** Point 2) risk analysis [should be italicized]. Defined in the code.	Agreed, 'risk analysis' is a glossary term and should be italicised.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.4._5	**Category:** addition **Proposed amended text :** 3）laboratories should be authorized by the competent authority with the capability to test on the specific diseases listed in Chapter 1.3 and the emerging diseases or other aquatic diseases	Did not agree to adding a general principle stating that laboratories should be authorised by the 'Competent Authority'. Information around the access to appropriate laboratories is adequately covered

	43) 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: 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'; fully activated in compliance with Article 4.Y.5.Chapter 4.Y. once the disease emergency has commenced during the 'emergency phase'. 54) simulation exercises should be planned and executed to test, and ultimately to improve, relevant elements of the disease preparedness framework. Simulation exercises supportensure that Competent Authorities and Aquatic Animal Health Services to beare trained and properly equipped and resourcedto manage suspicion and confirmation of an important disease in their territory, in accordance with Article 4.X.8.; 65) all elements of the framework should be regularly reviewed and revised as described in Article 4.X.9.; 7) relevant characters should be acquainted with their respective responsibilities and maintain good communication and information transferred. 86) 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. **Rationale:** Laboratory detection capability is an important element in the emergency disease preparedness planning and implementation process. Authorized by the competent department, the laboratory can ensure the reliability of detection capability and ensure that relevant departments can quickly start emergency disease preparedness according to the laboratory test results. The implementation of emergency disease preparedness is jointly completed by different organizations and stakeholders, which is a cross-department and cross-level collaborative work. Information flow shall be maintained between different departments and different levels.	in other articles of draft Chapters 4.X. and 4.Y. Specifically, point 3) of Article 4.X.7. covers the identification of and access to appropriate laboratories, equipment and trained personnel and point 2) of Article 4.Y.7. goes into further detail on laboratories during an emergency outbreak. It was noted that appropriate laboratories must be identified by the Competent Authority, however authorisation may not always be performed or applicable. Did not agree to add a new point on communication and information transfer to the general principles. Risk communication is referenced in point 7 of Article 4.X.7., and further elaborated in points 5 and 7 of Article 4.Y.6.

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.*;*

Reference	Comment	Aquatic Animals Commission Response
4.X.5._1	**Category**: deletion **Proposed amended text**: 1) recourse to *aquatic animal* health legislation which underpins the execution of all the elements and actions that are necessary to	Agreed, countries may not have specific legislation for aquatic animal health, thus it is more appropriate to refer to legislation

	manage suspicion and confirmation of an *outbreak* of an important *aquatic animal disease* as described in Article 4.X.6.;" **Rationale:** As countries may not have specific legislation for aquatic animal health, thus it may be better not to name the type of legislation. Suggest that the amendments highlighted in green be made so that the sentence just refers to the need for countries to have legislation allowing actions to be taken, when there is an outbreak of an aquatic animal disease.	without specifying aquatic animal health legislation.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.5._2	**Category**: change **Proposed amended text**: There are certain pre-requisites for an emergency disease preparedness framework including~~. Such pre-requisites include~~ that the *Competent* ~~*Authority*~~ *Authorities have* ~~has~~: … … Any delay in the ability of the *Competent* ~~*Authority*~~ *Authorities* 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. **Rationale:** We recommend changing "Competent Authority" to "Competent Authorities" since some members have more than 1 agency/group involved in the oversight of these activities.	Did not agree, see response for comment 4.X.3_6.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.6._1	**Category**: change **Proposed amended text**: *Risk analysis* plays an important role before, during and after a *disease outbreak*. It is therefore, of critical importance that this	Did not agree, in this context the lead Competent Authority will have completed the risk analysis and the

	expertise is available to the *Competent ~~Authority~~ Authorities* to ensure that the emergency disease preparedness framework can be efficiently executed. **Rationale:** We recommend changing "Competent Authority" to "Competent Authorities" since some members have more than 1 agency/group involved in the oversight of these activities.	plural 'Competent Authorities' is not necessary in this text.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.6._2	**Category**: change **Proposed amended text**: 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 quality *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.~~ **Rationale:** Clarity. Suggest deletion; repetitive. This and the previous sentences are stating the same thing. Just inserted 'quality' so that the second sentence can be deleted.	Agreed with the suggestion to make edits for clarity, however the text was amended differently than proposal.

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*.

Reference	Comment	Aquatic Animals Commission Response
4.X.6._3	**Category**: editorial **Proposed amended text**: 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 of being able to continue grow-out of existing ~~on-grow~~ stock in ~~on~~ an infected *aquaculture establishment* to achieve market ~~slaughter~~ weight before slaughter ~~(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*. **Rationale:** Clarity. Suggest rewording to make it easier for non-english speakers to understand	Did not agree that the proposed changes were needed for improved clarity.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.7._1	**Category**: general 1st para was repeated at Article 4.X.3. at the 3rd para. Either leave here or delete the same text at the introduction.	Did not agree, 4.X.3. introduces the concepts which are further elaborated in Article 4.X.7.
4.X.7._2	**Category**: deletion **Proposed amended text**: 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~~. **Rationale:** The Members suggest to delete the examples given in the above paragraph of Article 4.X.7., because we believe the examples given are too narrow.	Agreed with removing examples to avoid confusion as they may be too narrow.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.7._3	**Category**: editorial **Proposed amended text**: 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. **Rationale:** Editorial for clarity.	Agreed, to proposed editorial amendment.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.7._4	**Category:** Editorial **Proposed amended text:** **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, producer~~s'~~ group, mental health and psychological support group.	Agreed to proposed editorial amendment.

	Rationale: Removal of unnecessary pluralisation to improve readability	

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;

Reference	Comment	Aquatic Animals Commission Response
4.X.7._5	**Category**: change **Proposed amended text**: 4) General biosecurity measures as per Chapter 4.1. should still apply as contingency measures in a suspected or confirmed case of an important aquatic animal diseases. ~~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 oncomply 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; **Rationale:** Editorial for clarity.	Did not agree to re-word point 4 to emphasise biosecurity measures as per Chapter 4.1. Point 4 is intended to differentiate between the measures put in place when a suspect or confirmed case is present in comparison to the standard biosecurity measures present at peacetime. The measures when there is a suspect or confirmed case will be more stringent than the standard measures and the current wording reflects this difference. The word general was removed from this point to emphasise that these biosecurity measures are more rigorous than would be in place during peacetime

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.7._6	**Proposed amended text** Les actions nécessaires pour rendre les points 1) à 7) ~~ci-dessus~~susmentionnés opérationnels sont décrites au chapitre 4.Y. et sont reprises dans un Manuel opérationnel. **Rationale:** Le dernier alinéa précise que les actions à mettre en œuvre sont décrites dans le 4.Y. qui mentionne le Manuel opérationnel. Il pourrait être intéressant de mentionner ce manuel ici.	Agreed to include reference to the Operational Manual in the last sentence.

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.

Reference	Comment	Aquatic Animals Commission Response
4.X.8._1	**Category:** editorial **Proposed amended text:** 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	Agreed to edit text for clarity, however text amended differently than proposal.

	exercise, describing the actions necessary to ~~close~~address any gaps ~~which have been~~ identified in the *contingency plan*, or any other amendments ~~which are required~~ to the operational measures, ~~which are~~ as described in Chapter 4.Y. **Rationale:** editorial, for simplification, clarity and for consistency in language with point 1c.	
4.X.8._2	**Category:** Addition/Editorial **Proposed amended text:** An outcome report should be produced following each simulation exercise, highlighting lessons learnt, describing the actions necessary to close any gaps which have been identified in the *contingency plan*, ~~or~~ and other amendments which are required to the operational measures which are described in Chapter 4.Y ~~,~~ . This should include identification of individuals responsible for delivery and a timeframe within which the actions should be completed. **Rationale:** Reflection on lessons learnt is the essential first step to identify which parts of the contingency plan worked well so they can be maintained, which did not and need to be addressed, and also what new or unexpected challenges were faced that had not previously been anticipated. We also feel it is essential to establish task ownership and set timeframes for addressing any issues found.	Agreed to include edits on the inclusion of lessons learnt as this provides important information to identify what worked well, what needs to be addressed and unexpected challenges that can be addressed in the contingency plan. Agreed to include a sentence on identify individual responsibilities and timeframes to complete the tasks to ensure that the issues are appropriately addressed.

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;

Reference	Comment	Aquatic Animals Commission Response
4.X.8._3	**Category:** addition **Proposed amended text :** 4）Simulation exercise organized in the compartment should make detailed plan, including critical control points in the biosecurity system and the person working on the critical control points. ~~5~~4) exercises should test the capacity of the Competent Authority to manage every element of the emergency disease	Did not agree to adding additional point 4 on stimulation exercises in a compartment. However, in paragraph 2 it was clarified that simulation exercises could be organised in a country, zone or compartment. The approach as outlined in Article

	preparedness framework, from the initial disease alert to the end of the recovery phase; 6~~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: **Rationale:** Compartment are the most important positions for simulation exercise. Relevant personnel can further familiarize themselves with and understand the operation process of emergency disease preparedness through simulation exercises, so as to better achieve the goal of controlling or eliminating diseases. It is suggested to strengthen the guidance on the formulation of simulation exercises plans for compartment.	4.X.8. applies to stimulation exercises at any level.

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*;

Reference	Comment	Aquatic Animals Commission Response
4.X.10._1	**Category**: general Article 4.X.10. 2) et 3) les notions de “zone indemne” ou “compartiment indemne” citées au 2) sont bien définies dans le glossaire, mais la notion de “zone redéfinie (réduite) indemne”, citée au 3), n’est pas expliquée. De ce fait, la différence entre le 2) et le 3) est difficile à comprendre.	A redefined (reduced) disease free zone was originally part of a larger zone which lost its disease-free status. After loss of the disease-free status a new smaller disease free zone separate from the original zone can be established, and this is called the 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.

Reference	Comment	Aquatic Animals Commission Response
4.X.10._2	**Category**: change **Proposed amended text** Toutefois, ces maladies n'entrent pas dans le champ d'application des statuts ~~officiels~~ indemnes de maladie listée qui peuvent être établis pour un pays, une *zone* ou un *compartiment*~~, tels que~~comme décrit au chapitre 1.4. **Rationale:** Article 4.X.10. 7) A la fin du paraphe, "le champ d'application des statuts officiels indemnes de maladie comme décrit au chapitre 1.4." est mentionné. Cependant, il n'existe pas de statut officiel pour les maladies des animaux aquatiques, contrairement à certaines maladies des animaux terrestres (FA, PPCB, PPC…). Il semble donc nécessaire de supprimer le mot "officiel" qui porte à confusion et d'ajouter la notion de "maladie listée".	Agreed, remove reference to official status as there is no official disease status for aquatic animal diseases. Instead indicate disease free status for listed diseases in the text.

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.

Draft new Chapter 4.Y. 'Disease outbreak management'

Reference	Comment	Aquatic Animals Commission Response
4.Y._1	**Category:** general The Member supports the proposed Chapter and has included some comments within the chapter for consideration.	Noted
4.Y._2	**Category:** general The Member supports the proposed changes to this Chapter.	Noted
4.Y._3	**Category**: general Now that there are definitions for "Competent Authority" vs. "Veterinary Authority", we feel there may be areas of this chapter where the authority currently referenced is not in alignment with the glossary definitions as we understand them. We also emphasize the importance of working with industry to prepare for and during an outbreak, in addition to the roles of the Veterinary Authority, Competent Authorities, and Aquatic Animal Health Services.	Noted. In response to a similar comment concerning glossary definitions in the February 2024 report, the Commission highlighted that the 'Veterinary Authority' is a 'Competent Authority'. The definition of a 'Competent Authority' recognises that, in many countries, more than one governmental authority is responsible for implementing standards of the *Aquatic Code*. The term 'Competent Authority' is intended to apply to any governmental authority with some responsibility for the implementation of some WOAH standards. Depending on the administrative structures of a country, the Competent Authority may be a national or a regional governmental authority. The term 'Veterinary Authority' distinguishes the role of a single 'Competent Authority' that has responsibility for communicating with WOAH and an overarching responsibility for implementation of WOAH standards. The position of the Commission remains unchanged concerning these glossary definitions, and considers their use in Chapter 4.Y. to be appropriate.
4.Y._4	**Category**: general The Members thank the Aquatic Animals Commission for taking into account most of our previous comments on the draft chapter. However, the Members provide additional comment to Articles 4.Y.4 and 4.Y.6, due to the changes made in February 2024 to the draft chapter below.	Noted

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.Y.

DISEASE OUTBREAK MANAGEMENT

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.1._1	**Category**: change **Proposed amended text**: To provide specific recommended actions ~~recommendations concerning the actions~~ which should be taken by the *Competent Authority* and the *Aquatic Animal Health Services* to manage the emergency response to a suspected ~~suspicion~~ or confirmed case of an ~~confirmation of the presence of an~~ important aquatic animal disease or an emerging aquatic animal disease, and to activate its contingency plans as described in Chapter 4.X. **Rationale:** To align with what is stated at Chapter 4.X. Expand the scope for emerging diseases.	Did not agree, the current wording aligns with what is stated in Chapter 4.X. An important disease is defined in 4.X.1. as diseases that may be listed in Chapter 1.3., emerging disease or other diseases. Thus it is not necessary to include emerging diseases in Article 4.Y.1.
4.Y.1._2	**Category**: addition **Proposed amended text**: To provide recommendations concerning the actions which should be taken by the *Veterinary Authority,* *Competent* ~~*Authority*~~ *Authorities* and the *Aquatic Animal Health Services* including industry 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. **Rationale:** The suggested edits are intended to clarify that all these roles should be coordinating during disease outbreak management.	Did not agree, see response for comment 4.Y._3.

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*.

Reference	Comment	Aquatic Animals Commission Response
4.Y.2._1	**Category:** change **Proposed amended text:** To provide recommended ~~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* or an emerging aquatic animal 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*. **Rationale:** To align with what stated at Chapter 4.X. Expand the scope for emerging diseases.	Did not agree, see response for comment 4.Y.1._1.
4.Y.2._2	**Category:** editorial **Proposed amended text:** To provide recommendations concerning the actions, to be taken by the *Competent Authority* and the *Aquatic Animal Health Services,* as described in Article 4.X.6., from the point at which an important *aquatic animal 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*. **Rationale:** To align with the text of 'important aquatic animal disease' in 4.X.1. The cross reference to 4.X.6. should be included with the information regarding actions as current it might create confusion as the important disease is described in 4.X.1.	Agreed to specify that the important disease is an aquatic animal disease. The reference to Article 4.X.6. was changed to Article 4.Y.1. as this is the article where an important aquatic animal disease is described.
4.Y.2._3	**Category**: addition **Proposed amended text**: To provide recommendations concerning the actions which should be taken by the *Veterinary Authority, Competent* ~~*Authority*~~ *Authorities* and the *Aquatic Animal Health Services* including industry 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. **Rationale:** The suggested edits are intended to clarify that all these roles should be coordinating during disease outbreak management.	Did not agree, see response for comment 4.Y._3.

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.;

Reference	Comment	Aquatic Animals Commission Response
4.Y.3._1	**Category**: addition **Proposed amended text**: 1) the actions to be taken by the *Veterinary Authority,* *Competent* ~~*Authority*~~ *Authorities* and the *Aquatic Animal Health Services* with industry, should be based on the emergency *disease* preparedness framework which has been developed in accordance with Chapter 4.X.; **Rationale:** The suggested edits are intended to clarify that all these roles should be coordinating during disease outbreak management.	Did not agree, see response for comment 4.Y._3. Competent Authority was changed to Competent Authorities as this point is referring to all the stakeholders involved in responding to an emergency disease outbreak.

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;

Reference	Comment	Aquatic Animals Commission Response
4.Y.3._2	**Category**: general On point 2), Please note the difference between the contingency plan and operations manual. The Feb 2024 report has explanation on these two terms but still not clear.	A Contingency Plan is a documented work plan which provides details on the preparedness and response strategies to eradicate or control an outbreak of an important disease. The Contingency Plan will include all needed actions, roles and responsibilities, and ensure that resources are available to respond to an outbreak. An Operations Manual provides guidance on how to complete the required activities of the alert, emergency and recovery phases of an outbreak. This can consist of multiple documents, and offers procedural guidance on operational activities. Overall the Contingency Plan provides details on what activities need to be done to be prepared for and respond to an outbreak, and the Operations Manual provides details on how perform the activities. The Operations Manual operationalises the Contingency Plan.
4.Y.3._3	**Category:** Addition/Editorial **Proposed amended text:** the operational elements of the emergency *disease* preparedness framework should be described in an Operations Manual. The Operations Manual may be a single	Agreed to add references to relevant articles to aid navigation through the chapter.

	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 (refer to articles 4.Y.4, 4.Y.5, and 4.Y.9 respectively); **Rationale:** In line with the similar amendment now proposed in article 4.X.4 - to include the specific article references for these 3 important and defined phases, to aid navigation through the chapter.	

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;

Reference	Comment	Aquatic Animals Commission Response
4.Y.3._4	**Category**: addition **Proposed amended text**: 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 *Veterinary Authority and other relevant* Competent ~~*Authority*~~ *Authorities* to pursue an alternative pathway to recovery; **Rationale:** The suggested edits are intended to clarify that all these roles should be coordinating during disease outbreak management. We also feel that prior to eradicating a disease, the first step should be to contain the disease outbreak before you can initiate eradication steps. We recommend inserting a step before #3 in this section to address the importance of disease containment during an outbreak response.	Did not agree to changes relative to Veterinary Authority and Competent Authority; see response for comment 4.Y._3. Did not agree to insert a new point 3 to address disease containment as this is not the objective of this article. Biosecurity and other containment measures are described in Chapter 4.X., as referenced in the first point of this article. Point 3 as a general principle is indicating that the initial desired outcome following a disease outbreak is that the country, zone or compartment will regain its disease-free status. If that is not possible than alternative response options are to be considered.

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*.

Reference	Comment	Aquatic Animals Commission Response
4.Y.3._5	**Category**: addition **Proposed amended text**: 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*, and support the continuity of business as much as possible. **Rationale:** We feel supporting the continuity of business as much as possible during a disease outbreak is also an important general	Did not agree to add supporting the continuity of business as a general principle in point 4. During a disease response supporting the continuity of business in addition to managing the disease outbreak is the ideal circumstance. However, this may not be possible at all times, and different concerns may need to be prioritised over business continuity. While business continuity is an

	principle, which is similarly reflected in the WOAH terrestrial chapters on emergency disease response.	important consideration, managing the disease outbreak in a timely and successful way will take precedence.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._1	**Category**: addition **Proposed amended text**: 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 neighbouring country that shares common waterways or is a trading partner. **Rationale:** Clarity.	Agreed to clarify that a neighbouring country would share common waterbodies.
4.Y.4._2	**Category:** editorial **Proposed amended text:** The alert phase begins when there is suspicion of the presence of an important *aquatic animal 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. **Rationale:** For consistency of terminology with Chapter 4.X. and within the chapter.	Agreed to change to aquatic animal disease for consistency of usage.

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

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._3	**Category:** Editorial **Proposed text for amendment:** The main actions to be taken into account during the alert phase of an emergency should take the following factors into account: **Query:** The text in this sentence is repetitive and confusing, so we are unsure of the intent of the statement. As such, we cannot propose a suitable amendment, but we feel it needs to be addressed.	Agreed, text amended to improve clarity and reduce repetition.

~~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;~~

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._4	**Category**: deletion **Proposed amended text**: ~~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; **Rationale:** Repetitive.	Text had been removed in version of Chapter 4.Y. circulated with the Aquatic Animals Commission's February 2024 report.

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;

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._5	**Category**: change **Proposed amended text**: a) confirm or rule out the presence of the ~~*disease*~~ *pathogen*, in the shortest possible time frame; **Rationale:** We suggest changing "disease" to "pathogen" as the presence of a pathogen does not necessarily mean there are associated clinical signs/disease in a given population.	Did not agree, the Glossary definition of disease 'means clinical or subclinical infection with one or more pathogenic agents'. This definition takes into accounts that clinical signs may not be present when there is infection with a pathogenic agent.

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);

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._6	**Category**: deletion **Proposed amended text**: 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); **Rationale:** Need a working case definition for any diseases that are not listed in the code.	Agreed, amended point 1 b to make it clear that case definitions will have been established for important diseases as per Article 4.X.4. prior to the alert phase. Emerging diseases will not have case definitions available and this will need to be established in the alert phase.
4.Y.4._7	**Category**: deletion **Proposed amended text**: ~~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);~~ **Rationale:** It is preferable to develop case definitions prior to a disease outbreak (not in the middle of one). We recommend	Agreed that it is preferable to develop case definitions prior to a disease outbreak. As such Article 4.X.4. was amended to have a new point 2 indicating the creation of case definitions during disease preparedness activities.

	removing statement 1)b) from Chapter 4.Y. and instead include it in the draft Chapter 4.X.	

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._8	**Category**: addition **Proposed amended text**: 2) d) the initial working case definition should be reviewed and updated with further epidemiological information if the causative agent has not been identified. **Rationale:** Suggested additional point. A working case definition must be reviewed.	Did not agree to add new point 2d. Amendments made to point 1b addressed the need for a case definition for an emerging disease should be based on the best available science at the time. This addresses the need for any review if the pathogenic agent is unidentified.
4.Y.4._9	**Category:** Change **Proposed text for amendment:** **c~~b~~)** gather information to determine potential ~~if the~~ disease ~~has~~ spread from or to aquaculture establishments or waterbodies other than the one in which the original suspicion was raised in preparation for risk-based surveillance as described in Article 4.Y.8 to establish extent of disease spread should the disease be confirmed. **Rationale:** As written, this point implies actions should be initiated to determine disease spread (point 1c) during the alert/ suspicion phase, when a disease outbreak has not yet been confirmed and may not be. While contact tracing information should be gathered during the alert (suspicion) phase in preparation, actual contact tracing to determine disease spread wouldn't normally begin until the disease is confirmed (which initiates the emergency phase).	Agreed that point 1c as written indicated that activities related to contact tracing for disease spread should begin prior to disease confirmation. Amendments were made to 1c to indicate that information fathering around disease spread should begin during the alert phase to inform risk-based surveillance activities.
4.Y.4._10	**Category**: deletion **Proposed amended text**: c~~b~~) determine if the ~~*diseas e*~~*pathogen* has spread from or to *aquaculture establishments* or waterbodies other than the one in which the original suspicion was raised. **Rationale:** We suggest changing "disease" to "pathogen" since the pathogen may have spread outside the establishment but may not be causing signs of disease.	Did not agree, see response to comment 4.Y.4._5.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._11	**Category:** addition **Proposed amended text:** c) the initial working case definition should be reviewed and updated with further epidemiological information if the causative agent has not been identified. **Rationale:** A working case definition must be reviewed.	Did not agree to add new point 2c. Addressed, as per comment 4.Y.4._8.
4.Y.4._12	**Category:** Change **Proposed amended text:** ~~23) 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.~~ **Rationale:** These actions wouldn't normally begin until the disease is confirmed (which initiates the emergency phase). As they contribute to the execution of biosecurity and disease control, we recommend moving them to Article 4.Y.8.	Did not agree to delete point 2. Amendments made to 1c address the epidemiological investigation being included in the alert phase. Contact tracing and other epidemiological information will start to be gathered in the alert phase. This information will be used to inform risk-based surveillance which may commence during the alert phase and become fully applicable during the emergency phase if there is confirmation of disease.

34) 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*;

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._13	**Category**: deletion **Proposed amended text**: 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*; **Rationale:** The Members disagree to add "contaminated water" in the sentence. Movement of contaminated water should not be prohibited in the alert phase (i.e. the suspicion phase). The water in an aquaculture establishment in the alert phase is not known to be contaminated, and can only be assumed to be contaminated. In addition, it is impossible to stop the movement of water to or from most of all the commonly used types of aquaculture	Amended 'contaminated water' to add 'when feasible'. Agreed that in many aquaculture establishments it may not be possible to stop the movement of water, and thus the amendment indicates this movement should only be prohibited where possible.

	establishment – e.g. how should movement of water to and from a fish farm in net cages at sea be stopped? The newly added “, contaminated water” should therefore be deleted.	

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._14	**Category**: change **Proposed amended text**: 2~~3~~) during the alert phase, taking into account Chapter 4.1., the Veterinary Authority, *Competent Authorities* in partnership with aquatic animal health services and industry, 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. 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*;~~	Agreed to move point 3 above point 2, as the point on taking steps to prevent disease spread via biosecurity measures should come before the point on the epidemiological investigation. Did not agree to changes relative to Veterinary Authority and Competent Authority, see response for comment 4.Y._3.

	~~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.~~ **Rationale:** We suggest moving the "…during the alert phase…" step before "…during the epidemiological investigation…" because control measures should be in place before the commencement of the epidemiological investigation.	

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._15	**Category**: editorial (translation) **Proposed amended text** Les principales mesures à prendre en compte pendant la phase d'alerte d'une situation d'urgence ~~doivent tenir compte des facteurs suivants~~ sont notamment les suivantes : 1~~2~~) ~~après~~ dès le début de cette phase, une enquête épidémiologique doit être lancée afin de : [...] ~~23)~~ ~~a~~Au cours de ~~l'investigation~~l'enquête épidémiologique : a) la *surveillance* fondée sur le~~s~~ *risque~~s~~* est utilisée [...] 23~~4~~) au cours de la phase d'alerte, [...] **Rationale:** Article 4.Y.4. : la rédaction de cet article est à revoir en français pour faciliter sa compréhension	Agreed to editorial amendment to address translation in French.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.4._16	**Category:** Deletion **Proposed text for amendment:** 8~~9)~~ ~~the alert phase ends when the presence of an important disease is either confirmed or ruled out by the Competent Authority. R~~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. **Rationale:** This text is, in essence, repetition of point 8 but with language that could cause confusion ('suspicion has not been confirmed' is not the same epidemiological status as 'disease is ruled out'), so recommend removing it.	Agreed that wording of point 8 is repetitive to other points. Amendments made to text to clarify and remove repetition.
4.Y.4._17	**Category**: change **Proposed amended text**: 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 *Veterinary* ~~*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) … b) … c) … 5~~6~~) whilst confirmation of the presence of the ~~*disease*~~ *pathogen* in question is ongoing, the *Veterinary* ~~*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 *Veterinary* ~~*Competent*~~ *Authority* should endeavour to ensure that the alert phase is short enough to minimise ~~*disease*~~ *pathogen* 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*~~ *pathogen* is either confirmed or ruled out by the *Veterinary* ~~*Competent*~~ *Authority*. Relevant actors in the *Aquatic Animal Health Services* and industry 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.	Did not agree to change Competent Authority to Veterinary Authority; see response for comment 4.Y._3. Did not agree to change disease to pathogen; see response for comment 4.Y.4._5. In regards to communication in point 8, amendments were made to remove reference to Aquatic Animal Health Services and instead reference 'relevant actors'.

	Rationale: The "Veterinary Authority" should be the lead for the activities described above instead of the "Competent Authority". We suggest changing "disease" to "pathogen" as the presence of a pathogen does not necessarily mean there are associated clinical signs/disease in a given population. Communication plans should include pertinent industry members in addition to aquatic animal health services personnel.	

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:

Reference	Comment	Aquatic Animals Commission Response
4.Y.5._1	**Category:** editorial **Proposed amended text:** The emergency phase of *disease outbreak* management commences when the presence of an important *aquatic animal 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: **Rationale:** For consistency of terminology with Chapter 4.X. and within the chapter.	Agreed to editorial amendment to clarify aquatic animal disease for consistency of usage.
4.Y.5._2	**Category**: deletion **Proposed amended text**: The emergency phase of *disease outbreak* management commences when the presence of an important ~~*disease*~~ *pathogen* has been confirmed. **Rationale:** We suggest changing "disease" to "pathogen" as the presence of a pathogen does not necessarily mean there are associated clinical signs/disease in a given population.	Did not agree, see response for comment 4.Y.4._5.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.6._1	**Category**: change **Proposed amended text**: As soon as the *disease outbreak* has been confirmed, the *Veterinary Authority, Competent ~~Authority~~ Authorities, Aquatic Animal Health Services, including industry,* convene~~s~~ a meeting of the emergency management group as described in Chapter 4.X., and the activation of all elements of the *contingency plan* commences. **Rationale:** The suggested edits are intended to clarify that all these roles should be coordinating during disease outbreak management.	Did not agree, see response for comment 4.Y._3.

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*~~;

Reference	Comment	Aquatic Animals Commission Response
4.Y.6._2	**Category**: change **Proposed amended text**: b) inventory (e.g., animal counts, species, life stages) of species kept in the infected *aquaculture establishment(s)* ~~and the numbers and weights of the *aquatic animals*~~; **Rationale:** The suggested edits are intended to provide examples of "inventory" information that should be collected. We agree that the weight of animals is not essential information, and the number of animals or life stages are part of the inventory so does not need to be listed separately.	Agreed that with the removal of weights of aquatic animals, the numbers should be removed as well. Amendments made to indicate that relevant information should be provided without providing examples such as animal counts, species, and life stages.
4.Y.6._3	**Category**: deletion **Proposed amended text**: b) inventory of species kept in the infected *aquaculture establishment(s)* ~~and the numbers and weights of the *aquatic animals*~~; **Rationale:** According to page 25 of this report, the *Aquatic Commission* agreed with a comment that the details on numbers and weights of animals should be removed from point 1 b). However, only the weight part has been removed in the text above.	Agreed, see response for comment 4.Y.6._2.

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);

Reference	Comment	Aquatic Animals Commission Response
4.Y.6._4	**Category:** Editorial **Text for amendment:** e) details of susceptible species in the vicinity of the confirmed case(s); **Queries:** Seeking clarification on if this is meant to include both susceptible and vectors species? Also is this to be applied to both farmed and wild populations? Could clarification be provided on what is meant by "vicinity" – is this related to geographical area, shared water sources, or something else?	In response to the first question on whether point e) includes vectors – the *Aquatic Code* and the *Aquatic Manual* provide relevant information concerning susceptible species and vector species for listed diseases which should be taken into consideration. The approach to non-listed diseases and emerging diseases should be decided in advance by the Competent Authority and be guided by the risk assessment upon which the emergency response framework is based. In response to the second question – the recommendations apply to both farmed and wild populations. In response to the third question to clarify what is meant by vicinity – amendments were made to point e to change it to indicate the details of susceptible species with a potential epidemiological link to the confirmed cases.

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*;

Reference	Comment	Aquatic Animals Commission Response
4.Y.6._5	**Category**: deletion **Proposed amended text**: b~~a~~) details of the legal instrument which supports ~~the provision of funding for~~ the management of disease emergencies concerning *aquatic animals*; **Rationale:** The legal instrument is necessary not only for funding but also providing emergency response officers with the legal powers to enter private facilities and destroy animals.	Amended to indicate that the legal instrument can include the provision for funding but is not restricted to that purpose.

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~~;

Reference	Comment	Aquatic Animals Commission Response
4.Y.6._6	**Category**: change **Proposed amended text**: 5) agreed messages, format ~~for~~, and timing of, communications with the *Aquatic Animal Health Services* including industry who are responding to the emergency, relevant trading partners, and the public **Rationale:** Communication should also include pertinent industry personnel.	Amended to include other relevant stakeholders. For rationale, see response for comment 4.X.4._2.

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:

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._1	**Category**: change **Proposed amended text**: a) The *Veterinary* ~~*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: **Rationale:** The "Veterinary Authority" should oversee the establishment of a central disease control center.	Did not agree, see response for comment 4.Y._3.

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;

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._2	**Category:** editorial **Proposed amended text:** clinical inspections of *aquaculture establishments*, other establishments and wild *aquatic animals* ~~and wild aquatic habitats,~~ as relevant; **Rationale:** Glossary terms should be italicised.	Agreed to italicise aquatic animals as a Glossary term.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._3	**Category:** Addition **Proposed text amendment:** viii) finance and resource procurement **Rationale:** Situations can often change quickly, requiring the acquisition and deployment of different materials, equipment, and resources. Including individuals with the authority and capability to facilitate this is essential.	Agreed to add finance and resource procurement. As situations often rapidly change they can require the acquisition and deployment of resources.

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:

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._4	**Category**: addition **Proposed amended text**: a) During the emergency, the *Aquatic Animal Health Services including industry* 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: **Rationale:** Communication should also include pertinent industry personnel.	Agreed to add 'and industry' as communication should include pertinent industry members.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._5	**Category**: addition **Proposed amended text**: b) For *listed diseases*, laboratory methods should follow the relevant chapter of the ~~WOAH~~ *Aquatic Manual* *as well as the drafted case definitions for the pathogen*. 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. **Rationale:** Laboratory testing methods should be in alignment with both the WOAH and case definitions for the disease of concern.	Agreed that laboratory testing should be aligned with the case definition for non-listed diseases and emerging diseases, and the *Aquatic Manual* for listed diseases. Amendments made to the text to reflect the suggestion.

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:

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._6	**Category**: addition **Proposed amended text**: 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* *and vice versa*. Action should, therefore, be taken to ensure the availability of: **Rationale:** We suggest inserting "and vice versa" because disease outbreaks have the potential to spread from farmed to wild populations, as well as from wild to farmed populations.	Did not agree to add 'vice versa' at the end of the first sentence as the text is not meant to address direction spread. Text amended to clarify that the direction of disease spread is not the intent of this point.

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;

Reference	Comment	Aquatic Animals Commission Response

4.Y.7._7	**Category:** editorial **Proposed amended text:** e) communication specialist or journalist for media liaison **Rationale:** N/A	Agreed to editorial spelling amendment.

f~~e~~) telecommunications providers;

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._8	**Category**: editorial **Proposed amended text**: Service ~~P~~providers … ~~fc) telecommunications providers;~~ **Rationale:** Editorial.	Agreed to editorial amendments.
4.Y.7._9	**Category:** Editorial/Deletion **Proposed text amendment:** e) communication ~~specials~~ specialist or journalist for media liaison; f~~e~~) ~~telecommunications providers;~~ **Rationale:** Typo correction on point e and removal of point f as it is a duplicate of point d.	Agreed to editorial amendments.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.7._10	**Category:** Addition **Proposed text for amendment:**	Agreed to proposed amendments, as whether to include details of providers in points a to k is dependent on outbreak scenarios

	Subject to the relevant regulatory requirements, likely outbreak scenarios, and operational infrastructure, 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. **Rationale:** Whether to include details of the providers referred to in points a) to k) in the Ops Manual is not limited to regulatory requirements but also affected by the likely outbreak scenarios specific to the country and operational infrastructure.	and operational infrastructure in addition to regulatory requirements.

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:

Reference	Comment	Aquatic Animals Commission Response
4.Y.8._1	**Category**: change **Proposed amended text**: The actions which the *Veterinary Authority and Competent Authorit~~y~~ies* should take~~s~~ concerning *biosecurity* and other *disease* control measures during the emergency phase, are described in the Operations Manual and may include: **Rationale:** Both the "Veterinary Authority" and Competent Authorities may have roles in biosecurity and other disease control measures.	Did not agree, see response for comment 4.Y._3.

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.;

Reference	Comment	Aquatic Animals Commission Response
4.Y.8._2	**Category:** addition **Proposed text for amendment:** 1) risk-based prioritisation and surveillance sampling of aquatic animal populations identified during the epidemiological investigation described in Article 4.Y.4. For example, aquaculture establishments which are highly connected to the aquaculture establishment or waterbody in which disease has been confirmed, through movements of live aquatic animals and other transmission pathways, as described in Article 4.1.7., should be considered for clinical inspection and sampling; a) 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. 2 ~~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.;	Did not agree to proposed amendments on the initiation of risk-based surveillance in 4.Y.8. Amendments made to text in point 1c in Article 4.Y.4. and to point 2 in Article 4.Y.5. in regards to risk based surveillance and clarify when it can commence.

	Rationale: These actions would not be initiated until disease presence had been confirmed. As such, they contribute to the execution of biosecurity and disease control, and we recommend including them here with relevant renumbering of subsequent points.	

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

Reference	Comment	Aquatic Animals Commission Response
4.Y.8._3	**Category**: addition **Proposed amended text**: 2) appropriate classification of the health status of *aquaculture establishments* to define their *disease* status or *risk* of infection (e.g. Infected Premises, Suspected Premises, At-Risk Premises); **Rationale:** The classification of establishments may need examples.	Did not agree to the addition of examples as the point is clear without them.

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*;

Reference	Comment	Aquatic Animals Commission Response
4.Y.8._4	**Category**: change **Proposed amended text**: 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 *Veterinary* ~~*Competent*~~ *Authority* following *risk assessment*; **Rationale:** The "Veterinary Authority" should authorize the movements described in 5)a).	Did not agree, see response for comment 4.Y._3.

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;

e~~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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.8._5	**Category**: general On Point 5) e) - Is suppressive vaccination and slaughter applied for cultured aquatic animals? Would live attenuated vaccine have an impact on surveillance conducted to gather evidence for return to disease freedom?	Is suppressive vaccination and slaughter applied for cultured aquatic animals? Whether vaccinated fish could be put forward for slaughter would be decided by the Competent Authority and public health authorities. The decision would depend on the authorisation status of the vaccine. Would live attenuated vaccine have an impact on surveillance conducted to gather evidence for return to disease freedom? Aquatic animals subject to a surveillance programme with the aim to achieve disease freedom cannot be vaccinated. The suppressive vaccination referred to in point iv, is an emergency vaccination to be considered if there is a possibility that a disease outbreak will get out of control.

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;

Reference	Comment	Aquatic Animals Commission Response
4.Y.8._6	**Category**: change **Proposed amended text**: 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 *Veterinary ~~Competent~~ Authority*, and which meet the decontamination requirements concerning the *pathogenic agent* in question~~,~~ should also be specified; **Rationale:** The "Veterinary Authority" should authorize appropriate decontamination options for the disease response.	Did not agree, see response for comment 4.Y._3.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.8._7	**Category:** change **Proposed amended text:** h) where relevant, specifying the procedures to be used for the containment, *disinfection* and disposal of ~~*disease*~~ *pathogenic agent* contaminated water used for *aquatic animal* production. **Rationale:** Pathogenic agent or pathogen would be more appropriate terms to be used here in reference to contaminated water.	Agreed, pathogenic agent is a more appropriate Glossary term than disease in reference to contaminated water.
4.Y.8._8	**Category**: editorial (translation) **Proposed amended text** 5) h) : faute de frappe : "h) le cas échéant, spécifier les procédures devant être employées pour la rétention, la *désinfection* et l'élimination des eaux contaminées par des *agents pathogènes* et utilisées pour la production d'*animaux aquatiques*.	Agreed to editorial change in French translation.

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.

Reference	Comment	Aquatic Animals Commission Response

4.Y.9._1	**Category**: change **Proposed amended text**: The recovery phase of *disease outbreak* management is activated when the end of the emergency has been declared by the *Veterinary ~~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. **Rationale:** The "Veterinary Authority" should declare and authorize the commencement of the recovery phase.	Did not agree, see response for comment 4.Y._3.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.9._2	**Categoría**: Editorial **Texto modificado propuesto:** 2. En los casos en los que la fase de recuperación no incluye la ~~ambición~~ intención de volver al estatus libre de la enfermedad, las medidas necesarias para contener la enfermedad o mitigar sus efectos deberán identificarse y establecerse en el Manual de Operaciones. **Justificación:** Por coherencia con la definición de la palabra ambición según la RAE es: Deseo ardiente de conseguir algo, especialmente poder, riquez as, dignidades o fama. La palabra correcta a utilizar en lugar de ambición seria Intención. La definición de la palabra intención según la RAE es: Determinación de la voluntad en orden a un fin.	Agreed the word intention is more appropriate than ambition in reference with the intention to return to disease-freedom.

   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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.9._3	**Category**: addition **Proposed amended text**: In cases where the recovery phase includes the intention~~ambition~~ to return to ~~*disease*~~ *pathogen* freedom in accordance with ~~Pathway 4 as referred to in~~ Chapter 1.4. (Pathway 4), either for: a) … b) … …. 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*~~ *pathogen*, or to mitigate the impacts of the *disease*, should be identified and set out in the Operations Manual. Containment. Where the aim of the recovery plan is to contain the ~~*disease*~~ *pathogen*, the following measures may be described: **Rationale:** We suggest changing "disease" to "pathogen" in parts 1 and 2 of the "Return to freedom" section to more accurately reflect that fact that our goals include containing the pathogen (as the presence of a pathogen does not necessarily mean there are associated clinical signs/disease in a given population), and restoring freedom from the pathogen.	Did not agree, see response for comment 4.Y.4._5.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Y.9._4	**Category**: addition **Proposed amended text**: e) ongoing communication with *Aquatic Animal Health Services* *including industry* to explain relevant details of the recovery plan and to reinforce the role the *Aquatic Animal Health Services* and industry play in future *disease* prevention and control. **Rationale:** Communication should also include pertinent industry personnel.	Agreed to add 'and industry' as communication should include pertinent industry members.

Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'

Reference	Comment	Aquatic Animals Commission Response
4.Z._1	**Category**: general The Member supports the proposed chapter with comments included within the text. The Member looks forward to reviewing a new article on specific biosecurity measures for the collection and incubation centre in the Commissions September report.	Noted.
4.Z._2	**Category:** general The Member would like to thank the Aquatic Animal Commission for the continued work on this draft new chapter. Specific comments are provided below. The Member would additionally encourage the Aquatic Animal Commission to revisit the use of "should" throughout the chapter. The Member suggests the general use of "must", rather than "should", for obligatory actions.	This chapter covers recommendations which would therefore use the verb 'should' rather than 'must', however when choosing to put these recommendations in place the word to be used for the specific measures within those recommendations would be 'must'. The Commission has reviewed the chapter to align with this rationale.
4.Z._3	**Category:** general **Proposed amended text:** No text proposed. We would like to request WOAH to provide technical reasons on the replacing of the term "milt" with "gametes" for more clarification. **Rationale:** The use of both terms depends on the context of requirement.	The amendments to replace 'milt' with 'gametes' is to be consistent with the updates to the term gamete as defined in the Glossary and the use is aligned with this definition.
4.Z._4	**Category:** general We are unclear as to the rationale behind this chapter, as it encourages trade of materials from countries/zones/compartments without disease freedom to those that are free of disease, which goes against our understanding of WOAH's goals in aiding trade between countries of similar disease status to minimise the risks of disease spread without undue economic hardship on Members. Can the AAC please provide clarity on the justification for this proposed chapter.	Chapter 4.Z. provides a higher level of protection than the existing measures in the *Aquatic Code* which includes only egg disinfection for salmonid eggs being imported from a country, zone or compartment without disease freedom. This chapter therefore provides options for safe trade in milt and fertilised eggs of fish from areas which have not been declared free from infection with a listed disease.
4.Z._5	**Category**: general The Members thank the Aquatic Commission for this interesting initiative and for taking into account most of our preliminary comments on the draft chapter below. However, the Members provide additional comments to Article 4.Z.3., to Article 4.5.Z and to Article 4.6.Z. In parallel with this process, we intend to work with the European Food Safety Authority (EFSA), to obtain a Scientific Opinion which will describe the various elements which are necessary to underpin safe trade in genetic material of aquaculture animals. Ultimately, our final views on Chapter 4.Z. will be guided by that Scientific Opinion.	Noted.

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

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

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.;

Reference	Comment	Aquatic Animals Commission Response
4.Z.3._1	**Category**: change **Proposed amended text**: 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	Agreed. Text amended for clarity.

	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 the Member therefore suggests rephrasing part of this sentence to specify that the broodstock should test negative for the pathogenic agent of concern.	

1) *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.;

Reference	Comment	Aquatic Animals Commission Response
4.Z.3._2	**Category**: addition **Proposed amended text**: 2) *gametes*~~milt~~ and *fertilised eggs* should finally 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.; **Rationale:** The rationale is to make it clear that gametes and fertilised eggs can only be subject to trade when they are originated from a collection and incubation centre and not directly from the aquatic establishment where the broodstock is kept.	Did not agree. Broodstock may come from another establishment prior to entry into the collection and incubation centre; however, all gametes and fertilised eggs for trade will come from collection and incubation centres. Thus the point is considered clear as written.

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* 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.

Reference	Comment	Aquatic Animals Commission Response
4.Z.3._3	**Category**: addition, change **Proposed amended text**: 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 *individually* tested ~~free from~~ *negative for* the relevant ~~*disease*~~ *pathogenic agents*, and which meet the requirements in points 1, ~~and~~ 2 and 4.	Agreed. Amended the point to require individual testing for the pathogenic agents of concern. This is to improve clarity and ensure consistency with point 2 of Article 4.Z.6.

	Rationale: To improve clarity and ensure consistency with point 2 of Article 4.Z.6 the Member 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;

Reference	Comment	Aquatic Animals Commission Response
4.Z.4._1	**Category**: Addition **Proposed amended text**: 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.	Did not agree. Chapter 4.Z. clearly specifies the testing requirements and additional requirements for an official surveillance programme are not needed. Official surveillance programme is not defined in the *Aquatic Code* and as such this would add an undefined requirement.

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

Reference	Comment	Aquatic Animals Commission Response
4.Z.4._2	**Category:** Editorial **Proposed amended text:** it should implement~~have in place~~ a *biosecurity plan* which has been ~~drawn up~~ developed in accordance with Chapter 4.1.; **Rationale:** To align with the wording in Chapter 4.1.	Agreed. Text amended for alignment 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*;

Reference	Comment	Aquatic Animals Commission Response
4.Z.4._3	**Categoría: Cambio** **Texto modificado propuesto:** 3) las poblaciones reproductoras deberán ser sometidas a pruebas de detección de los agentes patógenos de preocupación ~~lo más cerca posible~~ en un plazo no mayor a 30 días de la fecha de entrada ~~antes de entrar en e al~~ centro de *recolección e incubación* utilizando una muestra lo suficientemente grande como para ~~con el fin de~~ demostrar, con un 95% de fiabilidad, que el agente patógeno se detectaría si estuviera presente por encima de una prevalencia del 2% utilizando los métodos de diagnóstico previstos en el *Manual Acuático.* Si los resultados de estas pruebas son positivos, las poblaciones reproductoras no deberán trasladarse al centro de *recolección e incubación*; **Justificación:** El plazo "lo más cerca posible" puede interpretarse de diferentes maneras, por lo que es importante contar con un plazo acotado de manera que la vigilancia represente el estatus sanitario del momento. Se propone este plazo netamente por la experiencia que se ha tenido con el programa de vigilancia y control del virus ISA.	Agreed. The period before the broodstock entry into the collection and incubation centre needs to better defined and point has been changed to clarify what is meant by 'as close as possible'. The period of 30 days provides enough time for testing including cell culture if necessary, receiving results and other logistics required for transport of multiple batches of broodstock.
4.Z.4._4	**Category**: change **Proposed amended text**: 3) prior to entering the *collection centre* and/or the *incubation centre*, the broodstock should demonstrate equal or higher health status for the *pathogenic agents* of concern; this may be accomplished by either: a) ~~be~~ test~~ed~~ the broodstock 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*; or b) source the broodstock from *aquaculture establishments* that have demonstrated freedom from the *pathogenic agents* of concern in accordance with the *Aquatic Code* at the premises, compartment, zone, or country level. **Rationale:** We disagree with the intent of statement 3 as written. In our view, the important point we are trying to make here is that any broodstock entering the collection/incubation center should be sourced from a population with a known health status for the pathogens of concern AND that health status should be equal or higher to the health status of the animals in the collection/incubation center. This could be accomplished via testing prior to movement (as suggested) or based on freedom claims at the premises/compartment/zone/country levels. One example for not testing prior to movement (as suggested) could be due to the value of the broodstock; in many cases, broodstock are a highly valuable life stage and, since there are not many non-lethal methods available, would therefore require lethal sampling for the pathogens of concern prior to movement.	Did not agree. The proposed changes of sourcing broodstock from establishments that have demonstrated freedom from pathogenic agents of concern do not fit with the purpose of the chapter. Chapter 4.Z. is intended to allow safe trade into a free country, zone or compartment from an establishment in a country, zone or compartment which may not be free from a disease. The import from establishments in countries, zones or compartments which are free from listed diseases are covered by other chapters in the *Aquatic Code* and do not need to be included in this chapter.

	We therefore suggest amending the language in statement 3 to maintain the premise that all animals entering a collection/incubation center should have an equivalent or higher health status compared to the animals already in the center, while also allowing flexibility in how this equivalency is determined.	

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.

Reference	Comment	Aquatic Animals Commission Response
4.Z.4._5	**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.	Did not agree. The definition of disease in the Glossary is 'clinical or non-clinical infection with one or more pathogenic agents' and thus refers to the pathogenic agents of concern as written.

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 aquatic animal health its operation;

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

Reference	Comment	Aquatic Animals Commission Response
4.Z.5._1	**Category:** editorial **Proposed amended text:** 2) implement~~have~~ a *biosecurity plan* which has been ~~drawn up~~ developed in accordance with Chapter 4.1.; **Rationale:** To align with the wording in Chapter 4.1.	Agreed. Text amended for alignment 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*~~;

Reference	Comment	Aquatic Animals Commission Response
4.Z.5._2	**Categoría:** Adición **Texto modificado propuesto:** 4) disponga de un sistema~~ de trazabilidad válido~~ que garantice que el semen ~~cada lote de gametos~~ o las ovas fecundadas ~~huevos fecundados~~ puedan rastrearse hasta un grupo o individuo separado epidemiológicamente, y que incluya la documentación ~~y auditoría~~ de los resultados de las pruebas, ~~el historial de la enfermedad y los desplazamientos de los animales acuáticos;~~ Cuando el sistema solo permita el rastreo al grupo y no al individuo, las medidas señaladas en el apartado 4.Z.6 numeral 5 deben aplicarse al grupo. **Justificación:** El propósito de este anexo es el control de los agentes patógenos en los gametos y las ovas fecundadas y el comercio seguro, por tanto es importante contar con información de los reproductores a nivel individual**.** **Evidencia de apoyo:** Res. Ex N° 70/2003 Programa Sanitario General de manejo sanitario de la reproducción de peces (Normativa vigente en Chile)	Agreed. The suggested addition point: 'where the system only allows tracking to the group and not to the individual level, the measures referred to in point 4 should apply to the group' is important. This suggestion was included in the new Article 4.Z.6. 'Biosecurity conditions applicable to collection and incubation centres'.
4.Z.5._3	**Category:** Change **Proposed amended text:** 4) has~~have in place~~ a ~~valid traceability~~ system in place to ensure that ~~milt~~~~each batch of gametes~~gametes or fertilised eggs can be traced back to an epidemiologically separate individual or group, and which includes~~include~~ documentation ~~and auditing~~ of tes~~ting~~ results, ~~disease history and movements of aquatic animals;~~ **Rationale:** According to the scope of this chapter, the requirement on traceability should cover gametes (milt and unfertilised eggs) as well as fertilised eggs. **Supporting evidence:** not relevant	Agreed. As per the scope of Chapter 4.Z., the requirement on traceability should cover gametes as well as fertilised eggs.

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~~.

Reference	Comment	Aquatic Animals Commission Response

4.Z.5._4	**Categoría:** Adición **Texto modificado propuesto:** 5) esté conformado por áreas dedicadas para: a) el mantenimiento de los reproductores antes de la recolección de semen; b~~a~~) una ~~sala de colecta~~ colección de ovas ~~huevos~~ y semen ~~lecha~~ c) pruebas y almacenamiento de semen; d) desinfección de ovas fecundadas; ~~e~~b) ~~un centro de~~ incubación de ovas fecundadas ~~huevos fecundados~~; ~~e) un laboratorio de lecha y una zona de almacenamiento de lecha~~; ~~f~~d) administración ~~oficinas administrativas~~ g) área exclusiva y aislada para acopio de productos y residuos de animales acuáticos **Justificación:** Es relevante contar con una zona aislada de las poblaciones de animales acuáticos para minimizar los riesgos de transmisión de enfermedades, en concordancia con el capítulo 1.4 del código sanitario. **Evidencia de apoyo:** Capítulo 1.4 del código sanitario.	Agreed. Having a dedicated location for waste is an important biosecurity consideration. This suggestion was included in the new Article 4.Z.6. 'Biosecurity conditions applicable to collection and incubation centres'.

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.

Reference	Comment	Aquatic Animals Commission Response
4.Z.5._5	**Category**: addition **Proposed amended text**: uses water from a source without contact to wild or farmed susceptible species known or suspected of being infected with the pathogenic agent. **Rationale:** The Members propose a new point 7) in Article 4.Z.5., as regards the requirements for the water source of the collection and incubation centres.	Agreed. Ensuring the water is pathogen free is an important biosecurity consideration. This suggestion was included in the new Article 4.Z.6. 'Biosecurity conditions applicable to collection and incubation centres'.

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*;

Reference	Comment	Aquatic Animals Commission Response
4.Z.6._1	**Category:** clarification **Proposed amended text** stripping and sampling should be carried out under the ~~supervision~~ oversight of the *Aquatic Animal Health Professional* or *veterinarian* who has responsibility for the *collection and incubation centre*; **Rationale:** Supervision implies that the aquatic animal health professional/veterinarian needs physically observe the whole process whereas oversight allows the veterinarian to approve SOPs and periodically validate onsight that they are being followed. If physical supervision is required during the entire process, then it forces a facility to have more than one veterinarian/aquatic animal health profession present on site since the same veterinarian/aquatic animal health professional would not be able to supervise both the stripping and the sampling/testing of the broodstock as these events typically occur simultaneously in industry.	Agreed. Oversight is a more appropriate term to supervision. Supervision implies that the aquatic animal health professional or veterinarian needs to physically observe the whole process. Oversight allows the veterinarian to approve SOPs and periodically validate their application onsite.
4.Z.6._2	**Category**: change **Proposed amended text**: ~~stripping and~~ sampling should be carried out under the supervision of the *Aquatic Animal Health Professional*, *Aquatic Animal Health Services* or *veterinarian* who has responsibility for the *collection and incubation centre*; **Rationale:** We suggest removing "stripping and" because not all broodstock testing may include/require stripping. Additionally, and we recommend expanding the level of supervision to include aquatic animal health services, in addition to a veterinarian or aquatic animal health professional, to allow more flexibility to member countries regarding who supervises this activity on behalf of the Competent Authority.	Did not agree. In the current context of the chapter, the term stripping is correct as it applies to salmonids. See the February 2024 report for the rationale of the application of Chapter 4.Z. only to the salmonid diseases. Further, Aquatic Animal Health Services are too broad a category of individuals and training to be the ones supervising the stripping and sampling.

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*;

Reference	Comment	Aquatic Animals Commission Response
4.Z.6._3	**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.	Did not agree. See response to 4.Z.4._5
4.Z.6._4	**Category**: change **Proposed amended text**:	Did not agree. See response to 4.Z.6._2.

	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*; **Rationale:** We suggest the edits above because not all broodstock testing may include/require stripping and, depending on the pathogen of concern, the pooling of samples for testing may be permissible based on the pathogen-specific guidance provided in the *Aquatic Manual*.	

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;

Reference	Comment	Aquatic Animals Commission Response
4.Z.6._5	**Category:** change **Proposed amended text :** 4）details of the results from testing relevant cohorts of broodstock as described in ~~paragraph 1~~point 2）should be provided to the Competent Authority of an importing country on request; **Rationale:** The "testing relevant cohorts of broodstock " is mentioned in point 2) of this article, not in paragraph 1.	Agreed.

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;

Reference	Comment	Aquatic Animals Commission Response
4.Z.6._6	**Category:** addition **Proposed amended text:** 5) in accordance with the *biosecurity plan* for the *collection and incubation centre,*~~and~~ all gametes and/or fertilized eggs 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; **Rationale:** Disease testing results may not be available until after fertilization of the eggs has occurred. Fertilized eggs should also be included within this point as they should be disposed of in the event of a positive result.	Agreed. Include fertilised eggs as well as gametes as testing results may not be available until after fertilisation has occurred, and all gametes and/or fertilised eggs should be discarded in the event of a positive test result.
4.Z.6._7	**Categoría: Adición y Supresión** **Texto modificado propuesto:** 5) de acuerdo con el plan de bioseguridad del centro de *recolección e incubación*, todos los gametos y peces ~~del grupo~~	Agreed. The suggested addition point: 'if incubation is not carried out individually and a positive individual is detected, all eggs that were

	~~epidemiológico~~ que hayan dado positivos deberán eliminarse de forma biosegura de acuerdo al capítulo 4.8, dejando un registro de esta actividad. Las instalaciones afectadas, así como los equipos y utensilios que tuvieron contacto con el grupo epidemiológico positivo, deberán desinfectarse para garantizar que no se produzca ninguna contaminación cruzada de otros lotes de semen o de ovas fecundadas. La desinfección deberá ser realizada según las recomendaciones del capítulo 4.4. Si la incubación no es realizada a nivel individual y se detecta un individuo positivo, deberán eliminarse todas las ovas que fueron incubadas conjuntamente. **Justificación:** No queda claro qué se entendería por "grupo epidemiológico", se propone suprimir o bien agregar su definición al glosario. En otros párrafos de este anexo solo se menciona grupo, por lo que es importante que el término a utilizar sea estandarizado. Es importante que los procedimientos mencionados en este anexo se realicen de una manera estandarizada que asegure su efectividad, por lo anterior, se sugiere que se realicen de acuerdo a las recomendaciones de los capítulos de la OMSA. En este caso, la eliminación de los gametos positivos debe realizarse según el capítulo 4.8 y la desinfección del establecimiento, equipos y utensilios de acuerdo al capítulo 4.4 Cabe comentar que, en caso de positividad de un reproductor podría existir contaminación de las ovas que se estén incubando conjuntamente. **Evidencia de apoyo:** Capítulo 4.4 Desinfección de establecimientos y equipos de acuicultura. Capítulo 4.8 Manipulación, eliminación y tratamiento de residuos de animales acuáticos	incubated together must be removed' is important. This suggestion was included in the new Article 4.Z.6. 'Biosecurity conditions applicable to collection and incubation centres'.

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

Reference	Comment	Aquatic Animals Commission Response
4.Z.6._8	**Category**: addition **Proposed amended text**: *6) fertilised eggs* should be surface disinfected using a method proven to inactive *pathogenic agents*, for salmonid eggs as described in Chapter 4.5. and kept in water known to be free of the pathogenic agent **Rationale:** None provided.	Did not agree. The protocol to be followed, including that the water used must be pathogen free, is described in Chapter 4.5. Text added to clarify where the protocol can be found.

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*;

Reference	Comment	Aquatic Animals Commission Response
4.Z.7._1	**Category**: General **Proposed amended text**: N/A at this stage **Rationale:** The Members 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?	Agreed. Text amended to clarify that diluents used should be pathogen free.

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

Reference	Comment	Aquatic Animals Commission Response
4.Z.7._2	**Category**: General **Proposed amended text**: N/A at this stage **Rationale:** The Member suggests that the Aquatic Animal Commission specifies minimum temperature requirements for the storage of the frozen milt.	Agreed. Text amended to clarify that milt should be stored at species-specific optimal temperatures to maintain their viability.

_____

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'

Reference	Comment	Aquatic Animals Commission Response
10.X.10._1	**Category:** general The Member supports the proposed changes	Noted.
10.X.10._2	**Category:** General The Member supports these proposed Model Articles.	Noted.
10.X.10._3	**Category**: general The Members thank the Aquatic Commission for this proposed model Article. Ultimately, our final views on Model Article 10.X.10. will be guided by the future Scientific Opinion of EFSA, as per our earlier comments on Annex 42.	Noted.

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]

[…]

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.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 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.~~

[…]

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'

Reference	Comment	Aquatic Animals Commission Response
10.X.10._1	**Category:** general The Member supports the proposed changes	Noted.
10.X.10._2	**Category:** General The Member supports these proposed Model Articles.	Noted.
10.X.10._3	**Category**: general Our final views on Model Article 10.X.10. will be guided by the future Scientific Opinion of EFSA, as per our earlier comments on Annex 42.	Noted.

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]

[…]

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.~~

[…]

Glossary

Reference	Comment	Aquatic Animals Commission Response
Glossary_1	**Category:** general The Member supports the proposed glossary definitions and thanks the Commission for the additional clarity with the proposed modifications to the definition of fertilized egg.	Noted.
Glossary_2	**Category:** General The Member supports the proposed changes to the Glossary.	Noted.
Glossary_3	**Category**: general The Members support these new glossary terms.	Noted.

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.

Reference	Comment	Aquatic Animals Commission Response
Glossary_4	**Category:** Editorial **Proposed amended text:** …means the sperm (contained within seminal fluid or milt) ~~or~~ and unfertilised eggs of aquatic animals that are held or transported separately prior to fertilisation. **Rationale:** To clarify that this definition covers both male and female reproductive cells.	Did not agree. The definition as written covers both male and female reproductive cells.

Glossary_5	**Category:** Change **Proposed text amendment:** FERTILISED EGG means a viable fertilised ovum of an aquatic animal. ~~'Green eggs'~~ 'Uneyed 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 ('Green eggs') of aquatic animals that are held or transported separately prior to fertilisation. **Rationale:** 'Green eggs' is most commonly used to refer to unfertilised ova, while 'Uneyed eggs' refers to newly fertilised ova.	Agreed with replacing 'green eggs' by 'uneyed eggs' in the definition for 'fertilised eggs' however did not agree to add 'green eggs' to the definition for 'gametes'. The term 'green eggs' has varying definitions in different regions and should therefore not be used.

[...]

ORNAMENTAL AQUATIC ANIMAL

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

[...]

Draft new Chapter 5.X. 'Movement of ornamental aquatic animals'

Reference	Comment	Aquatic Animals Commission Response
5.X._1	**Category**: general The Member strongly supports the development of the Chapter 5.X on the movement of ornamental aquatic animals, recognising that this chapter provides high level guidance for the management of disease risk associated with the ornamental aquatic animal trade. The Member welcomes WOAH's support and guidance in managing these risks on a global scale. The Member previously provided comments on the first draft of this Chapter provided in the September 2023 Report. We acknowledge and support the changes that have since been made to the draft chapter that incorporate the specific comments that have been made by members. These changes provide further clarity and address some unintended information gaps. For example, reference to international air transport association regulations for the transport of live animals; clarity on traceability of imported ornamental aquatic animals to commercial establishments, and, mention of morbidity or mortality of animals not related to disease as an animal welfare issue during transport.	Noted
5.X._2	**Category**: general The Member supports the proposed chapter and has inserted some comments within the chapter.	Noted
5.X._3	**Category:** General The Member supports the proposed draft new Chapter.	Noted
5.X._4	**Category**: general The Members thank the AAC and supports this new initiative.	Noted
5.X._5	**Category**: general The Members thank the Aquatic Animal Health Standards Code Commission (Aquatic Code Commission) for their work in developing the new draft Chapter 5.X. Movement of ornamental aquatic animals	Noted

SECTION 5

TRADE MEASURES, IMPORTATION/EXPORTATION PROCEDURES AND HEALTH CERTIFICATION

CHAPTER 5.X.

MOVEMENT OF ORNAMENTAL AQUATIC ANIMALS

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*.

Reference	Comment	Aquatic Animals Commission Response
5.X.1._1	**Category**: editorial **Proposed amended text**: ~~*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. *Ornamental aquatic animals* may originate from the wild or from *aquaculture establishments*. Supply chains may involve the aggregation of animals from multiple sources and their dissemination through retail trade as pets, providing opportunities for *disease* transmission and place other populations of susceptible species at risk. Once they have entered the supply chain they may be epidemiologically	Did not agree, text is clear as written.

	separated from farmed or wild populations but can be diverted to other end uses for which they were not intended. These characteristics of the movement of *ornamental aquatic animals* may present challenges for managing *aquatic animal disease risks*. **Rationale:** The second and third paragraphs of this section are very similar/ related; we therefore suggest the edits above to improve the flow of this section and avoid duplications.	

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.~~

Reference	Comment	Aquatic Animals Commission Response
5.X.2._1	**Category**: addition **Proposed amended text**: This chapter provides recommendations for managing the pathogen~~*disease*~~ *risks* associated with movement of any life stage of live *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 live *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.~~ **Rationale:** To distinguish from dead ornamental aquatic animal commodities (e.g. dried coral and shells).	Did not agree, the Glossary definition of aquatic animal disease 'means all viable life stages (including eggs and gametes) of fish, molluscs, crustaceans and amphibians originating from aquaculture establishments or from the wild'. The definition distinguishes that the animals are alive.
5.X.2._2	**Category**: deletion **Proposed amended text**: 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.~~ **Rationale:** We request the removal of "or other diseases identified as hazards" because that language goes beyond the scope of WOAH guidance. While there may be other diseases of concern to a given population, WOAH should only be making recommendations for listed pathogens of concern +/- emerging diseases. This suggestion is in alignment with other WOAH chapters.	Did not agree, text in Article 5.X.2. indicates that this chapter provides additional guidance on these hazards. The principles of Chapter 2.1. provide detail on how to identify hazards and complete risk assessment on these hazards. Throughout the *Aquatic Code* there are references to different hazards and the use here is appropriate.

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.;

Reference	Comment	Aquatic Animals Commission Response
5.X.3._1	**Category:** deletion **Proposed amended text** ~~1) the legalityeligibility 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.;~~ **Rationale:** The Member would like to reiterate that point 1 should be deleted from Article 5.X.3. The restrictions on trade to protect biodiversity and ecosystems are not "*disease* transmission" risk mitigations and fall outside of the scope of this chapter as outlined in Article 5.X.2. Restriction for biodiversity and ecosystems are already in place through member countries internal conservation laws, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or other national Competent Authorities. The competent authorities that have the legislative authority to control imports and certify exports for disease health status, may not be the Authority to control trade for ecological reasons. The Member is of the opinion that the requirement to ensure all import requirements are met, including CITES, alien invasive species, food safety concerns etc should be that of the importer and not the Competent Authority. Putting this responsibility onto the Competent Authority for Aquatic Animal Health then puts the onus on the Competent Authority for Aquatic Animal Health for items outside its responsibility or mandate and for which it likely does not have the regulatory authority. The Member is of the opinion that this importer responsibility is no different for ornamental aquatic animals than for any other aquatic animal traded for other end uses in the code. For example, CITES permits are not only required for live ornamental aquatic animals but for trade of an endangered species for any purpose, even products that meet the requirements for safe commodities. Inclusion of this point solely for movement of ornamental aquatic animals creates an inconsistency in the Aquatic Code.	Did not agree to delete point 1 in article 5.X.3. or Article 5.X.4., as the eligibility of an import is an important concern that should be duly considered prior to the import process. However, agreed that this consideration is not the responsibility of the Competent Authority but is the responsibility of the importer prior to initiating the import. The text was amended in point 1 of Article 5.X.3. and the first paragraph of 5.X.4. to clarify that the importer is responsible for determining the legality of the import such as whether the species is listed in CITES or is on an endangered or preserved species list by a Competent Authority.
5.X.3._2	**Category:** deletion **Proposed amended text:** Regarding Article 5.X.3.1. that reads:	See response to comment 5.X.3._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.;~~ **Rationale:** The Members request the deletion of the entirety of this point because it is outside of the scope of the chapter as outlined in Article 5.X.1. This chapter is intended to prevent the introduction and spread of disease, and the eligibility for import and potential impacts to biodiversity and ecosystem impacts does not fall within this scope. We are also of the opinion that the requirement to ensure all import requirements are met, including CITES, alien invasive species, food safety concerns etc should be that of the importer and not the Competent Authority. Putting this responsibility onto the Competent Authority for Aquatic Animal Health then puts the onus on the Competent Authority for Aquatic Animal Health for items outside its responsibility or mandate and for which it likely does not have the regulatory authority. This importer responsibility is no different for ornamental aquatic animals than for any other live aquatic animal traded for other end uses in the Aquatic Code. For example, CITES permits are not only required for live ornamental aquatic animals and the requirement to determine eligibility to import also applies to aquatic animal products. For example, the trade of an endangered species for any purpose, even products that meet the requirements for safe commodities, requires a CITES permit. Inclusion of this point solely for movement of ornamental aquatic animals potentially creates an inconsistency in the Aquatic Code. Respecto del Artículo 5.X.3.1. que dice: ~~La legalidad elegibilidad para el movimiento de una especie (o un grupo taxonómico de especies) deberá determinarse en base a las medidas reglamentarias existentes en el país importador su estado de conservación (por ejemplo, especies cubiertas por la Convención sobre el Comercio Internacional de Especies Amenazadas de Fauna y Flora Silvestres, CITES) yen base a los impactos potenciales sobre la biodiversidad y el ecosistema en el país importador (por ejemplo, la posibilidad de convertirse en una especie exótica invasora), como se describe en el Artículo 5.X.4.;~~ Los miembros solicitan la eliminación total de este punto porque está fuera del alcance del capítulo previsto en el Artículo 5.X.1. Este capítulo tiene como objetivo prevenir la introducción y propagación de enfermedades, y la elegibilidad para la importación y los posibles impactos a la biodiversidad y los ecosistemas no entran dentro de este alcance. También somos de la opinión de que el requisito de garantizar que se cumplan todos los requisitos de importación, incluidos los de la CITES, las especies exóticas invasoras, las preocupaciones sobre la seguridad alimentaria, etc., debería ser responsabilidad del importador y no de la autoridad competente. Al asignar esta responsabilidad a la Autoridad Competente de Sanidad de los Animales Acuáticos, la responsabilidad recae sobre la Autoridad Competente de Sanidad de los Animales Acuáticos respecto de elementos que escapan a su responsabilidad o mandato y para los	

	cuales probablemente no tiene la autoridad regulatoria. Esta responsabilidad del importador no es diferente para los animales acuáticos ornamentales que para cualquier otro animal acuático vivo comercializado para otros usos finales en el Código Acuático. Por ejemplo, los permisos CITES no sólo se requieren para animales acuáticos ornamentales vivos y el requisito de determinar la elegibilidad para importar también se aplica a productos de animales acuáticos. Por ejemplo, el comercio de una especie en peligro de extinción para cualquier propósito, incluso productos que cumplan con los requisitos de seguridad, requiere un permiso CITES. La inclusión de este punto únicamente para el movimiento de animales acuáticos ornamentales crea potencialmente una inconsistencia en el Código Acuático.	

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.;

Reference	Comment	Aquatic Animals Commission Response
5.X.3._3	**Category:** editorial **Proposed amended text** *3) risk management* measures for *listed diseases*, as described in Article 5.X.6., 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*, as described in Article 5.X.7., 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, as described in Articles 5.X.8. to 5.X.11. 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.;~~ **Rationale:** For readability, the cross reference should occur adjacent to the text it supports rather than at the end of the paragraph.	Did not agree, clear as written.
5.X.3._4	**Categoría:** Edición **Texto modificado propuesto** 5) Todas las medidas de *gestión del riesgo* deberán ser lo ~~menos~~ suficientemente restrictivas ~~posibles~~ con el fin de mitigar los riesgos de *enfermedad* identificados por una *evaluación del riesgo*, tal como se describe en los Artículos 5.X.8. a 5.X.11.	Agreed, amended to clarify that measures should be 'least trade restrictive' as the intention is to mitigate identified risks.

	Justificación: Mejorar la comprensión de la importancia de implementar medidas para mitigar los riesgos identificados.	

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*.

Reference	Comment	Aquatic Animals Commission Response
5.X.4._1	**Category:** deletion **Proposed amended text:** ~~**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*.~~ **Rationale:** The Member would like to reiterate that point 1 should be deleted from Article 5.X.3. The restrictions on trade to protect biodiversity and ecosystems are not "*disease* transmission" risk mitigations and fall outside of the scope of this chapter as outlined in Article 5.X.2. Restriction for biodiversity and ecosystems are already in place through member countries internal conservation laws, the	Did not agree to delete text (see response to comment 5.X.3._1.). The text was amended in point 1 of Article 5.X.3. and the first paragraph of 5.X.4. to clarify that the importer is responsible for determining the legality of the import such as whether the species is listed in CITES or is on an endangered or preserved species list by a Competent Authority.

	Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or other national Competent Authorities. The competent authorities that have the legislative authority to control imports and certify exports for disease health status, may not be the Authority to control trade for ecological reasons. The Member is of the opinion that the requirement to ensure all import requirements are met, including CITES, alien invasive species, food safety concerns etc should be that of the importer and not the Competent Authority. Putting this responsibility onto the Competent Authority for Aquatic Animal Health then puts the onus on the Competent Authority for Aquatic Animal Health for items outside its responsibility or mandate and for which it likely does not have the regulatory authority. The Member is of the opinion that this importer responsibility is no different for ornamental aquatic animals than for any other aquatic animal traded for other end uses in the code. For example, CITES permits are not only required for live ornamental aquatic animals but for trade of an endangered species for any purpose. Inclusion of this point solely for movement of ornamental aquatic animals creates an inconsistency in the Aquatic Code.	
5.X.4._2	**Category**: deletion **Proposed amended text**: 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*.~~ **Rationale:** This language should be removed from this chapter as WOAH guidelines should be focused on aquatic animal health and science. Whether a species is considered "invasive" is outside of the scope of WOAH.	See response to comments 5.X.3_1 and 5.X.4._1.
5.X.4._3	**Category:** deletion We are also requesting the deletion of the entire Article 5.X. 4 that reads: **Proposed amended text:** ~~**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~~	See response to comments 5.X.3_1 and 5.X.4_1.

	~~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.~~ **Rationale:** The rationale for deleting this entire article is that this point is outside of the scope of the chapter as outlined in Article 5.X.1. This chapter is intended to prevent the introduction and spread of disease, and the eligibility for import and potential impacts to biodiversity and ecosystem impacts does not fall within this scope. We are also of the opinion that the requirement to ensure all import requirements are met, including CITES, alien invasive species, food safety concerns etc. should be that of the importer and not the Competent Authority. Putting this responsibility onto the Competent Authority for Aquatic Animal Health then puts the onus on the Competent Authority for Aquatic Animal Health for items outside its responsibility or mandate and for which it likely does not have the regulatory authority. We are of the opinion that this importer responsibility is no different for ornamental aquatic animals than for any other live aquatic animal traded for other end uses in the code. For example, CITES permits are not only required for live ornamental aquatic animals and the requirement to determine eligibility to import also applies to aquatic animal products. For example, the trade of an endangered species for any purpose, even products that meet the requirements for safe commodities, requires a CITES permit. Inclusion of this point solely for movement of ornamental aquatic animals potentially creates an inconsistency in the Aquatic Code. También solicitamos la eliminación de todo el Artículo 5.X. 4 que dice: ~~**Elegibilidad de los animales acuáticos ornamentales para el movimiento internacional**~~ ~~Antes de considerar los riesgos para la sanidad de los animales acuáticos asociados a la importación de una especie de animal acuático ornamental, la autoridad competente de un país importador deberá determinar que la importación de la especie respeta consultar la reglamentación nacional pertinente y las obligaciones internacionales con el fin de determinar si la especie reúne todas las condiciones para la importación. Por ejemplo, Llas especies de animales acuáticos ornamentales pueden estar sujetas a controles de circulación o comercio internacionales debido a su estatus de conservación (por ejemplo, las incluidas en la CITES) o que forman parte de las especies en peligro de extinción o de las especies preservadas por una autoridad competente u otras autoridades de un país importador). Dichos controles tienen la potestad de prohibir los movimientos internacionales o exigir una documentación adicional para la importaci6n.~~ ~~Además, una autoridad competente u otra autoridad de un país importador podrá identificar como invasoras a las especies de~~	

	~~animales acuáticos ornamentales (o grupos taxonómicos de especies). Es posible prohibir el comercio, la propiedad o la cría de estas especies debido a los riesgos que representan para la biodiversidad, los ecosistemas, la industria, o las actividades públicas de ocio o de salud pública en el país importador.~~ La razón para eliminar este artículo completo es que este punto está fuera del alcance del capítulo como se describe en el Artículo 5.X.1. Este capítulo tiene como objetivo prevenir la introducción y propagación de enfermedades, y la elegibilidad para la importación y los posibles impactos a la biodiversidad y los ecosistemas no entran dentro de este alcance. También somos de la opinión de que el requisito de garantizar que se cumplan todos los requisitos de importación, incluidos los de la CITES, las especies exóticas invasoras, las preocupaciones sobre la seguridad alimentaria, etc., debería ser responsabilidad del importador y no de la autoridad competente. Al asignar esta responsabilidad a la Autoridad Competente de Sanidad de los Animales Acuáticos, la responsabilidad recae sobre la Autoridad Competente de Sanidad de los Animales Acuáticos respecto de elementos que escapan a su responsabilidad o mandato y para los cuales probablemente no tiene la autoridad regulatoria. Somos de la opinión de que esta responsabilidad del importador no es diferente para los animales acuáticos ornamentales que para cualquier otro animal acuático vivo comercializado para otros usos finales en el código. Por ejemplo, los permisos CITES no sólo se requieren para animales acuáticos ornamentales vivos y el requisito de determinar la elegibilidad para importar también se aplica a productos de animales acuáticos. Por ejemplo, el comercio de una especie en peligro de extinción para cualquier propósito, incluso productos que cumplan con los requisitos de seguridad, requiere un permiso CITES. La inclusión de este punto únicamente para el movimiento de animales acuáticos ornamentales crea potencialmente una inconsistencia en el Código Acuático.	

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.

Reference	Comment	Aquatic Animals Commission Response
5.X.5._1	**Category**: addition **Proposed amended text**: The *Aquatic Animal Health Services* including industry relevant to meeting *importing country* requirements should comply with the principles of Chapter 3.1.	Did not agree, in this context it is referencing the need to meet an importing country's requirements. As such Aquatic Animal Health Services as defined 'means the combination of governmental and non-governmental individuals and organisations that perform activities

	Rationale: Industry should also be responsible for complying with these requirements.	to implement the standards of the *Aquatic Code*' in the Glossary applies.

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.

Reference	Comment	Aquatic Animals Commission Response
5.X.5._2	**Category:** Change **Proposed amended text:** ~~If~~ A~~a~~*quaculture establishments* should be ~~are~~ required by the *Competent Authority* to develop and 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. **Rationale:** Biosecurity plans should be required of any facility wanting to do international trade to minimise.	Did not agree, while a biosecurity plan is always recommended, it may not be required by the Competent Authority of a country or that of the exporter.

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*.

Reference	Comment	Aquatic Animals Commission Response
5.X.8._1	**Categoría:** Edición **Texto modificado propuesto**: La autoridad competente del país importador deberá seleccionar las medidas ~~menos~~ suficientemente restrictivas necesarias para atenuar los riesgos de enfermedad identificados mediante una evaluación del riesgo.	Agreed, see response for comment 5.X.3._4.

	Justificación: Mejorar la comprensión de la importancia de seleccionar medidas para atenuar los riesgos identificados. **Evidencia documentada, si corresponde:** No corresponde	

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.;

Reference	Comment	Aquatic Animals Commission Response
5.X.9._1	**Category**: addition **Proposed amended text**: 2) confirmation that the exported *ornamental aquatic animals* are free from signs of *disease* or unexplained mortality at the place of ~~origin~~ export in the exporting country (as described in point 2 of Article 5.X.7.) and meet general health requirements in accordance with Article X.X.5.; **Rationale:** The term "origin" may be confusing. The place from where fish are exported, as described in point 2 of Article 5.X.7, could be a different place to the place of origin as described in point 1 of Article 5.X.7 which describes the country, zone or compartment of origin. Probably "the place of origin" for ornamental fish trade is misleading. Suggested changes to text above to make clear that point 2 refers to the place in the exporting country from where the fish are exported.	Agreed that the term origin may be confusing, text was amended for clarity to indicate 'aquaculture establishment from which they were exported'.

5.X.9._2	**Category:** change **Proposed amended text:** 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 5 ~~X~~.X.5.; **Rationale:** To include the appropriate cross-reference. Article X.X.5. Country free from Infection with [Pathogenic agent] would not be the appropriate reference here.	Agreed, reference to Article 5.X.5. is the appropriate reference.

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;

Reference	Comment	Aquatic Animals Commission Response
5.X.9._3	**Category**: addition **Proposed amended text**: 6) appropriate packaging (including packaging water) of *ornamental aquatic animals* to maintain their health status for the expected duration and conditions of the transport; **Rationale:** Packaging waters harbour disease risks.	Did not agree, the appropriate packaging for ornamental aquatic animals includes water and does not need to be specified.

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.

Reference	Comment	Aquatic Animals Commission Response
5.X.9._4	**Category**: addition **Proposed amended text**: 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. The certification should include information on pre-export application on veterinary medicines. **Rationale:** The information is necessary to assess if the fish are treated with antibiotics and other veterinary medicine to mask clinical signs of important diseases.	Agreed that risk management should include a requirement that ornamental aquatic animals not be treated with medicine that can mask clinical disease. However, this Article is not intended to be specific about what is on the certificate. A new point 7 was added to provide requirement around pharmacological therapies.
5.X.9._5	**Categoría: Adición**	Did not agree to add new point 8 around transport water and ice

	Texto modificado propuesto: 8) Garantías que el agua de transporte y el hielo en caso de que se utilice, se encuentre libre de patógenos. 9) En caso de cambios en el estatus sanitario respecto de las enfermedades de declaración obligatoria a la OMSA, o de importancia para el país de destino deberá ser informado de manera inmediata por la autoridad competente del país exportador al país importador. 10) Garantías oficiales que indiquen que los animales no fueron objeto de terapias farmacológicas que pudiesen enmascara signos clínicos de una enfermedad **Justificación:** Estos principios generales permiten mitigar el riesgo de transmisión de patógenos en el comercio internacional de especies ornamentales. **Evidencia de apoyo:** DS N° 72 //2012 Reglamento de certificación y otros requisitos sanitarios para la importación de especies hidrobiológicas	being pathogen free as this is covered in point 6 on appropriate packaging. Did not agree to add new point 9 on notification on changes in Health status of exporting country. This point is covered in point 1 of Article 5.1.4. of Chapter 5.1. 'General obligations related to certification'. Agreed with requirement that aquatic animals not be treated to mask disease, see response to comment 5.X.9._3.

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*.

Reference	Comment	Aquatic Animals Commission Response
5.X.12._1	**Category: change** **Proposed amended text:** Transport of *ornamental aquatic animals* in conditions that are not suited to their biological characteristics may increase morbidity or mortality, vulnerability to infection, ~~and~~ the development of clinical *disease*~~,~~ and lead~~ing~~ to an increased likelihood of *disease* transmission. ~~and morbidity or mortality of animals not related to *disease*.~~ **Rationale:** The Member is proposing amendments to address wording that is unclear and could compromise the understanding or the meaning of the proposed text.	Did not agree, clear as written.

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.

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

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._1	**Category**: general The Member is supportive of most of the assessments and recommendations however the Member has some concerns related to the inclusion of ISA HPRO within the document. ISA (including both ISA HPR-deleted and ISA HPRO) seems to be included within each table. However it is not clear throughout the text of the document if this is correct based on assessments and information provided. Article 10.4.7. Zone freedom from ISA requires demonstration of Freedom for both ISA HPR-deleted and HPRO. Without clear guidance or without an assessment of ISA HPRO, self-declaration using 10.4.7. is problematic. The default periods in Article 10.4.7. point 3 requires that the default period for BBC prior to TS apply to both HPR-deleted and HPR0 however the assessment in Appendix 2 only applies to HPR-deleted. The Member requests the completion of an assessment for HPRO or clarification that the default periods assessed for HPR-detected will be applied in Article 10.4.7. point 3 for both HPR-deleted and HPRO. The Member has a region which has susceptible aquaculture species and therefore cannot use pathway 1), Pathway 2 is not appropriate for ISA HPRO (as indicated within this document), therefore to declare freedom the Member has to use Pathway 3. The Member has completed significant amounts of targeted surveillance since 2012 for ISA (including both HPR-deleted and HPRO) in the impacted region to establish freedom from this pathogenic agent and have had BBC in place since 2011. However as currently presented, it is not clear how these default periods would be applied to support a self-declaration. We request clarity on how the default periods will be applied with respect to ISA and stress the need for guidance on all pathogenic agents.	Noted. In the updated assessment report, the assessments for ISAV (including HPR0 and HPR-deleted) and HPR-deleted ISAV have been presented separately to align with Chapter 10.4. These updated assessments reflect where pathways may not be appropriate such as with pathway 2 (historical freedom) for ISAV (including HPR0 and HPR-deleted).
BBS.TS._2	**Category:** general **Proposed amended text :** Throughout the document add an * to WSSV, crayfish plague and RSIV (now listed as ISKNV) and edit wording on broad host range to include these diseases. **Rationale:** The Member notes that WSSV, crayfish plague are listed as having a broad host range and ISKNV is suspected to have a broad host range based on the ad hoc Group report and the Commissions February 2024 report text indicating that Article 1.5.9. would likely be applied when revising the susceptible species. The Member requests that these diseases should be excluded from pathway 1. Pathway 1 is not considered suitable for pathogens with a broad host range because new susceptible species are expected to be determined with further research or spread of the pathogens to new geographic areas therefore demonstrating absence of susceptible species is not considered possible.	Agreed, WSSV and *Megalocyticirus pagrus 1* both have broad and varied host ranges and pathway 1 (absence of susceptible species) is not appropriate as it is not considered possible to show absence of susceptible species.
BBS.TS._3	**Category:** general The Member would request a revision of the document with respect to RSIV and viral species ISKNV.	Noted. The document was reviewed and updated to reflect the listing of 'infection with *Megalocytivirus pagrus 1*'.

BBS.TS._4	**Category**: general It is recommended that all koi herpesvirus (KHV) change to rank 2, including basic biosecurity conditions (BBC) for pathway 2 to 3 and targeted surveillance (TS) for pathway 3. For this reason, KHV disease is temperature-dependent and mainly occurs between 16 and 29°C. By using real-time PCR methods, sensitivity in detecting KHV can be enhanced within suitable water temperatures or during the season.	Did not agree to change KHV to rank 2. KHV is temperature dependent but not all countries or regions where koi are kept will reach the permissive temperature range for an adequate period of time every year. As such KHV is maintained at rank 3 to take this into account.
BBS.TS._5	**Category**: general The Member requests Commission to clarify the default period of targeted surveillance for "compartments" when using Pathway 4, which is missing in the Commission's report, while those for "countries or zones" are clearly stated. Since such period is provisionally indicated at each chapter for specific diseases such as 'at least [six months]' at this point, we would like to seek Commission's views on whether such provisional description will remain or whether additional discussion will be made in the future. Furthermore, the Member would like to point out that the shorter/flexible TS period than the default minimum period should be justified for compartments when returning to disease freedom, as well as countries and zones, since the premises* for applying such flexibility, which are set out in the Code, are more easily provided for compartments than countries or zones. * "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" (Article 1.4.14)	Point 3 'Requirements for targeted surveillance in a compartment' in Article 1.4.14. provides this detail for pathway 4 as detailed below: 'A single survey is required following restocking to demonstrate that eradication has been successful. The survey should be undertaken at least sixth months, or at the maximum length of time allowed by the production cycle of species, after the aquaculture establishment has been restocked to ensure that the reviewed basic biosecurity conditions are effective. The survey should take place during optimum seasons, temperatures, and priority life stages to optimise pathogenic agent detection.'
BBS.TS._6	**Category**: general Le Membre a pris connaissance de l'évaluation présentée dans l'annexe 47, basée sur les caractéristiques des agents pathogènes et de ses limites du fait de la non prise en compte de l'hôte et de l'environnement. Pour les pathologies des crustacés, présentant le principal intérêt pour le membre, l'insuffisance de données, en particulier en matière de persistance dans l'environnement, a bien été notée. Le membre n'a pas de commentaire sur le processus et les résultats de cette évaluation, mais elle salue ce travail qui est très utile, notamment pour contribuer aux analyses de risque réalisées sur ces agents pathogènes.	Noted
BBS.TS._7	**Category:** General The Member supports the recommendations.	Noted
BBS.TS._8	**Category:** General **Proposed amended text:** No text proposed. We would like to thank the Aquatic Animal Standard Commission for developing these recommendations. We look forward to the circulation of relevant disease-specific chapters and will provide further comments.	Noted

BBS.TS._9	**Category**: general The Members support the recommendations.	Noted

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

February 2024

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>
<tr><th>Reference</th><th>Comment</th><th>Aquatic Animals Commission Response</th></tr>
<tr>
<td>BBS.TS._9</td>
<td>
Category: general
Proposed amended text
<table>
<tr><th>Period</th><th>Diseases of fish</th><th>Diseases of crustaceans</th><th>Diseases of molluscs</th><th>Diseases of amphibians</th></tr>
<tr><td>6 months</td><td>EHNV
G. salaris
IHNV
ISAV
KHV
~~RSIV~~
SVCV
TiLV</td><td>AHPND
H. penai
IHHNV
IMNV
MrNV
~~WSSV~~
YHV1</td><td>AbHV
B. exitiosa
B. ostreae
P. marinus
M. refringens
X. californiensis</td><td>B. dendrobatidis
B. salamondrivorans
Ranavirus</td></tr>
<tr><td>12 months</td><td>SAV</td><td>~~Crayfish plague~~</td><td></td><td></td></tr>
<tr><td>Pathway not suitable</td><td>EUS
RSIV (ISKNV)
~~VHSV~~</td><td>Crayfish plague
WSSV</td><td>~~P. olseni~~</td><td></td></tr>
</table>
Rationale:
The Member notes that WSSV, crayfish plague are listed as having a broad host range and ISKNV is suspected to have a broad host range based on the ad hoc Group report and the Commissions February 2024 report text indicating that Article 1.5.9. would likely be applied when revising the susceptible species. The Member requests that these diseases should be excluded from pathway 1. Pathway 1 is not considered suitable for pathogens with a broad host range because new susceptible species are expected to be determined with further research or spread of the pathogens to new geographic areas therefore demonstrating absence of susceptible species is not considered possible.

The Member would like to request clarification as to why VHSV and P.olseni are deemed to have a broad host range and clarification on the criteria used to establish that this is the case when Article 1.5.9. Listing susceptible species at a taxonomic level at a taxonomic ranking of Genus or higher was not applied to the susceptible species for these diseases for listing within the Aquatic Code.
</td>
<td>
Agreed, that where there is a known broad host range it is hard to determine the full extent of species which are susceptible. As research is ongoing current absence of evidence of susceptibility in species, does not necessarily indicate lack of susceptibility. As such diseases with a broad host range are not suitable for pathway 1.

Due to broad and varied host range pathway 1 is considered not suitable for the following diseases: EUS, M. pagrus 1, VHSV, crayfish plague, WSSV, P. olseni, B. dendrobatidis and Ranavirus.

Article 1.5.9. ‘Listing susceptible species at a taxonomic ranking of Genus or higher’ may be applied when a disease has a broad host range. Article 1.5.9. may be applied to diseases with a broad host range. It has been applied to EUS, M. pagrus 1 and WSSV. Crayfish plague, B. dendrobatidis and Ranavirus have not had an updated assessments on susceptible species completed yet.

VHSV has a known broad host range with more than 70 species and more than 30 families in Article 10.10.2. As described in the AAC September 2019 report, the Commission considered whether Article 1.5.9. should be applied to VHSV. It was noted that there are numerous susceptible species within taxonomic groups containing many species but with a few found susceptible to VHSV. Further the geographic distribution of multiple VHSV genotypes combined with the diversity of susceptible host species across disparate taxonomic groups (including representatives of several classes of fishes) made application of Article 1.5.9. complex. Due to the complexity of these issues, the Commission did not apply Article 1.5.9.

P. olseni broad range of species including both bivalves and gastropods. In this AAC September 2024 meeting the Commission considered application of Article 1.5.9. The genera and family represented have large taxonomic groups with many species, and the species identified were not
</td>
</tr>
</table>

<table>
<tr><td></td><td></td><td>considered sufficient proportion to apply Article 1.5.9. (see item 6.8.).

Although the assessments have not been completed for B. dendrobatidis and Ranavirus to date it is known that these diseases have a broad host range. In regards to B. salmanondrivorans the Commission will consider pathway 1 applicable until the assessment by the ad hoc Group is completed.</td></tr>
<tr><td>BBS.TS._10</td><td>
Category: Cambio

Proposed amended text: En el cuadro1 cambiar H. penai por H. penaei.

Cuadro 2.
<table>
<tr><th>Periodo</th><th>Enfermedades de los peces</th><th>Enfermedades de los crustáceos</th><th>Enfermedades de los moluscos</th><th>Enfermedades de los anfibios</th></tr>
<tr><td>6 meses</td><td>VNHE
G. salaris
VNHI
VAIS
HVK
RSIV
VVPC
TiLV</td><td>NHPA
<s>H. penai</s>
H. penaei
VNHHI
IVMNI
NVMr
VSMB
VECA1</td><td>HVAb
B. exitiosa
B. ostreae
P. marinus
M. refringens
X. californiensis</td><td>B. dendrobatidis
B. salamondrivorans
Ranavirus</td></tr>
</table>
Rationale: En el cuadro 1 se menciona como enfermedad de los crustáceos H. penai (nombre correcto H. penaei), ya que H. penai se refiere a una especie de coleóptero de la familia Lucanidae.

En el capítulo 2.2.3 indica que la infección por Hepatobacter penaei es una infección por el agente patógeno Candidatus H. penaei, una bacteria intracellular estricta de la familia Holosporaceae, en el orden Rickettsiales.

Supporting documents:

Capítulo 2.2.3. Infección por Hepatobacter penaei Hepatopancreatitis Necrotizante OMSA.

2.2.03_NHP_2023.pdf (woah.org)
</td><td>Agreed, editorial amendment due to spelling error.</td></tr>
</table>

Table 3. 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*

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
15 years	*G. salaris* KHV			

<table>
<tr><th>Reference</th><th>Comment</th><th>Aquatic Animals Commission Response</th></tr>
<tr><td>BBS.TS._11</td><td>

Category: general

<table>
<tr><th>Period</th><th>Diseases of fish</th><th>Diseases of crustaceans</th><th>Diseases of molluscs</th><th>Diseases of amphibians</th></tr>
<tr><td>10 years</td><td>EHNV
EUS
IHNV
~~ISAV~~
ISAV HPR-deleted
RSIV
SAV
SVCV
TiLV
VHSV</td><td>AHPND
Crayfish plague
H. penai
IHHNV
IMNV
MrNV
WSSV
YHV1</td><td>AbHV
B. exitiosa
B. ostreae
P. marinus
M. refringens
P. olseni
X. californiensis</td><td>B. dendrobatidis
B. salamondrivorans
Ranavirus</td></tr>
</table>

Rationale: For consistency with table 7

</td><td>Agreed, that for pathway 2 (historical freedom), HPR-deleted ISAV should have BBC of 10 years. For ISAV (HPR0 and HPR-deleted), it is not possible to show historical freedom form HPR0 and thus pathway 2 is not suitable for ISAV (HPR0 and HPR-deleted).</td></tr>
<tr><td>BBS.TS._12</td><td>

Category: Cambio

Proposed amended text: En el cuadro 2, cambiar H. penai por H. penaei.

Cuadro 4. Recomendaciones para los períodos de implementación de las CEB utilizando el procedimiento 2. “Ausencia histórica”

<table>
<tr><th>Periodo</th><th>Enfermedades de los peces</th><th>Enfermedades de los crustáceos</th><th>Enfermedades de los moluscos</th><th>Enfermedades de los anfibios</th></tr>
<tr><td>10 años</td><td>VNHE
SUE
VNHI
VAIS
RSIV
AVS
VVPC
TiLV
VSHV</td><td>NHPA
Plaga del cangrejo de río
~~H. penai~~
H. penaei
VNHHI
VMNI
NVMr
VSMB
VECA1</td><td>HVAb
B. exitiosa
B. ostreae
P. marinus
M. refringens
P. olseni
X. californiensis</td><td>B. dendrobatidis
B. salamondrivorans
Ranavirus</td></tr>
</table>

Rationale: En el cuadro 2 se menciona como enfermedad de los crustáceos ***H. penai*** **(nombre correcto *H. penaei*)**, ya que H. penai se refiere a una especie de coleóptero de la familia Lucanidae.

En el capítulo 2.2.3 indica que la infección por Hepatobacter penaei es una infección por el agente patógeno Candidatus H. penaei, una bacteria intracellular estricta de la familia Holosporaceae, en el orden Rickettsiales.

</td><td>Agreed, editorial amendment due to spelling error.</td></tr>
</table>

	Supporting evidence Capítulo 2.2.3. Infección por Hepatobacter penaei Hepatopancreatitis Necrotizante OMSA.	

Table 5. 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				
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*	

<table>
<tr><th>Reference</th><th>Comment</th><th>Aquatic Animals Commission Response</th></tr>
<tr><td>BBS.TS._13</td><td>

Category: change

<table>
<tr><th>Period</th><th>Diseases of fish</th><th>Diseases of crustaceans</th><th>Diseases of molluscs</th><th>Diseases of amphibians</th></tr>
<tr><td colspan="5">BBC</td></tr>
<tr><td>1 year</td><td>EHNV
EUS
IHNV
~~ISAV~~
ISAV HPR-deleted
RSIV
SAV
SVCV
VHSV
TiLV</td><td>AHPND
Crayfish plague
H. penai
IHHNV
IMNV
MrNV
WSSV
YHV1</td><td>AbHV</td><td>B. dendrobatidis
B. salamondrivorans
Ranavirus</td></tr>
<tr><td>2 years</td><td>KHV
G. salaris</td><td></td><td>B. exitiosa
B. ostreae
P. marinus
M. refringens
P. olseni
X. californiensis</td><td></td></tr>
<tr><td colspan="5">TS</td></tr>
<tr><td>2 years</td><td>A. astacii
EHNV
EUS
IHNV
~~ISAV~~
ISAV HPR-deleted
RSIV
SAV
SVCV
VHSV</td><td>AHPND
Crayfish plague
H. penai
IHHNV
IMNV
MrNV
WSSV
YHV1</td><td>AbHV</td><td>B. dendrobatidis
B. salamondrivorans
Ranavirus</td></tr>
<tr><td>3 years</td><td>G. salaris
KHV</td><td></td><td>B. exitiosa
B. ostreae
P. marinus
M. refringens
P. olseni
X. californiensis</td><td></td></tr>
</table>

Rationale: (1) In page 13 it is stipulated that the ranking and recommendation for ISAV applied only to applications of disease freedom for the HPR deleted strain (2) To be consistent with Attachment 2

</td><td>Review of the default periods has included both ISAV (including HPR0 and HPR-deleted) and HPR-deleted ISAV. Pathway 3 with basic biosecurity conditions and targeted surveillance are applicable for both of these categories. Text has been amended to reflect this review.</td></tr>
<tr><td>BBS.TS._14</td><td>

Category: Cambio

Proposed amended text: En el cuadro 3, cambiar H. penai por H. penaei.

</td><td>Agreed, editorial amendment due to spelling error.</td></tr>
</table>

Cuadro 6. Recomendaciones para los períodos de implementación de las CEB y la VE para la solicitud del estatus libre de enfermedad para los países y las zonas que utilizan el procedimiento 3. "Vigilancia específica"

Periodo	Enfermedades de los peces	Enfermedades de los crustáceos	Enfermedades de los moluscos	Enfermedades de los anfibios
CEB				
1 año	VNHE SUE VNHI VAIS RSIV AVS VVPC VSHV TiLV	NHPA Plaga del cangrejo de río ~~*H. penai*~~ *H. penaei* VNHHI VMNI NVMr VSMB VECA1	HVAb	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*
2 años	HVK *G. salaris*		*B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *P. olseni* *X. californiensis*	
VE				
2 años	VNHI VAIS RSIV AVS VVPC VSHV SUE VNHE	NHPA Plaga del cangrejo del río *H. penaei* IHHNV VMNI NVMr VSMB VECA1	HVAb	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*

Rationale: En el cuadro 3 se menciona como enfermedad de los crustáceos ***H. penai*** **(nombre correcto *H. penaei*)**, ya que H. penai se refiere a una especie de coleóptero de la familia Lucanidae.

En el capítulo 2.2.3 indica que la infección por Hepatobacter penaei es una infección por el agente patógeno Candidatus H. penaei, una bacteria intracellular estricta de la familia Holosporaceae, en el orden Rickettsiales.

Supporting evidence: Capítulo 2.2.3. Infección por Hepatobacter penaei Hepatopancreatitis Necrotizante OMSA. (2.2.03_NHP_2023.pdf (woah.org))

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 7. 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 8. 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 9. 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**	

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._15	**Category:** change **Proposed amended text** (see table below) **Rationale:** The Member notes that WSSV, crayfish plague are listed as having a broad host range and ISKNV is suspected to have a broad host range based on the ad hoc Group report and the Commissions February 2024 report text indicating that Article 1.5.9. would	Agreed, see response for comment BBS.TS._9.

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**	

	likely be applied when revising the susceptible species. The Member requests that these diseases should be excluded from pathway 1. Pathway 1 is not considered suitable for pathogens with a broad host range because new susceptible species are expected to be determined with further research or spread of the pathogens to new geographic areas therefore demonstrating absence of susceptible species is not considered possible. The Member would like to request clarification as to why VHSV and P.olseni are deemed to have a broad host range and clarification on the criteria used to establish that this is the case when Article 1.5.9. Listing susceptible species at a taxonomic level at a taxonomic ranking of Genus or higher was not applied to the susceptible species for these diseases for listing within the Aquatic Code.	

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.

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._16	**Category: d**eletion and change **Proposed amended text** Pathway 1 is thus unsuitable for ~~three~~ four species – EUS, Crayfish plague, RSIV (ISKNV) and WSSV ~~VHSV, and *P. olseni*~~. **Rationale:** The Member notes that WSSV, crayfish plague are listed as having a broad host range and ISKNV is suspected to have a broad host range based on the ad hoc Group report and the Commissions February 2024 report text indicating that Article 1.5.9. would likely be applied when revising the susceptible species. The Member requests that these diseases should be exluded from pathway 1. Pathway 1 is not considered suitable for pathogens with a broad host range because new susceptible species are expected to be determined with further research or spread of the pathogens to new geographic areas therefore demonstrating absence of susceptible species is not considered possible. The Member would like to request clarification as to why VHSV and P.olseni are deemed to have a broad host range and clarification on the criteria used to establish that this is the case when Article 1.5.9. Listing susceptible species at a taxonomic level at a taxonomic ranking of Genus or higher was not applied to the susceptible species for these diseases for listing within the Aquatic Code.	Pathway 1 (historical freedom) unsuitable for EUS, *M. pagrus 1*, VHSV, WSSV, crayfish plague, *P. olseni*, *B. dendrobatidis* and *Ranavirus.* See response for comment BBS.TS._9.

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.

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._17	**Category: d**eletion and change **Proposed amended text** The rankings of pathogens by host group are set out in Table 7. All fish pathogens with the exception of KHV, ~~and~~ *G. salaris* and ISA HPRO 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. **Rationale:** In paragraph 4 of this section it indicates that this pathway is not appropriate for ISA HPRO. Paragraph 4 should be moved up so all information on diseases which are not suitable under this pathway are together.	Agreed, amended to reflect that for ISAV (including HPR0 and HPR-deleted) pathway 2 is not suitable.

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 10. 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	AbHV	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*

Ranking	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
		YHV1		
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*			

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._18	**Category :** change **Proposed amended text**	Agreed, amended to reflect that for ISAV (including HPR0 and HPR-deleted) pathway 2 is not suitable.

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			

<table>
<tr><td></td><td>
<table>
<tr><td></td><td>G. salaris</td><td></td><td></td><td></td></tr>
<tr><td>Not appropriate</td><td>ISAV HPRO</td><td></td><td></td><td></td></tr>
</table>

Rationale: In paragraph 4 of this section it indicates that this pathway is not appropriate for ISA HPRO. This line should be included within the table for clarity.
</td><td></td></tr>
<tr><td>BBS.TS._19</td><td>
Category: Cambio
Text amended to reflect: En el cuadro 7, cambiar H. penai por H. penaei.
Cuadro 11. Clasificación resumida de los patógenos para determinar el periodo mínimo de las CEB para el procedimiento 2. “Ausencia histórica”
<table>
<tr><th>Puntuación</th><th>Enfermedad de los peces</th><th>Enfermedad de los crustáceos</th><th>Enfermedad de los moluscos</th><th>Enfermedad de los anfibios</th></tr>
<tr><td>1</td><td>AVS</td><td>NHPA
Plaga del cangrejo de río
<s>H. penai</s>
H. penaei
VNHHI
VMNI
NVMr
VSMB
VECA1</td><td>HVAb</td><td>B. dendrobatidis
B. salamondrivorans
Ranavirus</td></tr>
</table>
Rationale: En el cuadro 7 se menciona como enfermedad de los crustáceos H. penai (nombre correcto H. penaei), ya que H. penai se refiere a una especie de coleóptero de la familia Lucanidae.
En el capítulo 2.2.3 indica que la infección por Hepatobacter penaei es una infección por el agente patógeno Candidatus H. penaei, una bacteria intracellular estricta de la familia Holosporaceae, en el orden Rickettsiales.
Supporting evidence:
Capítulo 2.2.3. Infección por Hepatobacter penaei Hepatopancreatitis Necrotizante OMSA.
2.2.03_NHP_2023.pdf (woah.org)
</td><td>Agreed, editorial amendment due to spelling error.</td></tr>
</table>

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.

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._20	**Category:** change **Proposed amended text:** 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.~~ **Rationale:** This sentence is contrary to the information in Article 1.4.3. which indicates that passive surveillance is a secondary evidence and the text in Article 1.4.13. which indicates 'However, the submission may also include an analysis of the passive surveillance information to provide supplemental evidence.' We note that indicating that passive surveillance is a pre-requisite for application of pathway 3 is problematic for HPRO as passive surveillance is not possible for this pathogen, which is indicated above which is why pathway 2 is not appropriate for HPRO.	Agreed, to remove the final sentence in paragraph 1. This sentence is contrary to the information in Article 1.4.3. which indicates 'the submission may also include an analysis of the passive surveillance information to provide supplemental evidence.' Passive surveillance may not be possible for all diseases and is not a prerequisite.

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 12. 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

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._21	**Category:** general **Ranking** / **Diseases of fish** / **Diseases of crustaceans** / **Diseases of molluscs** / **Diseases of amphibians** 1 / SAV / All / AbHV / *B. dendrobatidis* 2 / EHNV EUS / / / *B. salamondrivorans* (*Ranavirus**)	Assessment updated relative to ISAV, see response to comment BBS.TS._1.

<table>
<tr>
<td></td>
<td>
<table>
<tr><td></td><td>IHNV
~~ISAV~~
ISAV HPR-deleted
RSIV
SVCV
TILV
VHSV</td><td></td><td></td><td></td></tr>
</table>

Rationale: (1) In page 13 it is stipulated that the ranking and recommendation for ISAV applied only to applications of disease freedom for the HPR deleted strain (2) To be consistent with Attachment 2.
</td>
<td></td>
</tr>
<tr>
<td>BBS.TS._22</td>
<td>
Categoría: Cambio

Texto modificado propuesto: En el cuadro 8, cambiar H. penai por H. penaei.

Cuadro 13. Clasificaciones resumidas de patógenos para determinar los periodos mínimos de las condiciones básicas de bioseguridad para el procedimiento 3. “Vigilancia específica”
<table>
<tr><th>Puntuación</th><th>Enfermedad de los peces</th><th>Enfermedad de los crustáceos</th><th>Enfermedad de los moluscos</th><th>Enfermedad de los anfibios</th></tr>
<tr><td>1</td><td>AVS</td><td>NHPA
Plaga del cangrejo de río
~~H. penai~~
H. penaei
VNHHI
VMNI
NVMr
VSMB
VECA1</td><td>HVAb</td><td>B. dendrobatidis</td></tr>
</table>
Justificación: En el cuadro 8 se menciona como enfermedad de los crustáceos H. penai (nombre correcto H. penaei), ya que H. penai se refiere a una especie de coleóptero de la familia Lucanidae.

En el capítulo 2.2.3 indica que la infección por Hepatobacter penaei es una infección por el agente patógeno Candidatus H. penaei, una bacteria intracellular estricta de la familia Holosporaceae, en el orden Rickettsiales.

Evidencia documentada:

Capítulo 2.2.3. Infección por Hepatobacter penaei Hepatopancreatitis Necrotizante OMSA.

2.2.03_NHP_2023.pdf (woah.org)
</td>
<td>Agreed, editorial amendment due to spelling error.</td>
</tr>
</table>

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 14. 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*

Ranking	Fish	Crustacean	Molluscs	Amphibian
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

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._23	**Category: general** Ranking: 2 Fish: VHSV, IHNV, SVCV, RSIV, ~~ISAV~~, ISAV HPR-deleted, TiLV, EUS, EHNV Crustacean: Molluscs: Amphibian: (*Ranavirus**) **Rationale:** ISAV HPR0 does not result in observable clinical signs or mortality. There is thus not a high likelihood of rapid detection following introduction into a naïve population by passive surveillance.	Assessment updated relative to ISAV, see response to comment BBS.TS._1.
BBS.TS._24	**Categoría:** Cambio **Texto modificado propuesto**: En el cuadro 9, cambiar H. penai por H. penaei. **Cuadro 15**. Clasificación resumida de los patógenos para determinar el periodo mínimo de la VE del procedimiento 3. “Vigilancia específica” Puntuación: 1 Peces: AVS Crustáceos: NHPA, Plaga del cangrejo de río, ~~*H. penai*~~, *H. penaei* Moluscos: HVAb Anfibios: *B. dendrobatidis*, *B. salamondrivorans*	Agreed, editorial amendment due to spelling error.

		VNHHI VMNI NVMr VSMB VECA1		

Justificación: En el cuadro 9 se menciona como enfermedad de los crustáceos ***H. penai*** **(nombre correcto *H. penaei*)**, ya que H. penai se refiere a una especie de coleóptero de la familia Lucanidae.

En el capítulo 2.2.3 indica que la infección por Hepatobacter penaei es una infección por el agente patógeno Candidatus H. penaei, una bacteria intracellular estricta de la familia Holosporaceae, en el orden Rickettsiales.

Evidencia documentada:

Capítulo 2.2.3. Infección por Hepatobacter penaei Hepatopancreatitis Necrotizante OMSA.

2.2.03_NHP_2023.pdf (woah.org)

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 *Marteilia refringens*	Infection with *Perkinsus marinus*	Infection with *Perkinsus olseni*	Infection with *Xenohaliotis californiensis 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
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	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

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._25	**Category**: editorial **Proposed amended text**: In Attachment 1 – *A. invadens* should be italicized.	Agreed, editorial amendment.

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

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
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
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

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._26	**Category: g**eneral **Proposed amended text** ISA HPR0 should be assessed using this methodology and have be included with it's own rank within Attachment 2 below. **Rationale:** Only ISA HPR deleted strain is ranked in this table. All the BBC and TS scoring is based on the ranks from this table. ISA HPR0 needs a rank.	Agreed, assessment updated relative to ISAV, see response to comment BBS.TS._1.
BBS.TS._27	**Category**: editorial **Proposed amended text**: In Attachment 1 – *A. invadens* should be italicized.	Agreed, editorial amendment.
BBS.TS._28	**Category**: general **Comment on Transmission Period column in Attachment 2 -** From **Chapter 2.3.1, Infection with *A. invadens* (EUS),** point 2.3.5 on Environmental Factors, there are other factors in the environment which predispose fish to the expression of disease – such as low pH (6 – 7) skin damage, low oxygen concentration. See screen shot. Consider if there is a need to mention this in Attachment 2. https://www.woah.org/fileadmin/Home/fr/Health_standards/aahm/current/2.3.01_EUS.pdf	Agreed, for EUS to be clinically observed there need to be predisposing factors such low pH, low oxygen concentration, ectoparasites, among others. The ranking for EUS was changed to 3 to account for the need for predisposing factors for clinical expression.

	2.3.5. Environmental factors Under natural conditions, infection with *A. invadans* has been reported at water temperatures in the range 10–33°C (Bondad-Reantaso *et al*., 1992; Hawke *et al*., 2003) often associated with massive rainfall (Bondad-Reantaso *et al*., 1992). These conditions favour sporulation of *A. invadans* (Lumanlan-Mayo *et al*., 1997), and temperatures of 17–19°C have been shown to delay the inflammatory response of fish to oomycete infection (Catap & Munday, 1998, Chinabut *et al*., 1995). In some countries, outbreaks occur in wild fish first and then spread to fish ponds. Normally, a bath infection of *A. invadans* in healthy susceptible fish species does not result in clinical signs of disease. The presence of other pathogens (viruses, bacteria or ectoparasites, skin damage, water temperature (between 18 and 22°C), low pH (6.0–7.0) and low oxygen concentration in the water have all been hypothesised as predisposing factors for infection or factors influencing the expression of the disease (Oidtmann, 2012; Iberahim *et al*., 2018).	

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

Reference	Comment	Aquatic Animals Commission Response
BBS.TS._29	**Category: c**hange **Proposed amended text** In row "IHHNV" and in column "Rank" change ~~1~~ to 3 **Rationale:** IHHNV has a low likelihood of detection for P. vannamei. Since P. vannemei is highly cultured and traded internationally, this should have significant weight on the general BBC and TS recommendation. Whereas P.stylirostris isn't as common, If a facility is only culturing P. stylirostris then an individual risk assessment can be done to lower the mitigations.	Agreed, to change the ranking for IHHNV. Ranking changed from 1 to rank of 2. *P. vannemei* is a commonly cultured and traded internationally. IHHNV has a low likelihood of detection for *P. vannemei* leading to the change to rank 2.

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

Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus'

Reference	Comment	Aquatic Animals Commission Response
9.9.2._1	**Category**: general The Member supports the proposed changes to Article 9.9.2.	Noted.
9.9.2._2	**Category**: general We support this amendment.	Noted.
9.9.2._3	**Category:** General The Member supports the proposed changes to this Chapter.	Noted.
9.9.2._4	**Category**: general The Members support the proposed changes to this chapter.	Noted.

CHAPTER 9.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

[…]

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

[…]

Reference	Comment	Aquatic Animals Commission Response
9.9.2._5	**Category:** change **Proposed amended text :** **Family** / **Scientific name** / **Common name** ~~Calanidae~~ / ~~*Calanus pacificus californicus*~~ / ~~no common name~~ **Rationale:** At present, there is only one report[1] that white spot syndrome virus has been detected in Calanus pacificus californicus, but there is no experimental confirmation that the virus can reproduce in Calanus pacificus californicus or cause pathological changes. According to Article 1.5.6 of Chapter 1.5 of the Aquatic Code, Calanus pacificus californicus does not meet the criteria for determining susceptible species and is recommended to be deleted.	Did not agree. The assessment for *Calanus pacificus californicus* shows that the criteria for listing this host species as susceptible as stage 3 criterion A is met as there was increasing copy numbers over time after removal from exposure. From Article 1.5.7., criterion A alone is sufficient to determine infection. In the absence of evidence to meet criterion A, satisfying at least two of criteria B, C or D would be required to determine infection.
9.9.2._6	**Category:** Change **Proposed amended text:** We would like to express our concern about list of species susceptible to white spot syndrome virus (WSSV). Only crustacean species assessed by *ad Hoc* Group on Susceptibility of Crustacean Species to Infection with WSSV as shown in Section 4 (Results) of the *ad Hoc* Group report (November 2023), should be included in Article 9.9.2. **Rationale:** Determining species susceptible to WSSV should be based on specific scientific evidences for each species by using approach in Article 1.5.4-1.5.6 to assess susceptibility of species to infection with a specific pathogenic agent, rather than using criteria in Article 1.5.9 for listing susceptible species at a ranking of Genus to avoid trade barrier due to insufficient of scientific evidences. **Supporting evidence:** Report of the *ad Hoc* Group on Susceptibility of Crustacean Species to Infection with WSSV (November 2023)	Did not agree. See item 6.5.2. of the September 2024 report for a detailed response.

Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *P. olseni*'

Reference	Comment	Aquatic Animals Commission Response
11.6.1._11.6.2._1	**Category**: general The Member supports the proposed modifications and would like to thank the ad hoc Group for susceptibility of mollusc species for their work to complete the assessments for susceptibility.	Noted.
11.6.1._11.6.2._2	**Category**: general We support this amendment.	Noted.
11.6.1._11.6.2._3	**Category:** General The Member supports the proposed changes to this Chapter.	Noted.
11.6.1._11.6.2._4	**Category**: general The Members support the proposed changes to this chapter.	Noted.

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

Article 11.6.1.

For the purposes of the *Aquatic Code*, infection with *Perkinsus olseni* means *infection* with 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

Family	Scientific name	Common name
	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

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

[…]

Reference	Comment	Aquatic Animals Commission Response
11.6.1._11.6.2._5	**Category:** change **Proposed amended text :** <table><tr><th>Family</th><th>Scientific name</th><th>Common name</th></tr><tr><td rowspan="2">Arcidae</td><td>*Anadara kagoshimensis*</td><td>half-crenated ark ~~cockle~~</td></tr><tr><td>*Anadara trapezia*</td><td>no common name ~~ark cockle~~</td></tr><tr><td>Veneridae</td><td>*Ruditapes philippinarum*</td><td>Japanese carpet shell ~~clam~~</td></tr></table>**Rationale:** The common name of Anadara kagoshimensis is Half-crenated ark, Ruditapes philippinarum is Japanese carpet shell. Anadara trapezia has no common name. **Supporting evidence :** [1]FAOTERM[FAO Terminology Portal | Food and Agriculture Organization of the United Nations] [2]Sealifebase [Search SeaLifeBase]	Agreed. The common names for all species were amended to the ones in FAOTERM and SeaLifeBase.

Sections 2.2.1. and 2.2.2. of Chapter 2.2.8. 'Infection with white spot syndrome virus'

Reference	Comment	Aquatic Animals Commission Response
2.2.8. _1	**Category**: general The Member would like to thank the ad hoc Group for susceptibility of crustacean species for their assessments. The Member has inserted a comment within the body of the Chapter.	Noted.
2.2.8. _2	**Category**: general We support this amendment.	Noted.
2.2.8. _3	**Category:** General The Member supports the proposed changes to this Chapter.	Noted.
2.2.8. _4	**Category**: general The Members support the proposed changes to this chapter.	Noted.

CHAPTER 2.2.8.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

[…]

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

Reference	Comment	Aquatic Animals Commission Response
2.2.8. _5	**Category:** Change **Proposed amended text:** No text proposed. We would like to express our concern about list of species susceptible to white spot syndrome virus (WSSV). Only crustacean species assessed by *ad Hoc* Group on Susceptibility of Crustacean Species to Infection with WSSV as shown in Section 4 (Results) of the *ad Hoc* Group report (November 2023), should be included in Section 2.2.1. **Rationale:** Determining species susceptible to WSSV should be based on specific scientific evidences for each species by using approach in Article 1.5.4-1.5.6 to assess susceptibility of species to infection with a specific pathogenic agent, rather than using criteria in Article 1.5.9 for listing susceptible species at a ranking of Genus to avoid trade barrier due to insufficient of scientific evidences. **Supporting evidence:** Report of the *ad Hoc* Group on Susceptibility of Crustacean Species to Infection with WSSV (November 2023)	Did not agree. See item 6.5.2. of the September 2024 report for a detailed response.

~~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

Reference	Comment	Aquatic Animals Commission Response
2.2.8. _6	**Category:** request for review of additional papers for *Macrobrachium nipponense* for susceptibility for WSSV. **Rationale:** The Member notes that there is additional information published that has not been reviewed by the ad hoc Group. Since the Yun et al 2014 paper referenced in the ad hoc Group report, there are approximately 30 papers published investigating the effects of WSSV in M. nipponense on gene expression and vaccine efficacy. Most appear to be challenge studies and the Member has included 3 references below which involved an oral route of infection. **Supporting evidence:** Tong Y, Yang J, Wang L, Chi X, Zhu C, Yin R, Zhang L, Li Y, Zhao C, Jia R. (2023). Effects of dietary supplementation of Anabaena sp. PCC7120 expressing VP28 protein on survival and histopathology after WSSV infection in Macrobrachium nipponense. Fish Shellfish Immunol. 139,108865. doi: 10.1016/j.fsi.2023.108865. Hansam Cho, Ki Hoon Park, Yuyeon Jang, Yeondong Cho, Yoon-Ki Heo, Minjee Kim, Young Bong Kim. (2021) Identification and characterization of a Toll-like receptor gene from Macrobrachium nipponense, Fish & Shellfish Immunology, Volume 108, Pages 109-115, https://doi.org/10.1016/j.fsi.2020.12.003. Hansam Cho, Na Hye Park, Yuyeon Jang, Yong-Dae Gwon, Yeondong Cho, Yoon-Ki Heo, Ki-Hoon Park, Hee-Jung Lee, Tae Jin Choi, Young Bong Kim. (2017). Fusion of flagellin 2 with bivalent white spot syndrome virus vaccine increases survival in freshwater shrimp, Journal of Invertebrate Pathology, Volume 144, Pages 97-105, https://doi.org/10.1016/j.jip.2017.02.004.	See item 6.5.2. of the September 2024 report for a detailed response.

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.~~

[…]

Reference	Comment	Aquatic Animals Commission Response
2.2.8. _7	**Category:** change **Proposed amended text :** **Family** / **Scientific name** / **Common name** Artemiidae: *Artemia salina* — brine shrimp Artemiidae: *Artemia sp.* — ~~N/A~~brine shrimp Artemiidae: *Nitokra sp.* — N/A **Rationale:** *Artemia sp.*common name is brine shrimp.	Agreed. The common name for all *Artemia spp.* is brine shrimp.

Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *P. olseni*'

Reference	Comment	Aquatic Animals Commission Response
2.4.6. _1	**Category**: general The Member supports the proposed modifications and would like to thank the *ad hoc* Group for susceptibility of mollusc species for their work to complete the assessments for susceptibility.	Noted.
2.4.6. _2	**Category**: general We support this amendment.	Noted.
2.4.6._3	**Category:** General The Member supports the proposed changes to this Chapter.	Noted.
2.4.6._4	**Category**: general The Members support the proposed changes to this chapter.	Noted.

CHAPTER 2.4.6.

INFECTION WITH *PERKINSUS OLSENI*

[…]

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

Family	Scientific name	Common name
	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

Reference	Comment	Aquatic Animals Commission Response
2.4.6._5	**Category:** change **Proposed amended text :** **Family** / **Scientific name** / **Common name** Ostreidae / *Crassostrea gasar* / African mangrove oyster~~gasar cupped oyster~~ Ostreidae / *Ostrea angasi* / Australian mud oyster	African mangrove oyster is the common name for *Crassostrea tulipa*, which is a distinct species as described in Ferreira *et al.*, 2023. Refer to the *ad hoc* Group report for more information.

	.....			

Rationale: The common name of Anadara kagoshimensis is Half-crenated ark, Ruditapes philippinarum is Japanese carpet shell. Anadara trapezia has no common name.

Supporting evidence :

[1]FAOTERM[FAO Terminology Portal | Food and Agriculture Organization of the United Nations]

[2]Sealifebase [Search SeaLifeBase]

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
	Polititapes aureus	golden carpet shell
	Venus verrucosa	warty venus clam

[…]

Annex 4. Item 5. – Work Programme for the Aquatic Animal Health Standards Commission

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Aquatic Code					
Ch. 4.2.	Application of zoning	Revision of the chapter following the update to Ch. 4.3. to focus on the application of zoning.	Not started	Refer to Sep 2024 AAHSC report	**3**
Ch. 4.3.	Application of compartmentalisation	Revision of the chapter to focus on compartmentalisation. Members engaged through a questionnaire and discussion paper.	Preparatory work - new chapter for consideration at Feb 2025 meeting	Refer to Sep 2024 AAHSC report	**1**
Ch. 4.6.	Contingency planning	Removal of the chapter following the adoption of Ch 4.X. 'Emergency disease preparedness' and Ch. 4.Y. 'Disease outbreak management'.	Proposed for adoption in May 2025	Refer to Sep 2024 AAHSC report	**1**
Ch. 4.7.	Fallowing in aquaculture	Review of Ch. 4.7. following the drafting of Ch. 4.X. ‘Emergency disease preparedness’ and Ch. 4.Y. ‘Disease outbreak management’.	Preparatory work - revised chapter for consideration at Feb 2025 meeting	Refer to Sep 2024 AAHSC report	**2**
Ch. 4.X.	Emergency disease preparedness	Development of a new draft chapter based on the article structure circulated in the Feb 2021 Part B AAHSC report.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Sep 2023/3)	**1**
Ch. 4.Y.	Disease outbreak management	Development of a new draft chapter based on the article structure circulated in the Feb 2021 Part B AAHSC report.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Sep 2023/3)	**1**

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 4.Z.	Control of pathogenic agents in traded milt and fertilised eggs of fish	Development of a new draft chapter.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Sep 2023/3)	**1**
Ch. 5.1.	General obligations related to certification	Update certification procedures to align with Codex (e-certification).	Preparatory work	Refer to Sep 2024 AAHSC report	**3**
Ch. 5.2.	Certification procedures	Update certification procedures to align with Codex (e-certification).	Preparatory work	Refer to Sep 2024 AAHSC report	**3**
Ch. 5.11.	Model health certificates for international trade in live aquatic animals and aquatic animal products	Update certification procedures to align with Codex (e-certification).	Preparatory work	Refer to Sep 2024 AAHSC report	**3**
Ch. 5.X.	Movement of ornamental aquatic animals	Development of a new draft chapter.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Sep 2023/3)	**1**
Ch. 6.2.	Principles for responsible and prudent use of antimicrobial agents in aquatic animals	Consider the next steps of the work on antimicrobial use in aquatic animals standards. This is included in the Aquatic Animal Health Strategy and the Aquatic AMU/AMR workplan.	Preparatory work	Refer to Sep 2024 AAHSC report	**2**
Section 7	Welfare of farmed fish	Possible amendments and revision of standards on aquatic animal welfare, as part of the Aquatic Animal Health Strategy.	Preparatory work	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**3**
Disease-specific chapters	Articles X.X.5., X.X.6. and X.X.7.	Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 8.1.	Infection with *Batrachochytrium dendrobatidis*	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Not started	Refer to Sep 2024 AAHSC report	**3**
Ch. 8.2.	Infection with *Batrachochytrium salamandrivorans*	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Not started	Refer to Sep 2024 AAHSC report	**4**
Ch. 8.3.	Infection with *Ranavirus* species	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Not started	Refer to Sep 2024 AAHSC report	**4**
Ch. 9.2.	Infection with *Aphanomyces astaci* (Crayfish plague)	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Preparatory work	Refer to Sep 2024 AAHSC report	**3**

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 9.9.	Infection with white spot syndrome virus	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Feb 2024/2)	**1**
Ch. 10.2.	Infection with *Aphanomyces invadans* (Epizootic ulcerative syndrome)	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**
Ch. 10.8.	Infection with red sea bream iridovirus	Removal of the chapter following the change in listing of 'infection with red sea bream iridovirus' to 'infection with *Megalocytivirus pagrus 1*'	Proposed for adoption in May 2025	Refer to Sep 2024 AAHSC report	**1**
Ch. 10.X.	Infection with *Megalocytivirus pagrus 1*	Development of draft new chapter 10.X. 'Infection with *Megalocytivirus pagrus 1'* following the change in listing of 'infection with red sea bream iridovirus' to 'infection with *Megalocytivirus pagrus 1*'	Circulated for comments	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**
Ch. 11.6.	Infection with *Perkinsus olseni*	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Feb 2024/2)	**1**

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 11.7.	Infection with *Xenohaliotis californiensis*	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**
N/A	Emerging diseases	Review emerging diseases	Standing agenda item	Refer to Sep 2024 AAHSC report	**1**
Aquatic Manual					
Ch. 1.1.2.	Validation of diagnostic assays for infectious diseases of aquatic animals	New chapter for validation of diagnositic assays for infectious diseases of aquatic animals.	Preparatory work - new chapter for consideration at Feb 2025 meeting	Refer to Sep 2024 AAHSC report	**1**
Ch. 2.1.1.	Infection with *Batrachochytrium dendrobatidis*	Update the chapter to the new template for disease-specific chapter.	Not started	Refer to Sep 2024 AAHSC report	4
Ch. 2.1.1.	Infection with *Batrachochytrium dendrobatidis*	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Not started	Refer to Sep 2024 AAHSC report	**3**

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 2.1.2.	Infection with *Batrachochytrium salamandrivorans*	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Not started	Refer to Sep 2024 AAHSC report	**4**
Ch. 2.1.3.	Infection with *Ranavirus* species	Update the chapter to the new template for disease-specific chapter.	Not started	Refer to Sep 2024 AAHSC report	**4**
Ch. 2.1.3.	Infection with *Ranavirus* species	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Not started	Refer to Sep 2024 AAHSC report	**4**
Ch. 2.2.2.	Infection with *Aphanomyces astaci* (Crayfish plague)	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Preparatory work	Pending the assessments of the AHG	**3**
Ch. 2.2.5.	Infection with infectious hypodermal and haematopoietic necrosis virus	Revision of Section 6.1.2. 'Definition of confirmed case in apparently health animals'.	Preparatory work	Refer to Sep 2024 AAHSC report	**1**

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 2.2.9.	Infection with white spot syndrome virus	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Feb 2024/2)	**1**
Ch. 2.3.2.	Infection with *Aphanomyces invadans* (Epizootic ulcerative syndrome)	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**
Ch. 2.3.7.	Infection with red sea bream iridovirus	Removal of the chapter following the change in listing of 'infection with red sea bream iridovirus' to 'infection with *Megalocytivirus pagrus 1*'	Proposed for adoption in May 2025	Refer to Sep 2024 AAHSC report	**1**
Ch. 2.3.9.	Infection with spring viraemia of carp virus	Review the validation or publication of real-time PCR assays	Preparatory work	Refer to Sep 2024 AAHSC report	**3**
Ch. 2.3.X.	Infection with tilapia lake virus	New chapter for tilapia lake virus which was listed in the *Aquatic Code* in May 2022	Preparatory work - New chapter for consideration at Feb 2025 meeting	Refer to Sep 2024 AAHSC report	**2**
Ch. 2.4.2.	Infection with *Bonamia exitiosa*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**
Ch. 2.4.3.	Infection with *Bonamia ostreae*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**

Chapter	Subject	Summary of the work	Status – September 2024		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 2.4.5.	Infection with *Perkinsus marinus*	Update the chapter to the new template for disease-specific chapter.	Not started	Refer to Sep 2024 AAHSC report	**4**
Ch. 2.4.6.	Infection with *Perkinsus olseni*	Update the chapter to the new template for disease-specific chapter.	Preparatory work - revised chapter for consideration at Feb 2025 meeting	Refer to Sep 2024 AAHSC report	**2**
Ch. 2.4.6.	Infection with *Perkinsus olseni*	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Feb 2024/2)	**1**
Ch. 2.4.7.	Infection with *Xenohaliotis californiensis*	Update the chapter to the new template for disease-specific chapter.	Preparatory work - revised chapter for consideration at Feb 2025 meeting	Refer to Sep 2024 AAHSC report	**2**
Ch. 2.4.7.	Infection with *Xenohaliotis californiensis*	Sections 2.2.1. and 2.2.2. Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	Circulated for comments	Refer to Sep 2024 AAHSC report (Sep 2024/1)	**1**

* Description of priority order	
1	- active work for the AAHSC - to be put forward for next meeting agenda
2	- active work for the AAHSC - to be included in next meeting agenda if time allows, depending on other progress
3	- not immediate work for the AAHSC - needs to progress before consideration for next meeting agenda
4	- not active - not to be immediately started

List of abbreviations	
AHG	*Ad hoc* Group
Ch	Chapter
HQ	WOAH Headquarters
AAHSC	Aquatic Animal Health Standard Commission

Annex 5. Item 6.1. – Draft new Chapter 4.X. 'Emergency disease preparedness'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.X.

EMERGENCY DISEASE PREPAREDNESS

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. and which is subject to emergency disease preparedness measures. 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*, in order to minimise~~thereby minimising~~ the impact on *aquatic animal* populations, trade, the economy, and the financial resources that are required to manage the *disease outbreak*~~*s*~~. 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 diseases* 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 *aquatic animal disease*~~those~~ emergencies.

When developing the framework, it is of fundamental importance to ensure that the *aquatic animal diseases* 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 *diseases* that is developed after conducting a *risk analysis* as described in 4.X.6., may include *aquatic animal diseases* which are listed in Chapter 1.3., as well as other *diseases* which have been identified as being of importance to the country, *zone* or *compartment*. In addition to the *diseases* which a *Competent Authority* has identified through *risk analysis*, they may choose to add additional *diseases* to the list of important *diseases* to take account of other national considerations.

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 is most suitable~~best meets their needs~~, taking into account the *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) case definitions for suspect and confirmed cases should be established for all important *diseases* which are subject to the emergency disease preparedness framework. For *diseases* which are listed in Chapter 1.3., case definitions are set out in Sections 6.1. and 6.2. of the disease-specific chapters of the *Aquatic Manual*. For non-listed *diseases*, the *Competent Authority* should establish such definitions in peacetime, so that delays can be avoided in confirming or ruling out the presence of the *disease*. This task is more difficult to achieve in advance for *emerging diseases*, but the generic approach that the *Competent Authority* will take for suspect and confirmed cases of *emerging diseases* should be considered in peacetime.

3~~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;

4~~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 1 to 7~~(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'.

5~~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.;

6~~5~~) all elements of the framework should be regularly reviewed and revised as described in Article 4.X.9.;

7~~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 and the outcomes from those systems are heavily reliant on the quality of 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 a~~the~~ *Competent Authority* in overall command. This chain of command should include decision makers from other *Competent Authorities*~~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 Authorities~~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, producer~~s'~~ 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. and are included in an Operations Manual.

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, highlighting lessons learnt, describing the actions necessary to address~~close~~ any gaps which have been identified in the *contingency plan*, and any~~or~~ other necessary amendments ~~which are required~~ to the operational measures which are described in Chapter 4.Y. This should include identification of individuals responsible for delivery and a timeframe within which the actions should be completed.

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, covering the entire territory, or *zones* or *compartments* thereof, 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 for *listed diseases* 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.

Annex 6. Item 6.1. – Draft new Chapter 4.Y. 'Disease outbreak management'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.Y.

DISEASE OUTBREAK MANAGEMENT

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.1.~~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 Authorities*~~*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 (refer to Articles 4.Y.4., 4.Y.5. and 4.Y.9. respectively);

3) the preferred~~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 *aquatic animal disease* ~~of *aquatic animals*~~, generally as a consequence of active or *passive surveillance* in the country, or in another country, which is a neighbouring country that share common waterways or which is 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.

The main actions to be taken ~~into account~~ during the alert phase of an emergency should include ~~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,~~ the initiation of 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 by using the case definitions for suspect and confirmed cases of *listed diseases* and non-listed *diseases*, which have been recommended in Article 4.X.4. For an *emerging disease* establish working case definitions for suspect and confirmed cases based on the best scientific knowledge which exists at the time;

~~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);~~

b~~c~~~~b~~) gather information to determine potential ~~if the~~ *disease* ~~has~~ spread from or to *aquaculture establishments* or waterbodies other than the one in which the original suspicion was raised. This information can be used to inform *risk*-based *surveillance* as described in point 2 a), which may commence during the alert phase and become fully applicable during the emergency phase, if the *disease* is confirmed.

2~~3~~) 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 when feasible, 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.

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) 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, relevant~~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 by the *Competent Authority*, relevant actors are informed that the situation is moving back to peacetime, and any outcomes which warrant review of the *Contingency Plan*, are made;

8~~9~~) ~~the alert phase ends when~~ should the presence of an important *disease* be~~is either~~ confirmed ~~or ruled out~~ by the *Competent Authority*, relevant~~. Relevant~~ actors are informed ~~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 *aquatic animal 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 *risk*-based *surveillance* and sampling referred to in Article 4.Y.4.;

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

4~~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 including relevant information on~~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* and vectors with a potential epidemiological link to~~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 instruments which support~~s the provision of funding for~~ the management of disease emergencies concerning *aquatic animals*, including the provision of funding;

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* and other relevant stakeholders 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;

viii) finance and resource procurement.

2) Laboratories

a) During the emergency, the *Aquatic Animal Health Services* and industry should submit samples to the laboratories which have been identified in the *Contingency Plan* as per Article 4.X.7. 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* and where relevant the case definitions for non-listed and *emerging diseases* which are referred to in Articles 4.X.4. and 4.Y.4. 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 ~~P~~providers

The availability of relevant service providers during the emergency phase is of crucial importance, in particular, considering that a *disease outbreak* may include ~~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 specialist~~specials~~ or journalist for media liaison;

~~f) telecommunications providers;~~

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

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

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

i~~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;

j~~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, likely outbreak scenarios, and operational infrastructure which apply in a country, contact~~Contact~~ details of the providers referred to in points a) to j~~k~~~~h~~) above are detailed in the Operations Manual.

Article 4.Y.8.

Biosecurity and other disease control measures

The actions which a~~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;

e~~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 contaminated by a *pathogenic agent* which is 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 intention~~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 a~~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* and industry to explain relevant details of the recovery plan and to reinforce the role the *Aquatic Animal Health Services* and industry play in future *disease* prevention and control.

Annex 7. Item 6.2. – 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

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 from the traded *gametes* and *fertilised eggs* ~~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 are demonstrated to be ~~test~~ free from the *pathogenic agents* of concern, as described in point 3 of Article 4.Z.4., are suitable for movement~~supply~~ to *collection and incubation centres*~~, as described in Article 4.Z.4.~~;

2) *gametes*~~milt~~ and *fertilised eggs* must~~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* must~~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 must~~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 been individually tested and are negative for ~~tested free from~~ the relevant *pathogenic agent*~~*disease*~~, and which meet the requirements in points 1,~~ and~~ 2 and 4.

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

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

3) the broodstock to be transferred should be sampled and tested for the *pathogenic agents* of concern no more than 30 days before the broodstock's entry 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.

Article 4.Z.5.

Collection and incubation centres

Collection and incubation centres should be approved for that purpose by the *Competent Authority*, and be under its official control. ~~for that purpose on the basis that the~~ The *collection and incubation centre* should meet the following requirements ~~should~~:

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

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

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

4) have~~has~~~~have in place~~ a ~~valid traceability~~ system in place to ensure that *gametes* ~~milt~~~~each batch of *gametes*~~ or *fertilised eggs* can be traced back to an epidemiologically separate individual or group as relevant, 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;~~

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

~~c) milt testing and storage;~~

~~d) disinfection of *fertilised eggs*;~~

~~eb) an incubation of centre for *fertilised eggs*;~~

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

~~fd) administration offices.~~

5~~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.

Biosecurity conditions applicable to collection and incubation centres

Collection and incubation centres must have a *biosecurity plan* which has been developed in accordance with Chapter 4.1. To further minimise the risk of contamination of *gametes* and *fertilised eggs* by common microorganisms, some which may be pathogenic, the following measures should be taken:

1) the *collection and incubation centre* should be separated into dedicated areas for:

   a) holding broodstock prior to *gamete* collection;

   b) collection of *gametes*;

   c) milt testing and storage;

   d) disinfection of *fertilised eggs*;

   e) incubation of *fertilised eggs*;

   f) collection of *aquatic animal products* and waste;

   g) administration.

2) water used, including for production and shipment (such as ice), should be free from *pathogenic agents* of concern;

3) only fish directly associated with the production of *gametes* should be permitted to enter the *collection and incubation centre*;

4) when collecting *gametes* from broodstock, all necessary precautions should be taken to prevent the risk of contamination from the skin, surface, or blood;

5) procedures should include the use of sterile equipment, gloves and any other appropriate contamination-prevention measures to maintain the sanitary integrity of the *gametes* or *fertilised eggs*;

6) incubators should be cleaned and disinfected before and after each use;

7) each broodstock should be euthanized after removal of eggs or after the last collection of milt;

8) the system described in point 4 of Article 4.Z.5. should ensure that *gametes* or *fertilised eggs* can be traced back to the individual parent and the associated screening results;

9) where the system only allows tracking to the group and not to the individual, the measures referred to in point 5 of Article 4.Z.7. should apply to the group;

10) if *fertilised eggs* from multiple parents are incubated together and a positive individual is detected, all *fertilised eggs* that were incubated together should be discarded.

Article 4.Z.7~~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 oversight~~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*;

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 point 2 ~~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*, *fertilised eggs* 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 in accordance with the protocol ~~as~~ described in Article 4.5.2.;~~Chapter 4.5.~~

7) any broodstock mortality should be investigated to determine cause of death.

Article 4.Z.8~~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 pathogen free ~~produced in a way to protect against contamination with *pathogenic agents*~~;

4) frozen milt should be stored in hermetically sealed containers at a species-specific optimal temperatures to maintain their viability in a separate room.

Annex 8. Item 6.2. – 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]

[…]

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~~either~~ points~~s~~ 1 or~~and~~or~~and~~ 2 below:~~.:~~.

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

Either~~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~~Or~~

d)~~d) apply the requirements of Chapter 4.Z.~~apply the requirements of Chapter 4.Z. regarding *gametes* or *fertilized eggs*.

OR

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

Either~~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~~Or~~

c)~~c) apply the requirements of Chapter 4.Z.~~ apply the requirements of Chapter 4.Z. regarding *gametes* or *fertilized eggs*.

[…]

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~~either~~ points~~s~~ 1 or~~and~~or~~and~~ 2 below:~~:~~.

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

Either~~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~~Or~~

d)~~d) apply the requirements of Chapter 4.Z.~~apply the requirements of Chapter 4.Z. regarding *gametes* or *fertilized eggs*.

OR

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

Either~~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~~Or~~

c)~~c) apply the requirements of Chapter 4.Z.~~ apply the requirements of Chapter 4.Z. regarding *gametes* or *fertilized eggs*.

[…]

Annex 9. Item 6.2. – 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]

[…]

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

In this article, all statements referring to infection with ISAV includes HPR-deleted ISAV and HPR0 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 10. Items 6.2. and 6.3. – Glossary

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*. 'Uneyed~~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 11. Item 6.3. – 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

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) an importer should take into account the eligibility for international movement of a consignment of *ornamental aquatic animals,* as described in Article 5.X.4.; ~~the legalityeligibility 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 trade 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 consulting the *Competent Authority* with responsibility for *aquatic animal* health concerning ~~considering~~ the *aquatic animal* health *risks* associated with the import of a species of *ornamental aquatic animal*, an importer ~~the *Competent Authority* of an *importing country*~~ should first 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 trade 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 *aquaculture establishment* from which they are exported~~place of origin (as described in point 2 of Article 5.X.7.)~~ and meet general health requirements in accordance with Article 5~~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 duration~~length~~ of *quarantine* period and the *quarantine* conditions 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 that the consignment is ~~they are~~ free from *pathogenic agents* of concern; for *listed diseases* testing should comply with the recommendations in the *Aquatic Manual*;

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) A requirement that *aquatic animals* are not subject to pharmacological therapies prior to export which could mask clinical signs of *disease;*

8~~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.

Plans~~*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 12. Item 6.4. – 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

September 2024

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 or 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 nine 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). This pathway is not considered suitable for one pathogen.
- 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* HPR-deleted ISAV IHNV ISAV (including HPR0 and HPR-deleted) KHV SVCV TiLV	AHPND *H. penaei* IHHNV IMNV MrNV YHV1	AbHV *B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *X. californiensis*	*B. salamondrivorans*
12 months	SAV			
Pathway not suitable	EUS *M. pagrus 1*	crayfish plague DIV1	*P. olseni*	*B. dendrobatidis* *Ranavirus*

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
	VHSV	WSSV		

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 HPR-deleted ISAV IHNV *M. pagrus 1* SAV SVCV TiLV VHSV	AHPND crayfish plague DIV1 *H. penaei* 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			
Pathway not suitable	ISAV (including HPR0 and HPR-deleted)			

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				
1 year	EHNV HPR-deleted ISAV IHNV ISAV (including HPR0 and HPR-deleted) *M. pagrus 1* SAV SVCV VHSV TiLV	AHPND crayfish plague DIV1 *H. penaei* IHHNV IMNV MrNV WSSV YHV1	AbHV	*B. dendrobatidis* *B. salamandrivorans*

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
2 years	EUS *G. salaris* KHV		*B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *P. olseni* *X. californiensis*	*Ranavirus*
TS				
2 years	*A. astacii* EHNV HPR-deleted ISAV IHNV ISAV (including HPR0 and HPR-deleted) *M. pagrus 1* SAV SVCV TiLV VHSV	AHPND crayfish plague DIV1 *H. penaei* IHHNV IMNV MrNV WSSV YHV1	AbHV	*B. dendrobatidis* *B. salamondrivorans*
3 years	EUS *G. salaris* KHV		*B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *P. olseni* *X. californiensis*	*Ranavirus*

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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 and HPR0 infectious salmon anaemia virus
HPR-deleted ISAV	Infection with HPR-deleted infectious salmon anaemia virus
KHV	Infection with koi herpesvirus
M. pagrus 1	Infection with *Megalocytivirus pagrus 1*
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 listed 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) 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 aquatic animal 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	*G. salaris* KHV	AHPND WSSV* YHV1		
2	EHNV HPR-deleted ISAV IHNV ISAV (including HPR0 and HPR-deleted) *M. pagrus 1** SVCV TiLV VHSV*	DIV1* *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. Diseases have been determined to have a broad host range consistent with the criteria for application of *Aquatic Code* Article 1.5.9.

Pathway 1 is thus unsuitable for eight species - EUS, *M. pagrus 1*, VHSV, crayfish plague, DIV1, WSSV, *P. olseni*, *B. dendrobatidis* and *Ranavirus*. 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, *G. salaris* and ISAV (including HPR0 and HPR-deleted) have a high likelihood of detection by 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.

For infection with infectious salmon anaemia virus, the standards of the *Aquatic Code* apply to two categories of disease status: freedom from ISAV (including HPR0 and HPR-deleted) and freedom from HPR-deleted ISAV only. For HPR-deleted ISAV, infection in populations of Atlantic salmon may lead to clinical signs and an observable level of mortality and pathway 2 is applicable. For HPR0 ISAV, clinical disease is not expected so pathway 2 is not considered appropriate to claim freedom from the category with all forms of ISAV (including HPR0 and HPR-deleted).

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.

Claims of freedom from *B. dendrobatidis, B. salamondrivorans* and *Ranavirus* 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 DIV1 *H. penaei* IHHNV IMNV MrNV WSSV YHV1	AbHV	*B. dendrobatidis* *B. salamondrivorans* *Ranavirus*
2	EHNV IHNV HPR-deleted ISAV *M. pagrus 1* TiLV SVCV VHSV		*B. exitiosa* *B. ostreae* *M. refringens* *P. marinus* *P. olseni* *X. californiensis*	
3	*G. salaris* EUS KHV			

Ranking	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
Not suitable	ISAV (including HPR-deleted and HPR0)			

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.

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. For EUS, the likelihood of rapid detection is dependent on predisposing factors.
- The ranking and recommendations for ISAV was for each of the two categories of disease freedom available in the *Aquatic Code* (i.e. either ISAV (including HPR0 and HPR-deleted) or HPR-deleted ISAV only). HPR0 ISAV is not known to cause clinical disease and exists at very low prevalences in wild Atlantic salmon populations. Historical freedom is therefore not considered a suitable pathway for ISAV (including HPR0 and HPR-deleted). Pathway 2 is suitable for HPR-deleted ISAV as it is expected to cause clinical signs and mortality.

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 difficult thus a conservative approach to ranking was taken.

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 IHNV HPR-deleted ISAV ISAV (including HPR0 and HPR-deleted) *M. pagrus 1* SVCV TILV VHSV			*B. salamondrivorans*
3	EUS KHV *G. salaris*		*B. exitiosa* *B. ostreae* *P. marinus* *P. olseni* *M. refringens* *X. californiensis*	*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. For EUS, the likelihood of rapid detection is dependent on predisposing factors

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*
- Ranavirus is listed as a genus. Rate of spread and transmission varies considerably between hosts and viral species (multiple), making ranking at genus level difficult thus conservative approach to ranking was taken.

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*

Ranking	Fish	Crustacean	Molluscs	Amphibian
2	VHSV IHNV SVCV *M. pagrus 1* HPR-deleted ISAV ISAV (including HPR0 and HPR-deleted) TiLV EHNV			*B. salamondrivorans*
3	EUS *G. salaris* KHV		*B. exitiosa* *B. ostreae* *P. marinus* *P. olseni* *M. refringens* *X. californiensis*	*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 (including 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*). The pathway is not suitable for ISAV (Including HPR0 and HPR-deleted) because HPR0 ISAV is not expected to cause clinical signs. The pathway is however suitable for HPR-deleted ISAV. 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.

Ranavirus genus has a large variation in characteristics between the multiple hosts and pathogens and thus is difficult to fully assess. As such, *Ranavirus* was ranked as a 3 which provided a longer BBC and TS to account for the limited information available and the variation which exists within this genus. 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 are 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	*Megalocytivirus pagrus 1*	Spring viraemia of carp	Viral haemorrhagic septicaemia	Infection with abalone herpesvirus	Infection with *Bonamia ostreae*	Infection with *Bonamia exitiosa*	Infection with *Marteilia refringens*	Infection with *Perkinsus marinus*	Infection with *Perkinsus olseni*	Infection with *Xenohaliotis californiensis 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
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	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
M. pagrus 1	Simple-direct	High – very infectious, low minimum infectious dose	High: Rapid onset clinical signs	Restricted to summer months (water temp >25 C)	unknown	2
HPR-deleted ISAV	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
ISAV (including HPR0 and HPR-deleted)	Simple-direct	High- very infectious, low minimum infectious dose	Very low: HPR0 ISAV is not expected to cause clinical signs	Unrestricted with mortality peaks in early summer and winter	Low persistence – hours to days	2

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
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)	Low to High: Rapid onset clinical signs, but require predisposing factors for clinical expression.	Restricted 18-22 C.	Month-years (encysted form)	3
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
DIV1	Simple-direct	Rapid spread and high prevalence recorded in shrimp and crayfish	High: Rapid onset mortality	Infection recorded over a wide temperature range	No information available	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*, *P. monodon* (may go undetected for months)	High; *P. stylirostris* Low: *P.vannamei*, *P. monodon*	Unrestricted – reduced replication at high temp	No information available	2
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	Little information – probably unrestricted	viable in aerated seawater for 3 d	1

Pathogen	Life-cycle	Rate of spread	Early detection (LH)	Transmission period	Environmental persistence	Ranking
			Rapid onset mortality			

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 species	Simple - direct	Host species / viral species dependent	Host species / viral species dependent	Not known: Outbreaks area seasonal	Months	3*

LH = likelihood

* Due to the numerous viral species and broad host range of those viral species for *Ranavirus* species a conservative approach was utilised and *Ranavirus* species was ranked 3.

Annex 13. Item 6.4. – Default Periods of basic biosecurity conditions and targeted surveillance for disease-specific chapters of the *Aquatic Code*

Article	Amended Text
Article 8.1.5. Country free from infection with *B. dendrobatidis*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *B. dendrobatidis* ~~none of the *susceptible species* referred to in Article 8.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *B. dendrobatidis* for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. dendrobatidis*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of *B. dendrobatidis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of *B. dendrobatidis*; or ii) at least the last one ~~[one]~~ year~~s~~ without detection of *B. dendrobatidis* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 8.1.6. Zone free from infection with *B. dendrobatidis*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *B. dendrobatidis* ~~none of the *susceptible species* referred to in Article 8.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *B. dendrobatidis* for at least the last ten ~~[ten]~~ years, and: […]

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of *B. dendrobatidis* and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. dendrobatidis*.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of *B. dendrobatidis*; or ii) at least the last one year without detection of *B. dendrobatidis* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species.* […]
Article 8.1.7. Compartment free from infection with *B. dendrobatidis*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *B. dendrobatidis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *B. dendrobatidis* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 8.2.5. Country free from infection with *B. salamandrivorans*	[…] 1) none of the *susceptible species* referred to in Article 8.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *B. salamandrivorans* for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. salamandrivorans*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of *B. salamandrivorans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of *B. salamandrivorans*; or ii) at least the last one ~~[one]~~ year without detection of *B. salamandrivorans* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 8.2.6. Zone free from infection with *B. salamandrivorans*	[…] 1) none of the *susceptible species* referred to in Article 8.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *B. salamandrivorans* for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of *B. salamandrivorans* and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. salamandrivorans*.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of *B. salamandrivorans*; or

Article	Amended Text
	ii) at least the last one year without detection of *B. salamandrivorans* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 8.2.7. Compartment free from infection with *B. salamandrivorans*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one ~~[two]~~ year~~s~~ without detection of *B. salamandrivorans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] […] c) one survey for infection with *B. salamandrivorans* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 8.3.5. Country free from infection with *Ranavirus species*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *Ranavirus species* ~~none of the *susceptible species* referred to in Article 8.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *Ranavirus species* for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *Ranavirus species*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three ~~[two]~~ years without detection of *Ranavirus species*, and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three ~~[two]~~ years in wild and farmed *susceptible species* without detection of *Ranavirus species*; or

Article	Amended Text
	ii) at least the last one ~~[one]~~ year without detection of *Ranavirus species* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 8.3.6. Zone free from infection with *Ranavirus species*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *Ranavirus species* ~~none of the *susceptible species* referred to in Article 8.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *Ranavirus species* for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *Ranavirus species* and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for; ~~at least the last [two] years without detection of *Ranavirus species*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *Ranavirus species*; or ii) at least the last one year without detection of *Ranavirus species* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 8.3.7. Compartment free from infection with *Ranavirus species*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *Ranavirus species*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […]

Article	Amended Text
	c) one survey for infection with *Ranavirus species* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.1.5. Country free from AHPND	[…] 1) none of the *susceptible species* referred to in Article 9.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with AHPND for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with AHPND, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of AHPND, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of AHPND; or ii) at least the last one ~~[one]~~ year without detection of AHPND if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.1.6. Zone free from infection with AHPND	[…] 1) none of the *susceptible species* referred to in Article 9.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with AHPND for at least the last ten ~~[ten]~~ years, and: […]

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of AHPND and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of AHPND~~. i) at least the last two years in wild and farmed *susceptible species* without detection of AHPND; or ii) at least the last one year without detection of AHPND if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.1.7. Compartment free from infection with AHPND	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of AHPND, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with AHPND has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.2.5. Country free from *A. astaci*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *A. astaci* ~~none of the *susceptible species* referred to in Article 9.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *A. astaci* for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. astaci*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of *A. astaci*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of *A. astaci*; or ii) at least the last one ~~[one]~~ year without detection of *A. astaci* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.2.6. Zone free from infection with *A. astaci*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *A. astaci* ~~none of the *susceptible species* referred to in Article 9.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *A. astaci* for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of *A. astaci* and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *A. astaci*~~. i) at least the last two years in wild and farmed *susceptible species* without detection of *A. astaci*; or

Article	Amended Text
	ii) at least the last one year without detection of *A. astaci* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.2.7. Compartment free from infection with *A. astaci*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one[one] year without detection of *A. astaci*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one[one] year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *A. astaci* has been completed at least six months [six months] after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*pathogen. […]
Article 9.3.5. Country free from DIV1	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with DIV1 none of the *susceptible species* referred to in Article 9.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months; OR 2) there has been no occurrence of infection with DIV1 for at least the last ten[ten] years, years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with DIV1, as described in Article 1.4.8. of Chapter 1.4.the corresponding chapter of the *Aquatic Manual*; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten[ten] years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two[two] years without detection of DIV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one[one] year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two[two] years in wild and farmed *susceptible species* without detection of DIV1; or

Article	Amended Text
	ii) at least the last one~~[one]~~ year without detection of DIV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.3.6. Zone free from infection with DIV1	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with DIV1~~none of the *susceptible species* referred to in Article 9.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with DIV1 for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of DIV1 and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of DIV1~~. i) at least the last two years in wild and farmed *susceptible species* without detection of DIV1; or ii) at least the last one year without detection of DIV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.3.7. Compartment free from infection with DIV1	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of DIV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […]

Article	Amended Text
	c) one survey for infection with DIV1 has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.4.5. Country free from *H. penaei*	[…] 1) none of the *susceptible species* referred to in Article 9.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *H. penaei* for at least the last ten ~~[ten]~~ years, and: b) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *H. penaei*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of *H. penaei*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of *H. penaei*; or ii) at least the last one ~~[one]~~ year without detection of *H. penaei* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.4.6. Zone free from infection with *H. penaei*	[…] 1) none of the *susceptible species* referred to in Article 9.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *H. penaei* for at least the last ten ~~[ten]~~ years, and: […]

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of *H. penaei* and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *H. penaei*~~. i) at least the last two years in wild and farmed *susceptible species* without detection of *H. penaei*; or ii) at least the last one year without detection of *H. penaei* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.4.7. Compartment free from infection with *H. penaei*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of *H. penaei*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *H. penaei* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.5.5. Country free from IHHNV	[…] 1) none of the *susceptible species* referred to in Article 9.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with IHHNV for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHHNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of IHHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of IHHNV; or ii) at least the last one ~~[one]~~ year without detection of IHHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.5.6. Zone free from infection with IHHNV	[…] 1) none of the *susceptible species* referred to in Article 9.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with IHHNV for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of IHHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of IHHNV~~. i) at least the last two years in wild and farmed *susceptible species* without detection of IHHNV; or

Article	Amended Text
	ii) at least the last one year without detection of IHHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.5.7. Compartment free from infection with IHHNV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of *H. penaei*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *H. penaei* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.6.5. Country free from IMNV	[…] 1) none of the *susceptible species* referred to in Article 9.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with IMNV for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IMNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of IMNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of IMNV; or

Article	Amended Text
	ii) at least the last one ~~[one]~~ year without detection of IMNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.6.6. Zone free from infection with IMNV	[…] 1) none of the *susceptible species* referred to in Article 9.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with IMNV for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of IMNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place: ~~at least the last [two] years without detection of IMNV~~. i) at least the last two years in wild and farmed *susceptible species* without detection of IMNV; or ii) at least the last one year without detection of IMNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.6.7. Compartment free from infection with IMNV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of IMNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with IMNV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article	Amended Text
	[…]
Article 9.7.5. Country free from MrNV	[…] 1) none of the *susceptible species* referred to in Article 9.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with MrNV for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with MrNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of MrNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of MrNV; or ii) at least the last one ~~[one]~~ year without detection of MrNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.7.6. Zone free from infection with MrNV	[…] 1) none of the *susceptible species* referred to in Article 9.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with MrNV for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR

Article	Amended Text
	3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of MrNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:~~at least the last [two] years without detection of MrNV~~. i) at least the last two years in wild and farmed *susceptible species* without detection of MrNV; or ii) at least the last one year without detection of MrNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.7.7. Compartment free from infection with MrNV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of MrNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with MrNV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.8.5. Country free from infection with TSV	[…] 1) none of the *susceptible species* referred to in Article 9.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with TSV for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TSV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of TSV, and *basic biosecurity conditions* have been

Article	Amended Text
	continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of TSV; or ii) at least the last one ~~[one]~~ year without detection of TSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.8.6. Zone free from infection with TSV	[…] 1) none of the *susceptible species* referred to in Article 9.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with TSV for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of TSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for ~~:at least the last [two] years without detection of TSV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of TSV; or ii) at least the last one year without detection of TSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.8.7.	[…]

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Compartment free from infection with TSV	1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of TSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with TSV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.9.5. Country free from infection with WSSV	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with WSSV ~~none of the *susceptible species* referred to in Article 9.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with WSSV for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with WSSV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of WSSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of WSSV; or ii) at least the last one ~~[one]~~ year without detection of WSSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.9.6. Zone free from infection with WSSV	[…]

Article	Amended Text
	1) pathway 1 (absence of susceptible species) not suitable for infection with WSSV ~~none of the *susceptible species* referred to in Article 9.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with WSSV for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of WSSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of WSSV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of WSSV; or ii) at least the last one year without detection of WSSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.9.7. Compartment free from infection with WSSV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of WSSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with WSSV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 9.10.5. Country free from infection with YHV1	[…] 1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months;

Article	Amended Text
	OR 2) there has been no occurrence of infection with YHV1 for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with YHV1, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of YHV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of YHV1; or ii) at least the last one ~~[one]~~ year without detection of YHV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.10.6. Zone free from infection with YHV1	[…] 1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with YHV1 for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of YHV1 and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR

Article	Amended Text
	4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for; ~~at least the last [two] years without detection of YHV1~~. i) at least the last two years in wild and farmed *susceptible species* without detection of YHV1; or ii) at least the last one year without detection of YHV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 9.10.7. Compartment free from infection with YHV1	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of YHV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with YHV1 has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.1.5. Country free from infection with EHNV	[…] 1) none of the *susceptible species* referred to in Article 10.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with EHNV for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with EHNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of EHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […]

Article	Amended Text
	d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of EHNV; or ii) at least the last one ~~[one]~~ year without detection of EHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.1.6. Zone free from infection with EHNV	[…] 1) none of the *susceptible species* referred to in Article 10.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with EHNV for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of infection with EHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of EHNV~~. i) at least the last two years in wild and farmed *susceptible species* without detection of EHNV; or ii) at least the last one year without detection of EHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.1.7. Compartment free from infection with EHNV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of EHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR

Article	Amended Text
	2) […] c) one survey for infection with EHNV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.2.5. Country free from infection with *A. invadans*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *A. invadans* ~~none of the *susceptible species* referred to in Article 10.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;~~ OR 2) there has been no occurrence of infection with *A. invadans* for at least the last 15 ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. invadans*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last 15 ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three ~~[two]~~ years without detection of *A. invadans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three ~~[two]~~ years in wild and farmed *susceptible species* without detection of *A. invadans*; or ii) at least the last one ~~[one]~~ year without detection of *A. invadans* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.2.6. Zone free from infection with *A. invadans*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *A. invadans* ~~none of the *susceptible species* referred to in Article 10.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;~~ OR 2) there has been no occurrence of infection with *A. invadans* for at least the last 15 ~~[ten]~~ years, and:

Article	Amended Text
	[…] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last 15 ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *A. invadans* and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for; ~~at least the last [two] years without detection of *A. invadans*~~. i) at least the last three years in wild and farmed *susceptible species* without detection of *A. invadans*; or ii) at least the last one year without detection of *A. invadans* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.2.7. Compartment free from infection with *A. invadans*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of *A. invadans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *A. invadans* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.3.5. Country free from infection with *G. salaris*	[…] 1) none of the *susceptible species* referred to in Article 10.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *G. salaris* for at least the last 15~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *G. salaris*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last 15 ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three ~~[two]~~ years without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three ~~[two]~~ years in wild and farmed *susceptible species* without detection of *G. salaris*; or ii) at least the last one ~~[one]~~ year without detection of *G. salaris* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.3.6. Zone free from infection with *G. salaris*	[…] 1) none of the *susceptible species* referred to in Article 10.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *G. salaris* for at least the last 15~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last 15 ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *G. salaris* and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *G. salaris*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *G. salaris*; or

Article	Amended Text
	ii) at least the last one year without detection of *G. salaris* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.3.7. Compartment free from infection with *G. salaris*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *G. salaris* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent~~pathogen~~*. […]
Article 10.4.5. Country free from infection with ISAV	In this article, all statements referring to a country free from ISAV are for any detectable ISAV, including HPR0 ISAV. […] 1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) pathway 2 (historical freedom) is not suitable for infection with ISAV; ~~there has been no occurrence of infection with ISAV for at least the last [ten] years, and:~~ ~~a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with ISAV, as described in the corresponding chapter of the *Aquatic Manual*; and~~ ~~b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;~~ OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of ISAV; or

Article	Amended Text
	ii) at least the last one ~~[one]~~ year without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.4.6. Country free from infection with HPR-deleted ISAV	[…] If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with HPR-deleted ~~HPR0~~ ISAV if all shared water bodies are within countries or *zones* declared free from infection with HPR-deleted ~~HPR0~~ ISAV (see Article 10.4.8.). As described in Article 1.4.4., a Member Country may make a self-declaration of freedom with HPR-deleted ~~HPR0~~ ISAV for its entire territory if it can demonstrate that: 1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with HPR-deleted~~HPR0~~ ISAV for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with HPR-deleted~~HPR0~~ ISAV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of HPR-deleted~~HPR0~~ ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) it previously made a self-declaration of freedom from infection with HPR-deleted~~HPR0~~ ISAV and subsequently lost its free status due to the detection of HPR-deleted ~~HPR0~~ ISAV but the following conditions have been met: a) on detection of HPR-deleted~~HPR0~~ ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of HPR-deleted~~HPR0~~ ISAV, and the appropriate disinfection procedures (as described in Chapter 4.4.) have been completed followed by fallowing as described in Chapter 4.7.; and c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with HPR-deleted~~HPR0~~ ISAV; and d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of HPR0 ISAV.

Article	Amended Text
	i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of ISAV; or ii) at least the last one ~~[one]~~ year without detection of HPR-deleted ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.4.7. Zone free from infection with ISAV	[…] 1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) pathway 2 (historical freedom) is not suitable for infection with ISAV; ~~there has been no occurrence of infection with ISAV for at least the last [ten] years, and:~~ ~~a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with ISAV, as described in the corresponding chapter of the *Aquatic Manual*; and~~ ~~b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;~~ OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for : ~~at least the last [two] years without detection of ISAV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of ISAV; or ii) at least the last one year without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.4.8. Zone free from infection with HPR-deleted ISAV	[…] 1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with HPR-deleted ISAV for at least the last ten~~[ten]~~ years, and:

Article	Amended Text
	[…] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of HPR-deleted ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for; ~~at least the last [two] years without detection of HPR-deleted ISAV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of HPR-deleted ISAV; or ii) at least the last one year without detection of HPR-deleted ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.4.9. Compartment free from infection with ISAV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with ISAV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.4.10. Compartment free from infection with HPR-deleted ISAV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of HPR-deleted ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […]

Article	Amended Text
	c) one survey for infection with HPR-deleted ISAV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.5.5. Country free from infection with SAV	[…] 1) none of the *susceptible species* referred to in Article 10.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last 12 ~~[six]~~ months; OR 2) there has been no occurrence of infection with SAV for at least the last ten~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SAV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of SAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of SAV; or ii) at least the last one ~~[one]~~ year without detection of SAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.5.6. Zone free from infection with SAV	[…] 1) none of the *susceptible species* referred to in Article 10.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last 12 ~~[six]~~ months; OR 2) there has been no occurrence of infection with SAV for at least the last ten~~[ten]~~ years, and: […]

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of SAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of SAV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of SAV; or ii) at least the last one year without detection of SAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.5.7. Compartment free from infection with SAV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of SAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with SAV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.6.5. Country free from infection with IHNV	[…] 1) none of the *susceptible species* referred to in Article 10.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with IHNV for at least the last ten ~~[ten]~~ years, years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of IHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two ~~[two]~~ years in wild and farmed *susceptible species* without detection of IHNV; or ii) at least the last one ~~[one]~~ year without detection of IHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.6.6. Zone free from infection with IHNV	[…] 1) none of the *susceptible species* referred to in Article 10.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with IHNV for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of IHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place: ~~at least the last [two] years without detection of IHNV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of IHNV; or

Article	Amended Text
	ii) at least the last one year without detection of IHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.6.7. Compartment free from infection with IHNV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of IHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with IHNV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.7.5. Country free from infection with KHV	[…] 1) none of the *susceptible species* referred to in Article 10.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with KHV for at least the last 15~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with KHV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last 15 ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three ~~[two]~~ years without detection of KHV and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three ~~[two]~~ years in wild and farmed *susceptible species* without detection of KHV; or

Article	Amended Text
	ii) at least the last one ~~[one]~~ year without detection of KHV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.7.6. Zone free from infection with KHV	[…] 1) none of the *susceptible species* referred to in Article 10.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with KHV for at least the last 15~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last 15 ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of KHV and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of KHV.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of KHV; or ii) at least the last one year without detection of KHV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.7.7. Compartment free from infection with KHV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of KHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with KHV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~.

Article	Amended Text
	[…]
Article 10.9.5. Country free from infection with SVCV	[…] 1) none of the *susceptible species* referred to in Article 10.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with SVCV for at least the last ten~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SVCV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of SVCV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of SVCV; or ii) at least the last one~~[one]~~ year without detection of SVCV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.9.6. Zone free from infection with SVCV	[…] 1) none of the *susceptible species* referred to in Article 10.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with SVCV for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR

Article	Amended Text
	3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of SVCV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of SVCV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of SVCV; or ii) at least the last one year without detection of SVCV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.9.7. Compartment free from infection with SVCV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of SVCV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 1) […] c) one survey for infection with SVCV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 10.10.5. Country free from infection with VHSV	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with VHSV; ~~none of the *susceptible species* referred to in Article 10.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;~~ OR 2) there has been no occurrence of infection with VHSV for at least the last ten~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with VHSV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years; OR

Article	Amended Text
	3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of VHSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of VHSV; or ii) at least the last one~~[one]~~ year without detection of SVCV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.10.6. Zone free from infection with VHSV	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with VHSV; ~~none of the *susceptible species* referred to in Article 10.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;~~ OR 2) there has been no occurrence of infection with VHSV for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of VHSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for : ~~at least the last [two] years without detection of VHSV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of VHSV; or ii) at least the last one year without detection of VHSV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]

Article	Amended Text
Article 10.10.7. Compartment free from infection with VHSV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of VHSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with VHSV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~[pathogen~~. […]
Article 10.11.5. Country free from infection with TiLV	[…] 1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with TiLV for at least the last ten~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TiLV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of TiLV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of TiLV; or ii) at least the last one~~[one]~~ year without detection of TiLV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.11.6.	[…]

Article	Amended Text
Zone free from infection with TiLV	1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with TiLV for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of TiLV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of TiLV.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of TiLV; or ii) at least the last one year without detection of TiLV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 10.11.7. Compartment free from infection with TiLV	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of TiLV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with TiLV has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 11.1.5. Country free from infection with abalone herpesvirus	[…] 1) none of the *susceptible species* referred to in Article 11.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

Article	Amended Text
	OR 2) there has been no occurrence of infection with abalone herpesvirus for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with abalone herpesvirus, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of abalone herpesvirus and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of abalone herpesvirus; or ii) at least the last one ~~[one]~~ year without detection of abalone herpesvirus if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.1.6. Zone free from infection with abalone herpesvirus	[…] 1) none of the *susceptible species* referred to in Article 11.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with abalone herpesvirus for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of abalone herpesvirus and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR

Article	Amended Text
	4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of abalone herpesvirus.~~ i) at least the last two years in wild and farmed *susceptible species* without detection of abalone herpesvirus; or ii) at least the last one year without detection of abalone herpesvirus if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.
Article 11.1.7. Compartment free from infection with abalone herpesvirus	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of abalone herpesevirus, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with abalone herpesvirus has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 11.2.5. Country free from infection with *B. exitiosa*	[…] 1) none of the *susceptible species* referred to in Article 11.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *B. exitiosa* for at least the last ten ~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. exitosa*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *B. exitiosa* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

Article	Amended Text
	i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *B. exitiosa*; or ii) at least the last one~~[one]~~ year without detection of *B. exitiosa* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.2.6. Zone free from infection with *B. exitiosa*	[…] 1) none of the *susceptible species* referred to in Article 11.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with *B. exitiosa* for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *B. exitiosa* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. exitiosa*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *B. exitiosa*; or ii) at least the last one year without detection of *B. exitiosa* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.2.7. Compartment free from infection with *B. exitiosa*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *B. exitiosa*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […]

Article	Amended Text
	c) one survey for infection with *B. exitiosa* has been completed at least six months [six months] after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*[pathogen]. […]
Article 11.3.5. Country free from infection with *B. ostreae*	[…] 1) none of the *susceptible species* referred to in Article 11.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six [six] months; OR 2) there has been no occurrence of infection with *B. ostreae* for at least the last ten[ten] years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. ostreae*, as described in Article 1.4.8. of Chapter 1.4.the corresponding chapter of the *Aquatic Manual*; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten[ten] years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three[two] years without detection of *B. ostreae* and *basic biosecurity conditions* have been continuously met and have been in place for at least two[one] years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three[two] years in wild and farmed *susceptible species* without detection of *B. ostreae*; or ii) at least the last one[one] year without detection of *B. ostreae* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.3.6. Zone free from infection with *B. ostreae*	[…] 1) none of the *susceptible species* referred to in Article 11.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[six] months; OR 2) there has been no occurrence of infection with *B. ostreae* for at least the last ten[ten] years, and: […]

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *B. ostreae* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. ostreae*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *B. ostreae*; or ii) at least the last one year without detection of *B. ostreae* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.3.7. Compartment free from infection with *B. ostreae*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *B. ostreae*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *B. ostreae* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 11.4.5. Country free from infection with *M. refringens*	[…] 1) none of the *susceptible species* referred to in Article 11.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with *M. refringens* for at least the last ten~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. refringens*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

Article	Amended Text
	b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *M. refringens* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *M. refringens*; or ii) at least the last one~~[one]~~ year without detection of *M. refringens* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.4.6. Zone free from infection with *M. refringens*	[…] 1) none of the *susceptible species* referred to in Article 11.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with *M. refringens* for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *M. refringens* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *M. refringens*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *M. refringens*; or

Article	Amended Text
	ii) at least the last one year without detection of *M. refringens* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.4.7. Compartment free from infection with *M. refringens*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one[two] year~~s~~ without detection of *M. refringens*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one[one] year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *M. refringens* has been completed at least six months [six months] after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*[pathogen]. […]
Article 11.5.5. Country free from infection with *P. marinus*	[…] 1) none of the *susceptible species* referred to in Article 11.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[six] months; OR 2) there has been no occurrence of infection with *P. marinus* for at least the last ten[ten] years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. marinus*, as described in Article 1.4.8. of Chapter 1.4.[the corresponding chapter of the *Aquatic Manual*]; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten[ten] years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three[two] years without detection of *P. marinus* and *basic biosecurity conditions* have been continuously met and have been in place for at least two[one] years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three[two] years in wild and farmed *susceptible species* without detection of *P. marinus*; or

Article	Amended Text
	ii) at least the last one ~~[one]~~ year without detection of *P. marinus* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.5.6. Zone free from infection with *P. marinus*	[…] 1) none of the *susceptible species* referred to in Article 11.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with *P. marinus* for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *P. marinus* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *P. marinus*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *P. marinus*; or ii) at least the last one year without detection of *P. marinus* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.5.7. Compartment free from infection with *P. marinus*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *P. marinus*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *P. marinus* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~.

Article	Amended Text
	[…]
Article 11.6.5. Country free from infection with *P. olseni*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *P. olseni* ~~none of the *susceptible species* referred to in Article 11.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *P. olseni* for at least the last ten~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. olseni*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *P. olseni* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *P. olseni*; or ii) at least the last one~~[one]~~ year without detection of *P. olseni* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.6.6. Zone free from infection with *P. olseni*	[…] 1) pathway 1 (absence of susceptible species) not suitable for infection with *P. olseni* ~~none of the *susceptible species* referred to in Article 11.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~; OR 2) there has been no occurrence of infection with *P. olseni* for at least the last ten ~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten ~~[ten]~~ years;

Article	Amended Text
	OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *P. olseni* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *P. olseni*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *P. olseni*; or ii) at least the last one year without detection of *P. olseni* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.6.7. Compartment free from infection with *P. olseni*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *P. olseni*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *P. olseni* has been completed at least six months~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. […]
Article 11.7.5. Country free from infection with *X. californiensis*	[…] 1) none of the *susceptible species* referred to in Article 11.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months; OR 2) there has been no occurrence of infection with *X. californiensis* for at least the last ten~~[ten]~~ years, and: a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *X. californiensis*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years; OR

Article	Amended Text
	3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *X. californiensis* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *X. californiensis*; or ii) at least the last one~~[one]~~ year without detection of *X. californiensis* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]
Article 11.7.6. Zone free from infection with *X. californiensis*	[…] 1) none of the *susceptible species* referred to in Article 11.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months; OR 2) there has been no occurrence of infection with *X. californiensis* for at least the last ten~~[ten]~~ years, and: […] b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years; OR 3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three ~~[two]~~ years without detection of *X. californiensis* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*; OR 4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *X. californiensis*.~~ i) at least the last three years in wild and farmed *susceptible species* without detection of *X. californiensis*; or ii) at least the last one year without detection of *X. californiensis* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. […]

Article	Amended Text
Article 11.7.7. Compartment free from infection with *X. californiensis*	[…] 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *X. californiensis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) one survey for infection with *X. californiensis* has been completed at least six months ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~[pathogen~~. […]

Annex 14. Item 6.5.2. – Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus'

CHAPTER 9.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

[…]

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 clarkii ~~*spp.* (all species)~~	red swamp crawfish ~~N/A~~
	Procambarus zonangulus	no common name
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	*Macrobrachium nipponense*	Oriental river prawn
	Palaemon carinicauda ~~*spp.* (all species)~~	ridgetail prawn ~~N/A~~
	Palaemon orientis	no common name
	Palaemon ritteri	barred grass shrimp
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 15. Item 6.6. – Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with Aphanomyces invadans (epizootic ulcerative syndrome)'

CHAPTER 10.2.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

Article 10.2.1.

For the purposes of the *Aquatic Code*, infection with *Aphanomyces invadans* means *infection* with the *pathogenic agent A. invadans* (syn. *A. piscicida*) of the Genus *Aphanomyces* and Family Leptolegniaceae. The *disease* was previously referred to as epizootic ulcerative syndrome.

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

Article 10.2.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Alosidae	*Alosa sapidissima*	American shad
	Brevoortia tyrannus	Atlantic menhaden
Anabantidae	*Anabas testudineus*	climbing perch
Bagridae	*Mystus cavasius*	gangetic mystus
Centrarchidae	*Lepomis macrochirus*	bluegill
	Micropterus dolomieu	smallmouth bass
	Micropterus salmoides	largemouth black bass
Channidae	*Channa spp.*(all species)	N/A
Cichlidae	*Etroplus suratensis*	pearlspot
Clariidae	*Clarias gariepinus*	North African catfish
Cyprinidae	*Cirrhinus mrigala*	mrigal carp
	Dawkinsia filamentosa	blackspot barb
	Enteromius paludinosus	straightfin barb
	Labeo catla	catla
	Labeo rohita	roho labeo
	Pethia conchonius	rosy barb
Gobiidae	*Glossogobius giuris*	tank goby
Ictaluridae	*Ictalurus punctatus*	channel catfish

Mastacembelidae	*Mastacembelus armatus*	zig-zag eel
Mugilidae	*Mugil cephalus*	flathead grey mullet
Osphronemidae	*Trichogaster fasciata*	banded gourami
Siluridae	*Wallago attu*	wallago
Sparidae	*Archosargus probatocephalus*	sheepshead
Xenocyprididae	*Hypophthalmichthys nobilis*	bighead carp

~~yellowfin seabream *(Acantopagrus australis)*, climbing perch *(Anabas testudineus)*, eels (Anguillidae), bagrid catfishes (Bagridae), silver perch *(Bidyanus bidyanus)*, Atlantic menhaden*(Brevoortia tyrannus)*, jacks (*Caranx* spp.), catla *(Catla catla)*, striped snakehead *(Channa striatus)*, mrigal *(Cirrhinus mrigala)*, torpedo-shaped catfishes (*Clarias* spp.), halfbeaks flying fishes (Exocoetidae), tank goby *(Glossogobius giuris)*, marble goby *(Oxyeleotris marmoratus)*, gobies (Gobiidae), rohu *(Labeo rohita)*, rhinofishes (*Labeo* spp.), barramundi and giant sea perch *(Lates calcarifer)*, striped mullet *(Mugil cephalus)*, mullets (Mugilidae) (*Mugil* spp. and *Liza* spp.), ayu *(Plecoglossus altivelis)*, pool barb *(Puntius sophore)*, barcoo grunter *(Scortum barcoo)*, sand whiting *(Sillago ciliata)*, catfishes (Siluridae spp.), snakeskin gourami *(Trichogaster pectoralis)*, common archer fish *(Toxotes chatareus)*, silver barb *(Puntius gonionotus)*, spotted scat *(Scatophagus argus)*, giant gourami *(Osphronemus goramy)*, dusky flathead *(Platycephalus fuscus)*, spiny turbot (*Psettodes* sp.), Tairiku-baratanago *(Rhodeus ocellatus)*, Koti-Bangladeshi (*Rohtee* sp.), rudd *(Scaridinius erythrophthalmus)*, terapon (*Terapon* sp.) and three-spot gourami *(Trichogaster trichopterus)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

[…]

Annex 16. Item 6.7. – Articles 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia virus'

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

Article 10.4.12.

Maintenance of free status for infection with HPR-deleted ISAV

In this article, all statements refer to a country, *zone* or *compartment* free from infection with HPR-deleted ISAV, but not necessarily free from infection with HPR0 ISAV.

A country, zone or compartment that is declared free from infection with HPR-deleted~~HPR0~~ ISAV following the provisions of Articles 10.4.6., 10.4.8. and 10.4.10. (as relevant) may maintain its status as free from infection with HPR-deleted~~HPR0~~ ISAV provided that the requirements described in Article 1.4.15. are continuously maintained.

[…]

Annex 17. Item 6.8. – Draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus 1*'

CHAPTER 10.X.

INFECTION WITH *MEGALOCYTIVIRUS PAGRUS 1*

Article 10.X.1.

For the purposes of the *Aquatic Code*, infection with *Megalocytivirus pagrus 1* means *infection* with the *pathogenic agent Megalocytivirus pagrus 1* (including the genogroups infectious spleen and kidney necrosis virus, red sea bream iridovirus and turbot reddish body iridovirus) of the Genus *Megalocytivirus* and Family Iridoviridae.

All three genogroups should be notified in accordance with Chapter 1.1.

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

Article 10.X.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	Species	Common name
Apogonidae	*Pterapogon kauderni*	Banggai cardinalfish
Butidae	*Oxyeleotris marmorata*	marble goby
Carangidae	*Pseudocaranx dentex*	white trevally
	Seriola spp. (all species)	N/A
	Trachinotus spp. (all species)	N/A
	Trachurus japonicus	Japanese jack mackerel
Centrarchidae	*Lepomis macrochirus*	bluegill
Cichlidae	*Astronotus ocellatus*	Oscar
	Etroplus suratensis	pearlspot
	Oreochromis niloticus	Nile tilapia
	Pterophyllum spp. (all species)	N/A
Cyprinidae	*Epalzeorhynchos frenatum*	rainbow sharkminnow
Danionidae	*Danio rerio*	zebrafish
Ephippidae	*Platax orbicularis*	orbiculate batfish
Girellidae	*Girella punctata*	largescale blackfish
Haemulidae	*Parapristipoma trilineatum*	chicken grunt
	Plectorhinchus cinctus	crescent sweetlips
Latidae	*Lates calcarifer*	barramundi
Lethrinidae	*Lethrinus spp.* (all species)	N/A

Mugilidae	*Mugil cephalus*	flathead grey mullet
Nothobranchiidae	*Aphyosemion gardneri*	steel blue killifish
Oplegnathidae	*Oplegnathus spp.* (all species)	N/A
Osphronemidae	*Macropodus opercularis*	paradise fish
	Osphronemus goramy	giant gourami
	Trichogaster lalius	dwarf gourami
	Trichopodus spp. (all species)	N/A
Paralichthyidae	*Paralichthys olivaceus*	bastard halibut
Percichthyidae	*Maccullochella peelii*	Murray cod
Pleuronectidae	*Verasper variegatus*	spotted halibut
Poeciliidae	*Poecilia spp.* (all species)	N/A
	Xiphophorus spp. (all species)	N/A
Procatopodidae	*Poropanchax normani*	Norman's lampeye
Rachycentridae	*Rachycentron canadum*	Cobia
Sciaenidae	*Larimichthys crocea*	large yellow croaker
	Sciaenops ocellatus	red drum
Scombridae	*Scomber japonicus*	chub mackerel
	Scomberomorus niphonius	Japanese Spanish mackerel
	Thunnus orientalis	Pacific bluefin tuna
Scophthalmidae	*Scophthalmus maximus*	turbot
Serranidae	*Epinephelus spp.* (all species)	N/A
Sinipercidae	*Siniperca chuatsi*	Mandarin fish
Sparidae	*Acanthopagrus schlegelii*	blackhead seabream
	Dentex tumifrons	yellowback seabream
	Pagrus major	red sea bream
Stromateidae	*Pampus argenteus*	silver pomfret
Synanceiidae	*Inimicus japonicus*	no common name
Tetraodontidae	*Takifugu rubripes*	tiger pufferfish

Article 10.X.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *M. pagrus 1* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *M. pagrus 1*, regardless of the infection with *M. pagrus 1* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates *M. pagrus 1*;

2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates *M. pagrus 1*;

3) fish oil;

4) fish skin leather.

Article 10.X.4.

Requirements for self-declaration of freedom from infection with *M. pagrus 1*

A Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.X.5. to 10.X.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

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

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

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

Article 10.X.5.

Country free from infection with *M. pagrus 1*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *M. pagrus 1* if all shared water bodies are within countries or *zones* declared free from infection with *M. pagrus 1* (see Article 10.X.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for its entire *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for infection with *M. pagrus 1*;

OR

2) there has been no occurrence of infection with *M. pagrus 1* for at least the last ten years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. pagrus 1*, as described in in Article 1.4.8. of Chapter 1.4.; and

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

OR

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

OR

4) it previously made a self-declaration of freedom from infection with *M. pagrus 1* and subsequently lost its free status due to the detection of *M. pagrus 1* but the following conditions have been met:

   a) on detection of *M. pagrus 1*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. pagrus 1*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *M. pagrus 1*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last two years in wild and farmed *susceptible species* without detection of *M. pagrus 1*; or

      ii) at least the last one year without detection of *M. pagrus 1* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 10.X.6.

Zone free from infection with *M. pagrus 1*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *M. pagrus 1* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for a *zone* within its *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for this disease;

OR

2) there has been no occurrence of infection with *M. pagrus 1* for at least the last ten years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. pagrus 1*, as described in Article 1.4.8. of Chapter 1.4.; and

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

OR

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

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *M. pagrus 1* and subsequently lost its free status due to the detection of *M. pagrus 1* in the *zone* but the following conditions have been met:

   a) on detection of *M. pagrus 1*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. pagrus 1*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *M. pagrus 1*; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:

      i) at least the last two years in wild and farmed *susceptible species* without detection of *M. pagrus 1*; or

      ii) at least the last one year without detection of *M. pagrus 1* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 10.X.7.

Compartment free from infection with *M. pagrus 1*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus 1* for a *compartment* within its *territory* if it can demonstrate that:

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

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *M. pagrus 1* and subsequently lost its free status due to the detection of *M. pagrus 1* in the *compartment* but the *following* conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. pagrus 1*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.X.9. and 10.X.10. as appropriate; and

   c) one survey for infection with *M. pagrus 1* has been completed at least six months after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.X.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *M. pagrus 1* following the provisions of Articles 10.X.4. to 10.X.7. (as relevant) may maintain its status as free from infection with *M. pagrus 1* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.X.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *M. pagrus 1*

When importing *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.X.5., 10.X.6. or 10.X.7. (as applicable) and 10.X.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *M. pagrus 1*.

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

This article does not apply to *aquatic animal products* listed in Article 10.X.3.

Article 10.X.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *M. pagrus 1*

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

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

    a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

    b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.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 *M. pagrus 1* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

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

    a) In the *exporting country*:

        i) identify potential source populations and evaluate their *aquatic animal* health records;

        ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *M. pagrus 1* .

b) In the *importing country*:

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

ii) test the F-0 population for *M. pagrus 1* 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 *M. pagrus 1*, and sample and test for *M. pagrus 1* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.8. of the *Aquatic Manual*;

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

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

Article 10.X.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *M. pagrus 1*

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processing into one of the products referred to in Article 10.X.3. or in point 1 of Article 10.X.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4.and 4.8.

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

Article 10.X.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *M. pagrus 1*

When importing *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.X.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.X.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *M. pagrus 1*

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should ensure:

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

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

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

Article 10.X.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *M. pagrus 1* status of the exporting country, zone or compartment

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

   a) fish fillets or steaks (chilled).

   Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

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

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus 1*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Annex 18. Item 6.9. – Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *P. olseni*'

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

Article 11.6.1.

For the purposes of the *Aquatic Code*, infection with *Perkinsus olseni* means *infection* with 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.: ~~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*, *Barbatianovaezelandiae*, *Macomonaliliana*, *Paphies australis* and *Crassostrea ariakensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

Family	Scientific name	Common name
Arcidae	*Anadara kagoshimensis*	half-crenated ark ~~cockle~~
	Anadara trapezia	no common name ~~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 shell ~~clam~~

[…]

Annex 19. Item 6.10. – Articles 11.7.1. and 11.7.2. of Chapter 11.6. 'Infection with *X. californiensis*'

CHAPTER 11.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Article 11.7.1.

For the purposes of the *Aquatic Code*, infection with *Xenohaliotis californiensis* means *infection* with the pathogenic agent *Candidatus* Xenohaliotis californiensis of the Family Anaplasmataceae ~~*X. californiensis*~~.

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

Article 11.7.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Scientific name	Common name
Haliotidae	*Haliotis corrugata*	pink abalone
	Haliotis cracherodii	black abalone
	Haliotis discus discus	Japanese abalone
	Haliotis diversicolor	small abalone
	Haliotis fulgens	green abalone
	Haliotis kamtschatkana	pinto abalone
	Haliotis rufescens	red abalone
	Haliotis rufescens X *Haliotis discus hannai* hybrid	hybrid red and Japanese abalone
	Haliotis sorenseni	white abalone
	Haliotis tuberculata	tuberculate abalone

~~black abalone *(Haliotis cracherodii)*, white abalone *(Haliotis sorenseni)*, red abalone *(Haliotis rufescens)*, pink abalone *(Haliotis corrugata)*, green abalone (*Haliotis tuberculata* and *Haliotis fulgens*), flat abalone *(Haliotis wallalensis)* and Japanese abalone *(Haliotis discus-hannai)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

[…]

Annex 20. Item 8.1.1. – 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

[…]

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 clarkii ~~*spp.* (all species)~~	red swamp crawfish ~~N/A~~
	Procambarus zonangulus	no common name
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	*Macrobrachium nipponense*	Oriental river prawn
	Palaemon carinicauda ~~*spp.* (all species)~~	ridgetail prawn ~~N/A~~
	Palaemon orientis	no common name
	Palaemon ritteri	barred grass shrimp
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
	Palaemon adspersus	Baltic 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~~ brine shrimp
	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
Palaemonidae	*Palaemon gravieri*	Chinese ditch prawn
	Palaemon macrodactylus	migrant prawn
	Palaemon pandaliformis	potitinga prawn
	Palaemon pugio	daggerblade grass shrimp
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 21. Item 8.2.1. – Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)'

CHAPTER 2.3.1.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

[…]

2.2. Host factors

2.2.1. Susceptible host species

~~[Note: an assessment of species that meet the criteria for listing as susceptible to infection with *A. invadans* in accordance with Chapter 1.5. has not been completed]~~ Species that fulfil the criteria for listing as susceptible to infection with *A. invadans* (epizootic ulcerative syndrome) according to Chapter 1.5. of the *Aquatic Animal Health Code* (*Aquatic Code*) are:

~~Table 2.1. Fish species susceptible to infection with *Aphanomyces invadans*~~

Family	Scientific name	Common name
~~Alestidae~~	~~*Brycinus lateralis*~~	~~striped robber~~
	~~*Hydrocynus vittatus*~~	~~tigerfish~~
	~~*Micralestes acutidens*~~	~~silver robber~~
~~Ambassidae~~	~~*Ambassis agassizii*~~	~~chanda perch~~
~~Apogonidae~~	~~*Glossamia aprion*~~	~~mouth almighty~~
~~Ariidae~~	~~*Arius sp.*~~	~~fork-tailed catfish~~
~~Belonidae~~	~~*Strongylura kreffti*~~	~~long tom~~
Alosidae	*Alosa sapidissima*	American shad
	Brevoortia tyrannus	Atlantic menhaden
Anabantidae	*Anabas testudineus*	climbing perch
Bagridae	*Mystus cavasius*	gangetic mystus
Centrarchidae	*Lepomis macrochirus*	bluegill
	Micropterus dolomieu	smallmouth bass
	Micropterus salmoides	largemouth black bass
Channidae	*Channa spp.*(all species) ~~*marulius*~~	N/A ~~great snakehead fish~~
	~~spotted snakehead~~	~~*Channa punctatus*~~
	~~*Channa striatus*~~	~~striped snakehead~~
Cichlidae	*Etroplus suratensis*	pearlspot
	~~*Coptodon rendalli*~~	~~redbreast tilapia~~

	~~*Oreochromis andersoni*~~	~~three-spoted tilapia~~
	~~*Oreochromis machrochir*~~	~~greenhead tilapia~~
	~~*Sargochromis carlottae*~~	~~rainbow bream~~
	~~*Sargochromis codringtonii*~~	~~green bream~~
	~~*Sargochromis giardi*~~	~~pink bream~~
	~~*Serranochromis angusticeps*~~	~~thinface largemouth~~
	~~*Serranochromis robustus*~~	~~Nembwe~~
	~~*Tilapia sparrmanii*~~	~~banded tilapia~~
Clariidae	*Clarias gariepinus*	~~sharptooth~~ North African catfish
	~~*Clarias ngamensis*~~	~~blunt-toothed African catfish~~
	~~*Clarius batrachus*~~	~~walking catfish~~
~~Clupeidae~~	~~*Alosa sapidissima*~~	~~American shad~~
	~~*Brevoortia tyrannus*~~	~~Atlantic menhaden~~
	~~*Nematalosa erebi*~~	~~bony bream~~
Cyprinidae	~~*Barbus paludinosus*~~	~~straightfin barb~~
	~~*Barbus poechii*~~	~~dashtail barb~~
	~~*Barbus thamalakanensis*~~	~~Thamalakane barb~~
	~~*Barbus unitaeniatus*~~	~~longbeard barb~~
	~~*Carassius auratus*~~	~~goldfish~~
	~~*Catla catla*~~	~~Catla~~
	Cirrhinus mrigala	mrigal carp
	Dawkinsia filamentosa	blackspot barb
	Enteromius paludinosus	straightfin barb
	~~*Esomus sp.*~~	~~flying barb~~
	~~*Labeo cylindricus*~~	~~red-eye labeo~~
	~~*Labeo lunatus*~~	~~upper Zambezi labeo~~
	Labeo catla	catla
	Labeo rohita	roho labeo ~~Rohu~~
	Pethia conchonius	rosy barb
	~~*Puntius gonionotus*~~	~~silver barb~~
	~~*Puntius sophore*~~	~~pool barb~~
	~~*Rohtee sp.*~~	~~keti-Bangladeshi~~
~~Eleotridae~~	~~*Oxyeleotris lineolatus*~~	~~sleepy cod~~
	~~*Oxyeleotris marmoratus*~~	~~marble goby~~
Gobiidae	*Glossogobius giuris*	tank goby
Ictaluridae	*Ictalurus punctatus*	channel catfish
Mastacembelidae	*Mastacembelus armatus*	zig-zag eel

Mugilidae	*Mugil cephalus*	flathead grey mullet
Osphronemidae	*Trichogaster fasciata*	banded gourami
Siluridae	*Wallago attu*	wallago
Sparidae	*Archosargus probatocephalus*	sheepshead
Xenocyprididae	*Hypophthalmichthys nobilis*	bighead carp

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 *A. invadans* according to Chapter 1.5. of the *Aquatic Code* are: ~~[under study]~~

Family	**Scientific name**	**Common name**
Cyprinidae	*Labeo capensis*	orange river mudfish
	Pethia punctata	no common name
	Puntius mahecola	no common name
Elopidae	*Elops machnata*	tenpounder
Epinephelidae	*Epinephelus malabaricus*	Malabar grouper
Ictaluridae	*Ameiurus melas*	black bullhead
	Ameiurus nebulosus	brown bullhead
Mugilidae	*Mugil curema*	white mullet
	Planiliza macrolepis	largescale mullet
	Planiliza parsia	goldspot mullet
Pristolepididae	*Pristolepis malabarica*	no common name
Salmonidae	*Oncorhynchus mykiss*	rainbow trout
Scatophagidae	*Scatophagus argus*	spotted scat
Sciaenidae	*Bairdiella chrysoura*	goldtail croaker
	Pogonias cromis	black drum

[…]

CHAPTER 2.4.2.

INFECTION WITH *BONAMIA EXITIOSA*

1. Scope

Infection with *Bonamia exitiosa* means infection with the pathogenic agent *Bonamia exitiosa* of the Family *Haplosporiidae*.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

Bonamia exitiosa is a Haplosporidian protozoan parasite (Arzul & Carnegie, 2015; Carnegie & Cochennec-Laureau, 2004) infecting haemocytes of several oyster species, causing disease and mortality (Cranfield *et al.,* 2005; Dinamani *et al.,* 1987). Since the original description of the parasite in New Zealand in the mid-1980s, *B. exitiosa* and *B. exitiosa*-like microcells have been described in various locations globally. Species assignment was based primarily on the sequence of the ITS rDNA locus of the ribosomal DNA gene complex, as the available data on histology, ultrastructure and molecular sequences was insufficient to discriminate unequivocally between species (Hill et al. 2010b).

2.1.2. Survival and stability in processed or stored samples

No data available

2.1.3. Survival and stability outside the host

No data available.

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Ostreidae	*Crassostrea virginica*	eastern oyster
	Magallana (syn. *Crassostrea*) *ariakensis*	Ariake cupped oyster
	Ostrea angasi	Australian mud oyster
	Ostrea chilensis	Chilean flat oyster
	Ostrea edulis	European flat oyster
	Ostrea equestris	crested oyster
	Ostrea lurida	Olympia oyster
	Ostrea puelchana	Argentinean flat oyster

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 *B. exitiosa* according to Chapter 1.5 of the *Aquatic Code* are: dwarf oyster (*Ostrea stentina*).

Family	Scientific name	Common name
Ostreidae	*Ostrea stentina*	dwarf oyster

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
Ostreidae	*Magallana* (syn. *Crassostrea*) *gigas*	Pacific cupped oyster
	Saccostrea glomerata	Sydney rock oyster

2.2.3. Likelihood of infection by species, host life stage, population or sub-populations

Juveniles and adults are susceptible to infection however, prevalence and infection intensity are generally higher in individuals of 2 years of age. In *O. edulis*, *B. exitiosa* DNA has also been detected in larvae (Arzul *et al.,* 2010; Helmer *et al.,* 2020). *Bonamia exitiosa* is particularly pathogenic in young *M. ariakensis*, <50 mm in shell height (Bishop *et al.,* 2006).

2.2.4. Distribution of the pathogen in the host

Bonamia exitiosa is an intrahaemocytic protozoan, but it can be observed extracellularly (Dinamani *et al.,* 1987). Infection is systemic with the protozoan found in several organs and especially in the connective tissues of gills and mantle (Hine, 1991a). In *O. angasi*, the parasite has been observed in the gills, mantle and gonad and particularly in the connective tissue of the digestive gland (Buss *et al.,* 2020a). In *O. edulis*, the parasite is associated with heavy haemocytic infiltration and appears in the connective tissue of various organs mostly within haemocytes, but sometimes outside host cells (Abollo *et al.,* 2008). In *O. stentina*, haemocytosis was not observed in animals found to be infected with the parasite (Hill *et al.,* 2010).

2.2.5. Aquatic animal reservoirs of infection

Susceptible species (see Section 2.2.1) should be considered potential reservoirs.

None known.

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Mortality in *O. chilensis* occurs concurrently with the highest infection intensity, particularly in association with high intensity apicomplexan infections (Hine, 2002; Hine & Wesney, 1994). The disease seems to kill more than 80% of the oysters as the wave of infection passes through an oyster bed over a period of 2–3 years (Cranfield *et al.,* 2005). In *O. angasi*, >85% mortality was observed in oysters after 40 days of exposure with infected oysters (Buss *et al.,* 2020a).

Prevalence is variable in *O. chilensis* (from 0% to nearly 80%) (Cranfield *et al.,* 2005). In the Southern Hemisphere, infection with *B. exitiosa* shows the highest prevalence from January to April, with the parasite barely detectable in September and October (Hine, 1991a). Stressors such as exposure to extreme temperatures (below 7°C or above 26°C), high salinity (40 ppt), starvation (prolonged holding in filtered sea water), handling (vigorous stirring four times per day), or heavy infection with an apicomplexan (Hine, 2002), can affect the disease dynamics of *B. exitiosa* in *O. chilensis* (Hine *et al.,* 2002).

Prevalence is variable in *O. edulis* in which co-infection with *B. ostreae* was reported (Abollo *et al.,* 2008). In Galicia (Spain), the maximum reported prevalence of *B. exitiosa* in *O. edulis* was 34% in one batch collected in October (Abollo *et al.,* 2008). Despite some prevalence differences observed between sampling dates, it is not presently possible to determine the annual infection pattern of flat oysters with *B. exitiosa* in Europe.

In *Ostrea angasi*, no clear seasonal pattern was described and prevalence increased over time from 8 to 40% after 3 months to 57 to 88% after 1 year, depending on farming site (Buss *et al.,* 2020c).

2.3.2. Clinical signs, including behavioural changes

Clinical signs include dead or gaping oysters.

2.3.3 Gross pathology

Most live infected oysters appear normal, but sometimes the gills can appear to be eroded (Dinamani *et al*., 1987).

2.3.4. Modes of transmission and life cycle

Transmission by infective stages carried passively on water currents between oyster beds is suspected (Cranfield *et al.,* 2005; Hine, 1996). Studies with *O. chilensis* have shown that transmission of the parasite directly from host to host is possible; Hine (1991a; 1991b) has shown that released infective particles are ingested by oysters and enter the haemolymph from the gut. Infective particles are phagocytosed by agranular haemocytes, and are able to resist lysis within the haemocyte (Hine & Wesney, 1994).

Parasite DNA has been detected in larvae incubated in the palleal cavity of adult oysters suggesting possible transmission between these two age groups. Thus, larvae may contribute to the spread of the parasite during their planktonic life stage (Helmer *et al.,* 2020).

2.3.5. Environmental factors

Experimental studies using variations in temperature and salinity as stressors (Hine *et al.,* 2002) showed that prevalence was higher in oysters kept for a short period (14 days) in warm water (25–26°C for 1 hour daily) or in hypersaline (39–40 ppt) water compared with cold water (7°C for 1 hour daily) and to hyposaline water (15 ppt).

In *O. chilensis*, prevalence shows an annual pattern with two peaks reported in April (early autumn) and August (winter) (Hine, 1991a). The evolution of *B. exitiosa* in *O. edulis* or *O. stentina* according to the season has not been studied.

Increased water temperature increases the risk of death of *O. angasi* due to *B. exitiosa* infection particularly when it is combined with other stressors – both starvation and increased motion (Bradley *et al.,* 2020).

2.3.6. Geographical distribution

Infection with *B. exitiosa* has been reported from in *O. chilensis* in Oceania (Dinamani *et al*., 1987; Doonan *et al.,* 1994); in *O. angasi* in Oceania (Corbeil *et al.,* 2006b; Hine, 1996; Hine & Jones, 1994); in *O. edulis* in Europe (Abollo *et al.,* 2008; Narcisi *et al.,* 2010); and in *O. stentina* in Africa (Hill *et al.,* 2010).

See WAHIS (https://wahis.woah.org/#/home) for recent information on distribution at the country level.

2.4. Biosecurity and disease control strategies

2.4.1. Vaccination

None.

2.4.2. Chemotherapy including blocking agents

None.

2.4.3. Immunostimulation

None.

2.4.4. Breeding resistant strains

None.

2.4.5. Inactivation methods

40,000 ppm chlorine for 10 minutes and 2000 ppm iodine for 1 minute inactivate 100% of *B. exitiosa* isolated from infected oysters (Buss *et al.,* 2020b).

2.4.6. Disinfection of eggs and larvae

No data available.

2.4.7. General husbandry

Development of lighter dredges and less damaging fishing strategies should reduce the chance of disease outbreaks by lowering disturbance (Cranfield *et al.,* 2005). Avoiding stressors such as exposure to extreme temperatures (below

7 or above 26°C) and high salinity (40 ppt), starvation, handling, or heavy infection with other parasites, as well as decreasing stocking density, should mitigate the impact of the disease (Cranfield *et al.,* 2005; Hine *et al.,* 2002).

3. Specimen selection, sample collection, transportation and handling

This section draws on information in Sections 2.2, 2.3 and 2.4 to identify populations, individuals and samples that are most likely to be infected.

3.1. Selection of populations and individual specimens

Gaping or freshly dead individuals (2 or more years old) should be sampled as a priority, to increase the chances of detecting infected oysters. For histology, only live (including moribund) oysters should be sampled.

Sampling should be carried out when prevalence is known to be at a maximum, or during periods of higher water temperature e.g. between January and April in the Southern Hemisphere (Hine, 1991a).

3.2. Selection of organs or tissues

A 3–5 µm thick section of tissue that includes a sample of gills, mantle, gonad, and digestive gland, is used for histological examination. Gills or heart are preferred for some tests such as imprints. For PCR in *O. edulis* it is recommended to include gills and gonad.

3.3. Samples or tissues not suitable for pathogen detection

Tissues other than gills, heart, gonads and mantle are less suitable.

3.4. Non-lethal sampling

None.

3.5. Preservation of samples for submission

For guidance on sample preservation methods for the intended test methods, see Chapter 2.4.0 *General information* (*diseases of molluscs*).

3.5.1. Samples for pathogen isolation

Not applicable.

3.5.2. Preservation of samples for molecular detection

Tissue samples for PCR testing should be preserved in 80% (v/v) analytical-grade ethanol.

Standard sample collection, preservation and processing methods for molecular techniques can be found in Section B.5.5 of Chapter 2.4.0 *General information* (diseases of molluscs).

3.5.3. Samples for histopathology, immunohistochemistry or *in-situ* hybridisation

Standard sample collection, preservation and processing methods for histological techniques can be found in Section B.5.3 of Chapter 2.4.0 *General information* (diseases of molluscs).

3.5.4. Samples for other tests

None.

3.6. Pooling of samples

Pooling of samples from more than one individual animal for a given purpose is only recommended where robust supporting data on diagnostic sensitivity and diagnostic specificity have been evaluated and found to be suitable. The effect of pooling

on diagnostic sensitivity has not been thoroughly evaluated, therefore larger specimens should be processed and tested individually. Small life stages such as spat can be pooled to obtain the minimum amount of material for molecular detection.

4. Diagnostic methods

The methods currently available for pathogen detection that can be used in i) surveillance of apparently healthy animals, ii) presumptive diagnosis in clinically affected animals and iii) confirmatory diagnostic purposes are listed in Table 4.1. by animal life stage.

Ratings for purposes of use. For each recommended assay a qualitative rating for the purpose of use is provided. The ratings are determined based on multiple performance and operational factors relevant to application of an assay for a defined purpose. These factors include appropriate diagnostic performance characteristics, level of assay validation, availability cost, timeliness, and sample throughput and operability. For a specific purpose of use, assays are rated as:

+++ =	Methods are most suitable with desirable performance and operational characteristics.
++ =	Methods are suitable with acceptable performance and operational characteristics under most circumstances.
+ =	Methods are suitable, but performance or operational characteristics may limit application under some circumstances.
Shaded boxes =	Not appropriate for this purpose.

Validation stage. The validation stage corresponds to the assay development and validation pathway in chapter 1.1.2. The validation stage is specific to each purpose of use. Where available, information on the diagnostic performance of recommended assays is provided in Section 6.3.

WOAH Reference Laboratories welcome feedback on diagnostic performance of recommended assays, in particular PCR methods. Of particular interest are any factors affecting expected assay sensitivity (e.g. tissue components inhibiting amplification) or expected specificity (e.g. failure to detect particular genotypes, detection of homologous sequences within the host genome). These issues should be communicated to the WOAH Reference Laboratories so that advice can be provided to diagnostic laboratories and the standards amended if necessary.

Table 4.1. *WOAH recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals*

Method	A. Surveillance of apparently healthy animals				B. Presumptive diagnosis of clinically affected animals				C. Confirmatory diagnosis[1] of a suspect result from surveillance or presumptive diagnosis			
	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV
Imprints		++	++	2		+++	+++	NA				
Histopathology		++	++	2		+++	+++	2				
Transmission electron microscopy									+	+	+	NA
Real-time PCR	+++	+++	+++	3	+++	+++	+++	2	+++	+++	+++	NA
Conventional PCR	++	++	++	2	+++	+++	+++	NA				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	NA
In-situ hybridisation					+	+	+	1				
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
Other antigen detection methods												

LV = level of validation, refers to the stage of validation in the WOAH Pathway (chapter 1.1.2), Figures brackets mean that partial data are available; NA = not available; PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; Ab- or Ag-ELISA = antibody or antigen enzyme-linked immunosorbent assay, respectively; [1]For confirmatory diagnoses, methods need to be carried out in combination (see Section 6).
[2]Susceptibility of early and juvenile life stages is described in Section 2.2.3.
Shading indicates the test is inappropriate or should not be used for this purpose.

4.1. Imprints

Samples to be taken consist of heart (preferably the ventricle) or gills from fresh, gaping or freshly dead bivalves if they are sufficiently large. If bivalves are too small (such as spat), imprints should be done using the entire individual.

After drying tissues on absorbent paper, several imprints are made on a glass slide. Slides are air-dried, fixed (in methanol or absolute ethanol) and stained using a commercially available blood-staining kit, in accordance with the manufacturer's instructions. After rinsing in tap water and drying, the slides are mounted with a cover-slip using an appropriate synthetic resin. Slides are observed first at ×200 magnification and then under oil immersion at ×1000 magnification.

Infection with *Bonamia exitiosa* is indicated by the presence of small spherical or ovoid organisms (2–5 µm wide) within the haemocytes. However, the parasite might also occur extracellularly. These organisms show a basophilic cytoplasm often containing a lipid vacuole and an eosinophilic nucleus which is rather central unlike the *B. ostreae* nucleus which is rather eccentric (colours of cytoplasm and nucleus may vary with the stain used). Parasitic cells can appear larger on imprints than on histological examination. Multinucleated cells can be observed (Abollo *et al.,* 2008; Hine *et al.,* 2001). The technique is not parasite species specific.

A positive result is indicative of infection with a *Bonamia* species.

4.2. Histopathology

Samples to be taken consist of fresh, gaping or freshly dead bivalves.

Sections of tissue that include gills, digestive gland, mantle, and gonad should be fixed for 24 hours minimum in a recommended fixative followed by standard processing for histology as described in section 5.3 of Chapter 2.4.0 *General information* (diseases of molluscs). Observations are made at increasing magnifications up to ×1000.

Infection with *B. exitiosa* is indicated by the presence of parasites as small cells (2–5 µm in diameter) within the haemocytes or free in the connective tissue or sinuses of the gills, gonads, digestive gland, gut and mantle. The parasite causes different lesions according to it host. It is often associated with an intense disseminated haemocyte infiltration in *O. chilensis* but intense focal haemocyte infiltration in *O. angasi* in which it is epitheliotrophic (Engelsma & Hine, 2009). In *O. edulis*, it is associated with haemocyte infiltration of the connective tissues surrounding the digestive gland and the mantle (Longshaw *et al.,* 2013). To avoid any doubt, the parasite has to be observed inside the haemocyte for a positive diagnosis.

B. exitiosa is generally larger than *B. ostreae* and often has a central or subcentral nucleus. Plasmodia stages characterised by irregular shape were noted in the haemocyte cytoplasm but, unlike *B. perspora,* no spore has been described in *B. exitiosa*. The technique is not species-specific.

Positive result is indicative of infection with a *Bonamia* species.

4.3. Transmission electron microscopy

Samples to be taken consist of live, gaping or freshly dead bivalves.

A small sized piece of tissue (1–2 mm) should be fixed in an appropriate fixative for at least 1 hour and then processed as described in section 5.4 of Chapter 2.4.0 *General information* (diseases of molluscs).

Infection with *Bonamia exitiosa* is indicated by the presence of parasites within the haemocytes. Different stages, including uninucleated, binucleated and plasmodial stages have been reported; moreover, *B. exitiosa* has a large amoeboid trophic stage, apparently not present in *B. ostreae.* Intracellular structures include mitochondria, haplosporosomes, Golgi apparatus and persistent intranuclear microtubules. In *O. chilensis*, four parasite developmental stages have been described in infected oysters corresponding to dense forms, intermediate forms, plasmodial forms and vacuolated forms (Hill *et al.,* 2010; Hine, 1991b; Hine *et al.,* 2001).

Uninucleated stages of *B. exitiosa* are slightly larger in size in comparison with *B. ostreae* and have more haplosporosomes, mitochondrial profiles and lipoid bodies per ultrastructure section, as well as smaller tubulo-vesicular mitochondria. However, this stage is smaller in comparison with *B. perspora* which has also smaller haplosporosomes (Hine *et al.,* 2001; 2014).

4.4. Nucleic acid amplification

PCR assays should always be run with the controls specified in Section B.5.5 *Molecular methods* Chapter 2.4.0 *General information* (diseases of molluscs). Molluscs are known to potentially contain substances that can inhibit PCR reactions. It is recommended to check for the presence of PCR inhibitors in DNA extracts to avoid false negative results. In case PCR inhibitors are present, DNA samples can be diluted prior to PCR analyses (a 1/10 dilution usually resolves most cases of PCR inhibition). Each sample should be tested in duplicate.

Extraction of nucleic acids

Different kits and procedures can be used for nucleic acid extraction. The quality and concentration of the extracted nucleic acid is important and can be checked using a suitable method as appropriate to the circumstances.

4.4.1. Real-time PCR

Three TaqMan PCR assays are available for the detection of *Bonamia* spp.: one targeting the ITS1 (internal transcribed spacer) (Corbeil *et al.,* 2006a) and two targeting the 18S (small subunit rDNA) (Canier *et al.,* 2020; Marty *et al.,* 2006). The PCR assay developed by Canier *et al.* (2020) targets the 18S (small subunit rDNA) and allows the concomitant detection of *Bonamia* sp. and *Marteilia refringens* parasites.

Two other real-time PCR protocols have been developed to specifically detect *B. exitiosa*: one SYBR green PCR assay targeting the 18S-ITS1 region (Ramilo *et al.,* 2013), and a Taqman PCR protocol targeting the actin gene (https://www.eurl-mollusc.eu/SOPs). These two PCR assays allow the concomitant detection of *B. ostreae* and *B. exitiosa* parasites.

PCR assays are generally more sensitive than histology and/or cytology for the diagnosis of *B. exitiosa* (see Sections 6.1. and 6.2) although Buss *et al.* (2019) found that histology was more sensitive than real-time PCR in farmed populations of *Ostrea angasi*. Real-time PCR assays usually have higher sensitivity than conventional PCR assays (see Sections 6.1. and 6.2).

***Primers and probes* (*sequence*)**

Pathogen/ target gene	Primer/probe (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Corbeil *et al.,* 2006a; GenBank Accession No.: DQ312295			
Taqman® PCR *Bonamia* spp./ITS-1	ITS-For: CCC-TGC-CCT-TTG-TAC-ACA-C ITS-Rev: TCA-CAA-AGC-TTC-TAA-GAA-CGC-G Probe BonITS: TTA-GGT-GGA-TAA-GAG-CCG-C (FAM MGB-NFQ)	900 nM 900 nM 250 nM	35 cycles of: 95°C/15 sec and 63.6°C/60 sec
Method 2: Marty *et al.,* 2006; GenBank Accession No.: DQ312295			
Taqman® PCR *Bonamia* spp./18S	Fwd: CCC-GGC-TTC-TTA-GAG-GGA-CTA Rev: ACC-TGT-TAT-TGC-CCC-AAT-CTT-C Probe: CTG-TGT-CTC-CAG-CAG-A (FAM MGB-NFQ)	800 nM 800 nM 250 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 3: Canier *et al.,* 2020; GenBank Accession No.: EU016528			
Taqman® PCR *Bonamia* spp./18S	Bosp2-18S-F: CAG-GAT-GCC-CTT-AGA-TGC-TC Bosp2-18S-R: GTA-CAA-AGG-GCA-GGG-ACG-TA Probe Bosp-18S-IN: TTG-ACC-CGG-CTT-GAC-AAG-GC (HEX-BHQ1)	300 nM 500 nM 300 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 4: Ramilo *et al.,* 2013; GenBank Accession No: DQ312295			
SYBR Green PCR *B. exitiosa*/18S-ITS	BEXIT-F: GCG-CGT-TCT-TAG-AAG-CTT-TG BEXIT-R: AAG-ATT-GAT-GTC-GGC-ATG-TCT	300 nM 300 nM	35 cycles of: 95°C/30 sec and 58°C/45 sec, 72°C/60 sec Melt curve from 58°C to 95°C with 0.5°C increment/sec

Method 5: EURL for mollusc diseases (2023)			
Taqman® PCR *B. exitiosa/* actin	BEa_F: GAC-TTT-GAC-CAT-CGG-AAA-CG BEa_R: ATC-GAG-TCG-TAC-GCG-AGT-CT BEa_probe GGC-AGC-GAA-TCG-ATG-GGA-AT (FAM-BHQ-1)	300 nM 300 nM 200 nM	40 cycles of: 95°C/15 sec and 60°C/20 sec

[(a)]A denaturation step prior to cycling has not been included.

4.4.2. Conventional PCR

Two conventional PCR protocols targeting the 18S (small subunit rDNA) have been developed for the detection of *Bonamia sp.* (Carnegie *et al.,* 2000; Cochennec *et al*., 2000). Conventional PCRs are generally more sensitive than histology or cytology (see Sections 6.1. and 6.2). Under certain circumstances, the Cochennec *et al.* (2000) primers generate a 295 bp non-specific product of approximately the same size as the expected product of 300 bp (Engelsma *et al.,* 2014).

Primer sequences

Pathogen/ target gene	Primer (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Carnegie *et al.,* 2000 modified in Carnegie *et al.,* 2008; amplicon size [760 bp]			
Bonamia spp./18S amplifies most of the identified *Bonamia* sp. including *B. ostreae* and *B. exitiosa*	CF: CGG-GGG-CAT-AAT-TCA-GGA-AC CR: CCA-TCT-GCT-GGA-GAC-ACA-G	250 nM 250 nM	35 cycles of: 95°C/1 min and 59°C/1 min and 72°/1 min
Method 2: Cochennec *et al.,* 2000; amplicon size [304 bp]			
Bonamia spp./18S amplifies all identified *Bonamia* spp. and several members of *Haplosporidia*	BO: CAT-TTA-ATT-GGT-CGG-GCC-GC BOAS: CTG-ATC-GTC-TTC-GAT-CCC-CC	1 µM 1 µM	30 cycles of: 95°C/60 sec, 55°C/60 sec, 72°C/60 sec

[(a)]A denaturation step at 94–95°C prior to cycling and a final elongation step at 72°C (between 5 and 10 minutes) must be included.

4.4.3. Other nucleic acid amplification methods

None available.

4.5. Amplicon sequencing

The size of the PCR amplicon is verified by agarose gel electrophoresis and purified by excision from this gel. Obtained sequences are analysed and compared with published sequences.

Targeted regions are 18S, ITS1 and actin. Although the sequences are available in the public gene banks, it is recommended to refer such cases to the appropriate WOAH Reference Laboratory.

4.6. *In-situ* hybridisation

Samples to be taken consist of live or freshly dead oysters.

Several *in-situ* hybridisation protocols have been developed, two targeting the 18S and one the ITS1.

The first one (Cochennec *et al*., 2000) allows detection at the *Bonamia* genus level and uses a 300 bp labelled probe produced by PCR.

Two ISH protocols were designed to specifically detect *B. exitiosa* (Hill *et al.,* 2010; Ramilo *et al.,* 2014) but should also detect closely related parasites (belonging to the "clade *B. exitiosa*"). These assays rely on digoxigenin-labelled oligonucleotide probes.

Reference	Pathogen/target	ISH probe type	ISH probe
Method 1 Cochennec *et al.,* 2000	*Bonamia* spp. and several members of *Haplosporidia* 18S	Labelled BO–BOAS amplicons	BO–BOAS PCR product (300bp)
Method 2: Hill *et al.,* 2010	*Bonamia exitiosa* and closely related *Bonamia* sp. 18S	Three labelled oligonucletotides	CaBon166: CGA-GCA-GGG-TTT-GTC-ACG-TAT CaBon461: TTC-CGA-ATA-GGC-AAC-CGA-AG CaBon1704: CAA-AGC-TTC-TAA-GAA-CGC-GCC
Method 3: Ramilo *et al.,* 2014	*Bonamia exitiosa* and closely related *Bonamia* sp. ITS1	Labelled oligonucletotides	BEX_ITS: CAA-AGA-TTG-ATG-TCG-GCA-TG

Technical procedure

The first steps in the technical procedure follow the recommendations described in chapter 2.4.0.

Subsequent steps concerning Method 1 (Cochennec *et al.,* 2000) are that the probe is produced by PCR using the previously described primer pair Bo–Boas (Section 4.4.2) with digoxigenin incorporation and the PCR is performed as described in the section on PCR except that DIG dUTP 25 mM is added to the reaction mixture. The detection steps are performed according to the manufacturer's instructions. In other protocols, probes consist in digoxigenin-labelled nucleotides.

Slides are dehydrated by immersion in an ethanol series and air dried. The slides are then covered with hybridisation buffer (4 × SSC [standard saline citrate; 60 mM NaCl, 600 mM NaCl, pH 7], 50% formamide, 1 × Denhardt's solution, 250 µg ml^{-1} yeast tRNA, 10% dextran sulphate) containing approx. 20 ng of the digoxigenin-labelled probe (1–2 µl of the probe produced by PCR, or 1 µl at 100 µm of labelled nucleotides). Sections are covered with *in-situ* plastic cover-slips and placed for 5 minutes at 95°C. Slides are then cooled on ice for 1– 5 minutes before overnight hybridisation at 42°C in a humid chamber Sections are washed twice for 5 minutes in 2 × SSC at room temperature, and once for 10 minutes in 0.4 × SSC at 42°C. The detection steps are performed according to the manufacturer's instructions. The slides are then rinsed with appropriate buffer. The sections are counter-stained with an appropriate staining, rinsed in tap water, immersed in 95% and 100% ethanol for 30 seconds for each, rinsed for 10–30 seconds in xylene and cover-slips are applied using an appropriate mounting medium.

Interpretation of results:

A positive result corresponds to labelled parasites inside the haemocytes, with all negative controls (including non-infected sample and no probe ISH reaction control) negative and all positive controls (including infected sample) positive. In addition, non-specific probe such as SSUrDNA can be used to verify the integrity of DNA in paraffin blocks.

4.7. Immunohistochemistry

Not available.

4.8. Bioassay

Not available.

4.9. Antibody- or antigen-based detection methods (ELISA, etc.)

Not available.

4.10. Other methods

Not available.

5. Test(s) recommended for surveillance to demonstrate freedom in apparently healthy populations

Real-time PCR is recommended for targeted surveillance to declare freedom from infection with *B. exitiosa*. Histology, tissue imprint and conventional PCR can also be used (see Table 4.1).

6. Corroborative diagnostic criteria

This section only addresses the diagnostic test results for detection of infection in the absence (Section 6.1.) or in the presence of clinical signs (Section 6.2.) but does not evaluate whether the infectious agent is the cause of the clinical event.

The case definitions for a suspect and confirmed case have been developed to support decision-making related to trade and confirmation of disease status at the country, zone or compartment level. Case definitions for disease confirmation in endemically affected areas may be less stringent. If a Competent Authority does not have the capability to undertake the necessary diagnostic tests it should seek advice from the appropriate WOAH Reference Laboratory, and if necessary, refer samples to that laboratory for confirmatory testing of samples from the index case in a country, zone or compartment considered free.

6.1. Apparently healthy animals or animals of unknown health status[1]

Apparently healthy populations may fall under suspicion, and therefore be sampled, if there is an epidemiological link(s) to an infected population. Hydrographical proximity to, or movement of animals or animal products or equipment, etc., from a known infected population equate to an epidemiological link. Alternatively, healthy populations are sampled in surveys to demonstrate disease freedom.

6.1.1. Definition of suspect case in apparently healthy animals

The presence of infection with *Bonamia exitiosa* shall be suspected if at least one of the following criteria is met:

i) Observation of parasite cells in tissue imprints

ii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iii) Positive result by conventional PCR

iv) Positive result by real-time PCR

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *Bonamia exitiosa* is considered to be confirmed if the following criterion is met:

i) Positive result by tissue imprints or histology followed by real-time PCR or by conventional PCR and sequencing

6.2 Clinically affected animals

Clinical signs are not pathognomonic for a single disease; however they may narrow the range of possible diagnoses.

6.2.1. Definition of suspect case in clinically affected animals

The presence of infection with *Bonamia exitiosa* shall be suspected if at least one of the following criteria is met:

i) Gross pathology or clinical signs associated with the disease as described in this chapter

ii) Observation of parasite cells in tissue imprints

iii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iv) Positive result by real-time PCR

v) Positive result by conventional PCR

vi) Positive result by *in-situ* hybridisation

6.2.2. Definition of confirmed case in clinically affected animals

1 For example transboundary commodities.

The presence of infection with *Bonamia exitiosa* is considered to be confirmed if the following criterion is met:

i) Positive result by real-time PCR or by conventional PCR and sequencing

6.3. Diagnostic sensitivity and specificity for diagnostic tests

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with *B. exitiosa* are provided in Tables 6.3.1. and 6.3.2. This information can be used for the design of surveys for infection with *B. exitiosa*, however, it should be noted that diagnostic performance is specific to the circumstances of each diagnostic accuracy study (including the test purpose, source population, tissue sample types and host species) and diagnostic performance may vary under different conditions. Data are only presented where tests are validated to at least level 2 of the validation pathway described in Chapter 1.1.2. and the information is available within published diagnostic accuracy studies.

Data on analytical performances (stage 1 validation) are often missing for diagnostic tests described in this chapter: the limit of detection is rarely available, and the inclusivity of molecular assays is not always fully evaluated (missing information on the detection of *Bonamia* sp. lineages/ species other than *B. ostreae* and *B. exitiosa*).

Diagnostic sensitivity (DSe) and specificity (DSp) (stage 2 validation) are available for most diagnostic tests. However, these values depend on the studied mollusc population (host species, prevalence, intensity of infection, etc.), the protocol (tissue analysed, DNA extraction, use of cut-off value for PCR assays, etc.) and test purpose. Additionally, as no gold standard exists for the detection of *B. exitiosa*, several approaches can be used for DSe and DSp estimation, such as the use of a combination of tests to establish reference results or latent class analysis (maximum likelihood or Bayesian method). If Bayesian Latent class is used, the analysis can incorporate prior knowledge about the performance of compared diagnostic tests. The choice of the overall approach used will have an impact on DSe & DSp estimates. It is therefore complex to compare DSe/DSp estimates from different studies.

Real-time PCR is generally considered as the most sensitive method except in some particular cases as for example for the diagnostic of *Bonamia* sp. in a population of farmed *O. angasi* in Australia, where histology was found to be more sensitive (Buss *et al.,* 2019). This population was characterised by a high *Bonamia* prevalence but low intensity of infection with focal lesions. The fact that PCR diagnosis is performed in a small part of tissue could explain this result.

Two real-time PCR (Canier *at al.,* 2020 and EURL, 2023) were evaluated for their reproducibility (stage 3 validation) in the context of interlaboratory comparison tests.

6.3.1. For presumptive diagnosis of clinically affected animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Taqman PCR *Bonamia* sp. (Corbeil *et al.,* 2006a) (with epidemiological Ct cut-off)	Diagnosis	Two farms in *B. exitiosa* endemic areas in Australia: a coastal lease with *B. exitiosa* associated mortalities, a land-based hatchery with no *B. exitiosa* associated mortalities (prevalences ~30 and 60%)	Gills	*Ostrea angasi*	93.5% (232)	92.2% (232)	Histology Bayesian latent class analysis	Bradley *et al.*, 2020
Histology	Diagnosis		Tissue slide		50.8% (232)	98.2% (232)	Taqman PCR Bayesian latent class analysis	

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction.

6.3.2. For surveillance of apparently healthy animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Histology	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Tissue section	*O. chilensis*	44.4% (28)	100% (28)	Combination conventional PCR and ISH (DSe & DSp: 100%)	Diggles *et al.,* 2003
	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA, where *B. ostreae* is endemic). Low prevalence populations	Tissue section	*Ostrea edulis* (1–2.5 years)	56% (607)	100% (607)	Combination histology and real-time PCR (DSe: 88%, DSp: 99%)	Marty *et al.,* 2006
	Surveillance	Flat oysters produced in hatchery derived from five origins, deployed in the field, in a *B. ostreae* & *B. exitiosa* endemic area (Galicia, Spain). High prevalence populations	Tissue section	*Ostrea edulis* (2–3 years)	54% (137)	96% (137)	Real-time PCR (DSe: 100%, DSp: 77%) and conventional PCR. Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2013
	Surveillance	30 flat oysters from an area affected by *Bonamia ostreae* and *B. exitiosa* in Galicia, Spain. High prevalence populations	Tissue section	*Ostrea edulis*	63% (30)	88% (30)	ISH (DSe: 82%, DSp:88%), PCR-RFLP (DSe 91%, DSp 100%), real-time PCR (DSe 100%, DSp 75%). Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2014
	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Tissue section	*Ostrea angasi*	76% (400)	93% (400)	Real-time PCR (DSe: 69%, DSp:93%) and heart imprint (DSe: 61%, DSp: 60%). Bayesian latent class analysis	Buss *et al.,* 2019
Cytology	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Heart imprints	*Ostrea angasi*	61% (400)	60% (400)	Histology (DSe: 76%, DSp: 93%) and real-time PCR (DSe: 69%, DSp:93%) Bayesian latent class analysis	Buss *et al.,* 2019
	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Heart imprints	*O. chilensis*	59.3% (28)	100% (28)	Combination conventional PCR and ISH (DSe & DSp: 100%)	Diggles *et al.,* 2003
In situ hybridisation (Cochennec *et al.,* 2000)	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Tissue section	*O. chilensis*	100% (28)	27.3% (28)	Combination heart imprint and histology (DSe & DSp: 100%)	Diggles *et al.,* 2003

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Conventional PCR *Bonamia* sp. (Cochennec *et al.,* 2000)	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Gonad and digestive gland	*O. chilensis*	88.2% (28)	36.4% (28)	Combination heart imprint and histology (DSe & DSp: 100%)	Diggles *et al.,* 2003
	Surveillance	Eight batches of 30 flat oysters, Spain (tested by two laboratories) (total prevalence 10–30%)	NA	*Ostrea edulis*	93% (240)	85-90% (240)	Combination histology and gill imprints (DSe: 64-69%, DSp: 97.5%)	Balseiro *et al.,* 2006
	Surveillance	30 flat oysters from an area affected by *Bonamia ostreae* and *B. exitiosa* in Galicia, Spain	Gills	*Ostrea edulis*	91% (30)	100% (30)	ISH (DSe: 82%, DSp:88%), Histology (Des 63%, DSp 88%), and real-time PCR (DSe 100%, DSp 75%) Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2014
	Surveillance	Flat oysters from the three main production sites in France representative of three different levels of *B. ostreae* prevalence (very low, low, high)	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	82.8% (349)	98.7% (349)	Real-time PCR (DSe: 77.5%, DSp: 98.4%) Bayesian latent class analysis	Canier *et al.*, 2020
Taqman real-time PCR *Bonamia* sp.	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA, where *B. ostreae* is endemic). Low prevalence populations	Heart	*Ostrea edulis* (1–2.5 years)	88% (607)	99% (607)	Combination histology and real-time PCR; histology (DSe: 56%, DSp: 100%)	Marty *et al.,* 2006
Taqman real-time PCR *Bonamia* sp. (Corbeil *et al.,* 2006a),	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Mantle, gill, heart (DNA tested pure and 1/10 diluted)	*Ostrea angasi*	69% (400)	93% (400)	Histology (DSe: 76%, DSp: 93%) and heart imprint (DSe: 61%, DSp: 60%) Bayesian latent class analysis	Buss *et al.,* 2019
Taqman real-time PCR *Bonamia* sp.	Surveillance	Flat oysters from the three main production sites in France representative of three different levels of *B. ostreae* prevalence (very low, low, high)	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	77.5% (349)	98.4% (349)	Conventional PCR (DSe : 82.8%, DSp : 98.7%) Bayesian latent class analysis	Canier *et al.,* 2020
SYBR Green real-time PCR *B. exitiosa* (Ramilo *et al.,* 2013)	Surveillance	Flat oysters produced in hatchery derived from 5 origins, deployed in the field, in a *B. ostreae* & *B. exitiosa* endemic area (Galicia, Spain). High prevalence populations	Gills	*Ostrea edulis* (2–3 years)	100% (137)	77% (137)	Histology (DSe: 54%, DSp: 96%) and conventional PCR. Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2013

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
	Surveillance	30 flat oysters from an area affected by *Bonamia ostreae* and *B. exitiosa* in Galicia, Spain	Gills	*Ostrea edulis*	100% (30)	75% (30)	ISH (DSe: 82%, DSp:88%), histology (DSe 63%, DSp 88%), and PCR-RFLP (DSe 91%, DSp 100%). Maximum likelihood latent class analysis, (TAGS)	Ramilo *et al.,* 2014

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction.

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NB: There is a WOAH Reference Laboratory for infection with *Bonamia exitiosa*
(please consult the WOAH web site:
https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3).
Please contact WOAH Reference Laboratories for any further information on infection with *Bonamia exitiosa*

NB: FIRST ADOPTED IN 1995 AS BONAMIOSIS. MOST RECENT UPDATES ADOPTED IN 2022 (SECTIONS 2.2.1 AND 2.2.2).

CHAPTER 2.4.3.

INFECTION WITH *BONAMIA OSTREAE*

1. Scope

Infection with *Bonamia ostreae* means infection with the pathogenic agent *Bonamia ostreae* of the Family Haplosporiidae.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

Bonamia ostreae is a *Haplosporidian* protozoan parasite (Arzul & Carnegie, 2015; Carnegie & Cochennec-Laureau, 2004) infecting haemocytes of flat oysters, *Ostrea edulis,* and causing disease and mortality (Grizel, 1985).

2.1.2. Survival and stability in processed or stored samples

No data available.

2.1.3. Survival and stability outside the host

After its release from *Ostrea edulis*, *B. ostreae* can survive at least 4 days in seawater, however more than 90% of shed parasites are no longer detected after 2 days outside the oysters (Mérou *et al.,* 2020). Up to 58% of parasites isolated from highly infected oysters seem to survive after 1 week in seabed bore water at 15°C (Arzul *et al.,* 2009).

For inactivation methods, see Section 2.4.5.

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Ostreidae	*Magallana* (syn. *Crassostrea*) *ariakensis*	Ariake cupped oyster
	Ostrea chilensis	Chilean flat oyster
	Ostrea edulis	European flat oyster

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 *B. ostreae* according to Chapter 1.5 of the *Aquatic Code* are:

Family	Scientific name	Common name
Ostreidae	*Ostrea puelchana s*	Argentinean flat oyster

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
Actiniidae	*Actina equina*	beadlet anemone
Ascidiidae	*Ascidiella aspersa*	European sea squirt
Ophiotrichidae	*Ophiothrix fragilis*	brittle star
Ostreidae	*Magallana* (syn. *Crassostrea*) gigas	Pacific cupped oyster
N/A	grouped zooplankton	zooplankton

2.2.3. Likelihood of infection by species, host life stage, population or sub-populations

All ages of oysters appear susceptible to *B. ostreae* including larvae and spat (Arzul *et al.,* 2010), however, prevalence and infection intensity are generally higher in individuals of 2 years of age or more particularly post-spawning (Culloty & Mulcahy, 1996).

2.2.4. Distribution of the pathogen in the host

Bonamia ostreae is an intrahaemocytic protozoan (Comps *et al*., 1980; Pichot *et al*., 1979) but it can be observed extracellularly between epithelial or interstitial cells in the gills and stomach or in necrotic connective tissue areas. Intraepithelial localisation has also been reported in gills (Montes *et al*., 1994). The parasite was also reported in ovarian tissue (van Banning, 1990). Advanced infections become systemic. In larvae, the parasite was observed in the epithelium surrounding the visceral cavity (Arzul *et al.,* 2010).

2.2.5. Aquatic animal reservoirs of infection

Any susceptible species (see Section 2.2.1) and any species with incomplete evidence for susceptibility (see Section 2.2.2.) should be considered as potential reservoir. In addition, the observation of parasites presumably *B. ostreae* in *O. angasi* displayed in a zone infected with *B. ostreae*, suggests that this species could also be a reservoir for *B. ostreae* (Bougrier *et al.,* 1986).

2.2.6. Vectors

The possible role of benthic macroinvertebrates and zooplankton in the life cycle of *B. ostreae* was investigated. The brittle star *Ophiothrix fragilis* was identified as a possible vector for the parasite (Lynch *et al.,* 2006).

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Infection of wild and cultured flat oysters is often lethal, and death usually occurs concurrently with the highest intensity of infection.

Prevalence is variable (from 0% to 80%) and is higher in individuals older than 2 years. The disease occurs and can be transmitted throughout the year, but there is a seasonal variation in infection with *B. ostreae,* with prevalence of infection increasing from autumn and showing a peak in late winter/early spring (Arzul *et al.,* 2006; Culloty & Mulcahy, 1996; Engelsma *et al.,* 2010; Grizel, 1985; Mérou *et al.,* 2023).

2.3.2. Clinical signs, including behavioural changes

Clinical signs include dead or gaping oysters.

2.3.3 Gross pathology

Gross pathology includes occasional yellow discoloration, extensive lesions including perforated ulcers in the connective tissues of the gills, mantle and digestive gland (Comps *et al*., 1980). These gross signs are not pathognomonic for infection with *B. ostreae* and most infected oysters appear normal.

2.3.4. Modes of transmission and life cycle

Direct transmission from host to host is possible. Transmission of the parasite directly from host to host by cohabitation or by inoculation of purified parasites has been demonstrated experimentally (Hervio *et al.,* 1995), suggesting that no intermediate host is needed. This is supported by the correlation between oyster density and prevalence of bonamiosis (Grizel, 1985).

The observation of parasites in the epithelium of palleal organs including gills suggests that the parasite enters into and is released from the oysters through these organs.

Moreover, the parasite was observed in larvae incubated in the pallial cavity of adult oysters suggesting possible transmission between these two age groups. Thus, larvae may contribute to the spread of the parasite during their planktonic life stage (Arzul *et al.,* 2010).

A lag time of at least 3 months is generally observed before detecting the parasite in disease free batches moved into infected areas.

2.3.5. Environmental factors

Survival of parasites purified and maintained in sea water is lower at 25°C than at 4°C or 15°C (Arzul *et al.,* 2009). High salinities (35, 40 and 45 ppt) appear to favour parasite survival (Arzul *et al.,* 2009). Prevalence shows an annual pattern that may differ according to areas. Prevalence of infection increases from autumn and shows a peak in late winter/early spring. Two peaks generally occurring in winter/spring and in autumn have been reported (Arzul *et al.,* 2006; Culloty & Mulcahy, 1996; Mérou *et al.,* 2023). Lower summer temperatures and higher summer salinities induce higher prevalence the following winter (Arzul *et al.,* 2006). *Ostrea edulis* appears to be more susceptible to *B. ostreae* following a period of lower food availability and lower salinities (Engelsma *et al.,* 2010).

2.3.6. Geographical distribution

Infection with *B. ostreae* has been found in Europe, North America (Carnegie & Cochennec-Laureau, 2004) and Oceania (Lane *et al.,* 2016).

See WAHIS (https://wahis.woah.org/#/home) for recent information on distribution at the country level.

2.4. Biosecurity and disease control strategies

2.4.1. Vaccination

None.

2.4.2. Chemotherapy including blocking agents

None.

2.4.3. Immunostimulation

None.

2.4.4. Breeding resistant strains

Selective breeding has been shown to be effective in reducing susceptibility and mortality caused by *B. ostreae* (Lynch *et al.,* 2014; Naciri-Graven *et al.,* 1998).

2.4.5. Inactivation methods

Peracetic acid bath (0.001% and 0.005%) has been shown to reduce contamination of oysters by *B. ostreae* (Grizel, 1985). Bench scale experiment showed that a 94 mJ/cm^2 UV C exposure inactivates up to 40% of *B. ostreae* isolated from infected oysters (Fernandez-Boo *et al.,* 2021).

2.4.6. Disinfection of eggs and larvae

No data available.

2.4.7. General husbandry

Mortalities caused by bonamiosis can be reduced using suspension culture, lower stocking densities or by culturing *Ostrea edulis* with *Magallana* (*Crassostrea) gigas,* which are not naturally susceptible to infection (Carnegie & Cochennec-Laureau, 2004). Oyster seed from hatcheries are preferred to seed from natural settlements which appears to have higher levels of parasites (Conchas *et al*., 2003). In an infected zone, harvesting larger oysters should allow reducing the parasite load in the population.

3. Specimen selection, sample collection, transportation and handling

This section draws on information in Sections 2.2, 2.3 and 2.4 to identify populations, individuals and samples that are most likely to be infected.

3.1. Selection of populations and individual specimens

Gaping or freshly dead individuals (2 or more years old) should be sampled by priority, to increase the chances of detecting infected oysters. For histology, only live (including moribund) oysters should be sampled.

Sampling of bivalves should be carried out when prevalence is known to be at a maximum. When such data are not available in a particular ecosystem, sampling should preferably be carried out in late winter-early spring (Arzul *et al.,* 2006; Culloty & Mulcahy, 1996; Engelsma *et al.,* 2010).

3.2. Selection of organs or tissues

A 3–5 µm thick section of tissues including gills, mantle, gonad, and digestive gland, is used for diagnosis of *B. ostreae* by histology. Gills or heart are preferred for some tests, including imprints and PCR.

3.3. Samples or tissues not suitable for pathogen detection

Tissues other than gills, heart and mantle are less suitable.

3.4. Non-lethal sampling

No difference was observed between results obtained using real-time PCR from a mix of gill, mantle and digestive gland tissues and using real-time PCR from a biopsy of gills collected on anaesthetised oysters (Kamermans *et al.,* 2023).

Environmental DNA- and RNA-based approaches have been successfully developed allowing the detection of parasite DNA or RNA in sea water (Mérou *et al.,* 2020; von Gersdorff Jorgensen *et al.,* 2020). Although these methods allow detection in experimental conditions, their application in the field has not been validated (Mérou *et al.,* 2023).

3.5. Preservation of samples for submission

For guidance on sample preservation methods for the intended test methods, see Chapter 2.4.0 *General information* (*diseases of molluscs*).

3.5.1. Samples for pathogen isolation

Not applicable.

3.5.2. Preservation of samples for molecular detection

Tissue samples for PCR testing should be preserved in 70–100% (v/v) analytical-grade ethanol.

Standard sample collection, preservation and processing methods for molecular techniques can be found in Section B.5.5 of Chapter 2.4.0 *General information* (diseases of molluscs).

3.5.3. Samples for histopathology, immunohistochemistry or *in-situ* hybridisation

Standard sample collection, preservation and processing methods for histological techniques can be found in Section B.5.3 of Chapter 2.4.0 *General information* (diseases of molluscs).

3.5.4. Samples for other tests

None.

3.6. Pooling of samples

Pooling of samples from more than one individual animal for a given purpose is only recommended where robust supporting data on diagnostic sensitivity and diagnostic specificity have been evaluated and found to be suitable. The effect of pooling on diagnostic sensitivity has not been thoroughly evaluated, therefore larger specimens should be processed and tested individually. Small life stages such as spat can be pooled to obtain the minimum amount of material for molecular detection.

Performances of diagnostic methods applied on pools have not been evaluated. However, the detection of *B. ostreae* DNA was found similar between individuals and pools of five individuals when using a real-time PCR assay targeting the multiple copy 18S gene (Lane *et al.,* 2017).

4. Diagnostic methods

The methods currently available for pathogen detection that can be used in i) surveillance of apparently healthy animals, ii) presumptive diagnosis in clinically affected animals and iii) confirmatory diagnostic purposes are listed in Table 4.1. by animal life stage.

Ratings for purposes of use. For each recommended assay a qualitative rating for the purpose of use is provided. The ratings are determined based on multiple performance and operational factors relevant to application of an assay for a defined purpose. These factors include appropriate diagnostic performance characteristics, level of assay validation, availability cost, timeliness, and sample throughput and operability. For a specific purpose of use, assays are rated as:

+++ =	Methods are most suitable with desirable performance and operational characteristics.
++ =	Methods are suitable with acceptable performance and operational characteristics under most circumstances.
+ =	Methods are suitable, but performance or operational characteristics may limit application under some circumstances.
Shaded boxes =	Not appropriate for this purpose.

Validation stage. The validation stage corresponds to the assay development and validation pathway in chapter 1.1.2. The validation stage is specific to each purpose of use. Where available, information on the diagnostic performance of recommended assays is provided in Section 6.3.

WOAH Reference Laboratories welcome feedback on diagnostic performance of recommended assays, in particular PCR methods. Of particular interest are any factors affecting expected assay sensitivity (e.g. tissue components inhibiting amplification) or expected specificity (e.g. failure to detect particular genotypes, detection of homologous sequences within the host genome). These issues should be communicated to the WOAH Reference Laboratories so that advice can be provided to diagnostic laboratories and the standards amended if necessary.

Table 4.1. *WOAH recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals*

Method	A. Surveillance of apparently healthy animals				B. Presumptive diagnosis of clinically affected animals				C. Confirmatory diagnosis[1] of a suspect result from surveillance or presumptive diagnosis			
	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV
Imprints		++	++	2		+++	+++	NA				
Histopathology		++	++	2		+++	+++	NA				
Transmission electron microscopy									+	+	+	NA
Real-time PCR	+++	+++	+++	3	+++	+++	+++	NA	+++	+++	+++	NA
Conventional PCR	++	++	++	3	+++	+++	+++	NA				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	NA
In-situ hybridisation									++	++	++	NA
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
Other antigen detection methods												

LV = level of validation, refers to the stage of validation in the WOAH Pathway (chapter 1.1.2), Figures in brackets mean that partial data are available; NA = not available; PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; Ab- or Ag-ELISA = antibody or antigen enzyme-linked immunosorbent assay, respectively;
[1]For confirmatory diagnoses, methods need to be carried out in combination (see Section 6). [2]Susceptibility of early and juvenile life stages is described in Section 2.2.3.
[3]Specify the test used. Shading indicates the test is inappropriate or should not be used for this purpose.

4.1. Imprints

Samples to be taken consist of heart (preferably the ventricle) or gills from fresh, gaping or freshly dead bivalves if they are sufficiently large. If bivalves are too small (as spat), imprints should be done using the entire individual.

After drying tissues on absorbent paper, several imprints are made on a glass slide. Slides are air-dried, fixed and stained using a commercially available blood-staining kit, in accordance with the manufacturer's instructions. Fixation can be done using methanol or absolute ethanol. After rinsing in tap water and drying, the slides are mounted with a cover-slip using an appropriate synthetic resin. Slides are observed first at ×200 magnification and then under oil immersion at ×1000 magnification.

Imprints are generally less sensitive than PCR methods (see Sections 6.1. and 6.2).

Infection with *Bonamia ostreae* is indicated by the presence of small spherical or ovoid organisms (2–5 µm wide) within haemocytes. However, the parasite might also occur extracellularly. These organisms show a basophilic cytoplasm often containing a lipid vacuole and an eosinophilic nucleus which is rather eccentric in the case of *B. ostreae* and rather centred in the case of *B. exitiosa* (colours of cytoplasm and nucleus may vary with the stain used). Parasitic cells can appear wider on imprints than on histological examination. Multinucleated cells can be observed (Balouet *et al.,* 1983; Bucke, 1988). The technique is not parasite species specific.

A positive result is indicative of infection with a *Bonamia* species.

4.2. Histopathology

Samples to be taken consist of fresh, gaping or freshly dead bivalves.

Sections of tissue that include gills, digestive gland, mantle, and gonad should be fixed for 24 hours minimum in a recommended fixative followed by standard processing for histology as described in section 5.3 of Chapter 2.4.0 *General information* (diseases of molluscs). Observations are made at increasing magnifications up to ×1000.

Histology is generally less sensitive than PCR methods (see Sections 6.1. and 6.2).

Infection with *Bonamia ostreae* is indicated by the presence of small cells of 2–5 µm wide within the haemocytes or free in the connective tissue or sinuses of gills, gut, digestive gland, gonad and mantle, often associated with an intense inflammatory reaction. Parasite cells could be observed in some epithelia including stomach or mantle epithelia (Balouet *et al.,* 1983). To avoid any doubt, the parasite has to be observed inside the haemocyte for a positive diagnosis. Although *B. ostreae* is slightly smaller than *B. exitiosa* and usually presents an eccentric nucleus, both species are difficult to distinguish in histology. No spore has been described in *B. ostreae* unlike *B. perspora* which has also a central to slightly eccentric nucleus. The technique is not species specific.

A positive result is indicative of infection with a *Bonamia* species.

4.3. Transmission electron microscopy

Samples to be taken consist of live, gaping or freshly dead bivalves.

A small sized piece of tissue (1–2 mm) should be fixed in an appropriate fixative for at least 1 hour and then processed as described in section 5.4 of Chapter 2.4.0 *General information* (diseases of molluscs).

Infection with *B. ostreae* is indicated by the presence of parasites within the haemocytes. Different stages, including uninucleated, and rarely binucleated and plasmodial stages have been reported (Montes *et al*., 1994; Pichot *et al*., 1979). Intracellular structures include mitochondria, haplosporosomes, Golgi apparatus and persistent intranuclear microtubules. Two forms were described including a dense form rich in ribosomes and haplosporosomes and a light form, slightly larger with less dense cytoplasm and a nucleus showing a large nucleolus (Bucke, 1988; Pichot *et al.,* 1979).

Uninucleated *B. ostreae* stages are smaller than *B. exitiosa* or *B. perspora* ones and have larger haplosporosomes than other *Bonamia* spp (Hine *et al.,* 2014). They are also denser and have fewer lipoid bodies than other *Bonamia* species (Hine *et al.,* 2001).

4.4. Nucleic acid amplification

PCR assays should always be run with the controls specified in Section B.5.5 *Molecular methods* Chapter 2.4.0 *General information* (diseases of molluscs). Molluscs are known to potentially contain substances that can inhibit PCR reactions. It is recommended to check for the presence of PCR inhibitors in DNA extracts to avoid false negative results. In case PCR inhibitors are present, DNA sample can be diluted prior to PCR analyses (a 1/10 dilution allows to resolve most cases of PCR inhibition). Each sample should be tested in duplicate.

Extraction of nucleic acids

Different kits and procedures can be used for nucleic acid extraction. The quality and concentration of the extracted nucleic acid is important and can be checked using a suitable method as appropriate to the circumstances.

4.4.1. Real-time PCR

Three TaqMan PCR assays are available for the detection of *Bonamia* spp.: one targeting the ITS1 (internal transcribed spacer) (Corbeil *et al.,* 2006) and two targeting the 18S (small subunit rDNA) (Canier *et al.,* 2020; Marty *et al.,* 2006). The PCR assay developed by Canier *et al.* (2020) targets the 18S (small subunit rDNA) and allows the concomitant detection of *Bonamia* sp. and *Marteilia refringens* parasites.

Two other real-time PCR protocols have been developed to specifically detect *B. ostreae*: one-SYBR green PCR assay targeting the 18S-ITS1 region (Ramilo *et al.,* 2013), and a Taqman PCR assay targeting the actin gene (https://www.eurl-mollusc.eu/SOPs). These PCR assays allow the concomitant detection of *B. ostreae* and *B. exitiosa* parasites.

PCR assays are generally more sensitive than histology or cytology for the diagnosis of *B. ostreae* (see Sections 6.1. and 6.2). Real-time PCR usually have a better sensitivity than conventional PCR (see Sections 6.1. and 6.2).

***Primers and probes* (*sequences*)**

Pathogen/ target gene	Primer/probe (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Corbeil *et al.,* 2006; GenBank Accession No.: JN040831			
Taqman® PCR *Bonamia* spp./ITS-1	ITS-For: CCC-TGC-CCT-TTG-TAC-ACA-C ITS-Rev: TCA-CAA-AGC-TTC-TAA-GAA-CGC-G Probe Bon ITS: TTA-GGT-GGA-TAA-GAG-CCG-C (FAM MGB-NFQ)	900 nM 900 nM 250 nM	35 cycles of: 95°C/15 sec and 63.6°C/60 sec
Method 2: Marty *et al.,* 2006; GenBank Accession No.: AF192759			
Taqman® PCR *Bonamia* spp./18S	Fwd: CCC-GGC-TTC-TTA-GAG-GGA-CTA Rev: ACC-TGT-TAT-TGC-CCC-AAT-CTT-C Probe: CTG-TGT-CTC-CAG-CAG-A (FAM MGB-NFQ)	800 nM 800 nM 250 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 3: Canier *et al.,* 2020; GenBank Accession No. AF192759			
Taqman® PCR *Bonamia* spp./18S	Bosp2-18S-F: CAG-GAT-GCC-CTT-AGA-TGC-TC Bosp2-18S-R: GTA-CAA-AGG-GCA-GGG-ACG-TA Probe Bosp-18S-IN: TTG-ACC-CGG-CTT-GAC-AAG-GC (HEX-BHQ1)	300 nM 500 nM 300 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 4: Ramilo *et al.,* 2013; GenBank Accession No. AF262995			
SYBR Green PCR *B. ostreae*/18S-ITS	BOSTRE-F: TTA-CGT-CCC-TGC-CCT-TTG-TA BOSTRE-R: TCG-CGG-TTG-AAT-TTT-ATC-GT	300 nM 300 nM	35 cycles of: 95°C/30 sec and 55°C/45 sec, 72°C/60 sec Melt curve from 55°C to 95°C with 0.5°C increment/sec
Method 5: EURL for mollusc diseases; GenBank Accession No: AF192759			

Taqman® PCR *B. ostreae/* actin	BO2_F: AAA-TGG-CCT-CTT-CCC-AAT-CT BO2_R: CCG-ATC-AAA-CTA-GGC-TGG-AA BO2 probe: TGA-CGA-TCG-GGA-ATG-AAC-GC (HEX BHQ1)	300 nM 300 nM 200 nM	40 cycles of: 95°C/15 sec and 60°C/20 sec

[(a)]A denaturation step prior to cycling has not been included.

4.4.2. Conventional PCR

Three conventional PCR protocols targeting the 18S (small subunit rDNA) have been developed for the detection of *Bonamia* sp. (Carnegie *et al.,* 2000; Cochennec *et al*., 2000) or *B. ostreae* (Engelsma *et al.,* 2010).

The PCR assay described by Carnegie *et al.* (2000) amplifies most of the identified *Bonamia* spp. including *B. ostreae* and *B. exitiosa*, while the Cochennec *et al.* (2000) PCR amplifies *Bonamia* spp. and several members of *Haplosporidia.* The Engelsma *et al.* (2010) PCR was shown not to detect *B. exitiosa* and *Haplosporidium armoricanum.*

Conventional PCR assays were generally more sensitive than histology or cytology (see Sections 6.1. and 6.2) although Lynch *et al.* (2008) found that heart imprint was more sensitive than the conventional PCR from Cochennec *et al.* (2000). Under certain circumstances, the primers from Cochennec *et al.* (2000) can generate a 295 bp non-specific product (Engelsma *et al.,* 2014).

Primer sequences

Pathogen / target gene	Primer (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Carnegie *et al.,* 2000 modified in Carnegie *et al.,* 2008; amplicon size [760 bp]			
Bonamia spp./18S amplifies most of the identified *Bonamia* spp including *B. ostreae* and *B. exitiosa*	CF: CGG-GGG-CAT-AAT-TCA-GGA-AC CR: CCA-TCT-GC-TGGA-GAC-ACA-G	250 nM 250 nM	35 cycles of: 95°C/1min and 59°C/1 min and 72°/1min
Method 2: Cochennec *et al.,* 2000; amplicon size [300 bp]			
Bonamia spp./18S amplifies all identified *Bonamia* spp. and several members of *Haplosporidia*	BO: CAT-TTA-ATT-GGT-CGG-GCC-GC BOAS: CTG-ATC-GTC-TTC-GAT-CCC-CC	1 µM 1 µM	30 cycles of: 95°C/60 sec, 55°C/60 sec, 72°C/60 sec
Method 3: Engelsma *et al.,* 2010; amplicon size [352 bp]			
B. ostreae/18S	BoosF03: CAA-TGG-TGC-GTT-CAA-CGA-GT BoosR03: GGG-TTC-GCG-GTT-GAATTT-TA	400 nM 400 nM	40 cycles of: 95°C/30 sec, 58°C/30 sec, 72°C, 45 sec

[(a)]A denaturation step at 94-95°C prior to cycling and a final elongation step at 72°C (between 5 and 10 minutes) must be included.

The PCR methods 1 and 2 are not specific for *B. ostreae*. Sequence analysis of the amplicons must be used to confirm identity. Amplicons obtained by method 2 can be digested with the Bgl enzyme which allows to distinguish two profiles: *B. ostreae* (two bands of 120 and 180 bp) and *B. exitiosa* (not digested).

4.4.3. Other nucleic acid amplification methods

None available.

4.5. Amplicon sequencing

The size of the PCR amplicon is verified by agarose gel electrophoresis and purified by excision from this gel. Obtained sequences are analysed and compared with published sequences.

Sequencing is recommended as one of the final steps for confirmatory diagnosis. Targeted regions are 18S, ITS1 and actin. Although the sequences are available in the public gene banks, it is recommended to refer such cases to the appropriate WOAH Reference Laboratory.

4.6. *In-situ* hybridisation

Samples to be taken: live or freshly dead oysters.

Several *in situ* hybridisation (ISH) protocols targeting the 18S have been developed.

The first one (Cochennec *et al.*, 2000) allows a detection at the *Bonamia* genus level and uses a 300 bp labelled probe produced by PCR.

Two ISH protocols were designed to specifically detect *B. ostreae* (Carnegie *et al.,* 2003; Hill *et al.,* 2014), and rely on labelled oligonucleotide probes. However, the ISH protocol from Carnegie *et al.* (2003) should also detect *B. exitiosa* according to probe sequence analysis.

Reference	Pathogen/target	ISH probe type	ISH probe
Method 1 Cochennec *et al.,* 2000	*Bonamia* spp. and several members of *Haplosporidia* 18S	Labelled BO–BOAS amplicons	BO–BOAS PCR product (300bp)
Method 2: Carnegie *et al.,* 2003	*B. ostreae*, and *B. exitiosa* 18S	Labelled oligonucleotides	UME-BO-1: CGA-GGC-AGG-GTT-TGT; UME-BO-2: GGG-TCA-AAC-TCG-TTG-AAC UME-BO-3: CGC-TCT-TAT-CCA-CCT-AAT
Method 3 Hill *et al.,* 2014	*B. ostreae* 18S	Labelled oligonucleotides	Bost171: CCG-CCG-AGG-CAG-GGT-TTG-T

Technical procedure

The first steps in the technical procedure follow the recommendations described in chapter 2.4.0.

Subsequent steps concerning Method 1 (Cochennec *et al.,* 2000) are that the probe is produced by PCR using the previously described primer pair Bo–Boas (Section 4.4.2) with digoxigenin incorporation and the PCR is performed as described in the section on PCR except that DIG dUTP 25 mM is added to the reaction mixture. The detection steps are performed according to the manufacturer's instructions. In other protocols, probes consist in digoxigenin-labelled nucleotides.

Slides are dehydrated by immersion in an ethanol series and air dried. The slides are then covered with hybridisation buffer (4 × SSC [standard saline citrate; 60 mM NaCl, 600 mM NaCl, pH 7], 50% formamide, 1 × Denhardt's solution, 250 µg ml^{-1} yeast tRNA, 10% dextran sulphate) containing approx. 20 ng of the digoxigenin-labelled probe (1–2 µl of the probe produced by PCR, or 1 µl at 100 µm of labelled nucleotides). Sections are covered with *in-situ* plastic cover-slips and placed for 5 minutes at 95°C. Slides are then cooled on ice for 1– 5 minutes before overnight hybridisation at 42°C in a humid chamber Sections are washed twice for 5 minutes in 2 × SSC at room temperature, and once for 10 minutes in 0.4 × SSC at 42°C. The detection steps are performed according to the manufacturer's instructions. The slides are then rinsed with appropriate buffer. The sections are counter-stained with an appropriate staining, rinsed in tap water, immersed in 95% and 100% ethanol for 30 seconds for each, rinsed for 10–30 seconds in xylene and cover-slips are applied using an appropriate mounting medium.

In Carnegie et al. (2003)after proteinase K treatment, slides are washed in several baths including PBS plus 0.2% glycine for 5 minutes, acetylated using 5% anhydrous acetic in 0.1 M triethanolamine/HCl (pH 8), for 10 minutes at room temperature, washed again in PBS for 10 minutes and lastly equilibrated in 5 × SET (750 mM NaCl, 6.4 mM EDTA, 100 mM Tris Base) for 10 minutes at room temperature. Slides are then covered with 200 µl of prehybridisation buffer (5 × SET, 0.02% bovine serum albumin, 0.025% sodium dodecyl sulphate [SDS]) for 30 minutes at 45°C. Prehybridisation buffer is replaced with 10 to 12 µl of the prehybridisation buffer containing 2–10 ng μl^{-1} of the oligonucleotides and slides are incubated overnight in a humid chamber at 45°C. Slides are then washed three times in 0.2 × SET for 5 minutes at 42°C, air dried and mounted before being examined using an epifluorescence microscope at ×600–1000.

Interpretation of results:

A positive result corresponds to labelled parasites inside the haemocytes, with all negative controls (including non-infected sample and no probe ISH reaction control) negative and all positive controls (including infected sample) positive. In addition, non-specific probe such as SSUrDNA can be used to verify the integrity of DNA in paraffin blocks.

4.7. Immunohistochemistry

Not available.

4.8. Bioassay

Not available.

4.9. Antibody- or antigen-based detection methods (ELISA, etc.)

Although an immunofluorescent technique based on monoclonal antibodies was developed It has never been validated and it is no longer available (Carnegie & Cochennec-Laureau, 2004).

4.10. Other methods: agent purification

Bonamia ostreae can be purified from highly infected oysters (Mialhe *et al.,* 1988). All organs are homogenised except the adductor muscle, and parasites are concentrated by differential centrifugation on sucrose gradients and then purified by isopycnic centrifugation on a Percoll gradient.

5. Test(s) recommended for surveillance to demonstrate freedom in apparently healthy populations

Real-time PCR is recommended for targeted surveillance to declare freedom from infection with *B. ostreae*. Histology, tissue imprint and conventional PCR can also be used (see Table 4.1)

6. Corroborative diagnostic criteria

This section only addresses the diagnostic test results for detection of infection in the absence (Section 6.1.) or in the presence of clinical signs (Section 6.2.) but does not evaluate whether the infectious agent is the cause of the clinical event.

The case definitions for a suspect and confirmed case have been developed to support decision making related to trade and confirmation of disease status at the country, zone or compartment level. Case definitions for disease confirmation in endemically affected areas may be less stringent. If a Competent Authority does not have the capability to undertake the necessary diagnostic tests it should seek advice from the appropriate WOAH Reference Laboratory, and if necessary, refer samples to that laboratory for confirmatory testing of samples from the index case in a country, zone or compartment considered free.

6.1. Apparently healthy animals or animals of unknown health status[1]

Apparently healthy populations may fall under suspicion, and therefore be sampled, if there is an epidemiological link(s) to an infected population. Hydrographical proximity to, or movement of animals or animal products or equipment, etc., from a known infected population equate to an epidemiological link. Alternatively, healthy populations are sampled in surveys to demonstrate disease freedom.

6.1.1. Definition of suspect case in apparently healthy animals

The presence of infection with *Bonamia ostreae* shall be suspected if at least one of the following criteria is met:

i) Observation of parasite cells in tissue imprints

ii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iii) Positive result by conventional PCR

iv) Positive result by real-time PCR

1 For example transboundary commodities.

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *Bonamia ostreae* is considered to be confirmed if the following criterion is met:

i) Positive result by tissue imprints or histology followed by real-time PCR or by conventional PCR and sequencing or by species-specific *in-situ* hybridisation

6.2 Clinically affected animals

Clinical signs are not pathognomonic for a single disease; however they may narrow the range of possible diagnoses.

6.2.1. Definition of suspect case in clinically affected animals

The presence of infection with *Bonamia ostreae* shall be suspected if at least one of the following criteria is met:

i) Gross pathology or clinical signs associated with the disease as described in this chapter

ii) Observation of parasite cells in tissue imprints

iii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iv) Positive result by real-time PCR

v) Positive result by conventional PCR

6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection with *Bonamia ostreae* is considered to be confirmed if the following criterion is met:

i) Positive result by real-time PCR or by conventional PCR and sequencing or by species-specific *in-situ* hybridisation

6.3. Diagnostic sensitivity and specificity for diagnostic tests

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with *B. ostreae* are provided in Tables 6.3.1. (no data are currently available) and 6.3.2. This information can be used for the design of surveys for infection with *B. ostreae*, however, it should be noted that diagnostic performance is specific to the circumstances of each diagnostic accuracy study (including the test purpose, source population, tissue sample types and host species) and diagnostic performance may vary under different conditions. Data are only presented where tests are validated to at least level 2 of the validation pathway described in Chapter 1.1.2. and the information is available within published diagnostic accuracy studies.

Data on analytical performances (stage 1 validation) are often missing for diagnostic tests described in this chapter: the limit of detection is rarely available, and the inclusivity of molecular assays is not fully evaluated (missing information on the detection of *Bonamia* sp. lineages/species other than *B. ostreae* and *B. exitiosa*).

Diagnostic sensitivity (DSe) and specificity (DSp) (stage 2 validation) are available for most diagnostic tests. However, these values depend on the studied mollusc population (host species, prevalence, intensity of infection, etc.), the protocol (tissue analysed, DNA extraction, use of cut-off value for PCR assays, etc.) and test purpose. Additionally, as no gold standard exists for the detection of *B. ostreae*, several approaches can be used for DSe and DSp estimation, such as the use of a combination of tests to establish reference results or latent class analysis (maximum likelihood or Bayesian method). If Bayesian latent class is used, the analysis can incorporate prior knowledge about the performance of compared diagnostic tests. The choice of the overall approach used will have an impact on DSe & DSp estimates. It is therefore complex to compare DSe/DSp estimates from different studies.

Few assays were evaluated for their reproducibility (stage 3 validation). Two real-time PCR (Canier *et al.,* 2020, and EURL, 2023) were evaluated in the context of interlaboratory comparison tests. Additionally, a study comparing conventional PCR, ISH, heart imprint and histology in three laboratories showed that conventional PCR produces the highest rate of positive *Bonamia ostreae* detection but also had the lowest agreement amongst laboratories (Flannery *et al.,* 2014).

6.3.1. For presumptive diagnosis of clinically affected animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction.

6.3.2. For surveillance of apparently healthy animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Histology	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA, where *B. ostreae* is endemic). Low prevalence populations	Tissue section	*Ostrea edulis* (1–2.5 years)	56% (607)	100% (607)	Combination histology and real-time PCR (DSe: 56%, DSp: 100%)	Marty *et al.,* 2006
	Surveillance	Flat oysters produced in hatchery derived from five origins, deployed in the field, in a *B. ostreae* & *B. exitiosa* endemic area (Galicia, Spain). High prevalence populations	Tissue section	*Ostrea edulis* (2–3 years)	64% (137)	98% (137)	Real-time (DSe 99%, DSp 72%) and conventional PCR Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2013
	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Tissue section	*Ostrea angasi*	76% (400)	93% (400)	Real-time PCR Corbeil *et al.,* 2006 (DSe: 69%, DSp: 93%) and Heart imprint (DSe 61%, DSp 60%) Bayesian latent class analysis	Buss *et al.,* 2019
Tissue imprints	Surveillance	Flat oysters from 3 farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Heart	*Ostrea angasi*	61% (400)	60% (400)	Histology (DSe: 76%, DSp: 93%) and real-time PCR Corbeil *et al.,* 2006 (DSe: 69%, DSp: 93%). Bayesian latent class analysis	Buss *et al.,* 2019
Conventional PCR *Bonamia* sp. (Cochennec *et al.,* 2020)	Surveillance	Eight batches of 30 flat oysters, Spain (tested by two laboratories) (total prevalence 10–30%)	NA	*Ostrea edulis*	93% (240)	85–90% (240)	Combination histology and gill imprints (DSe: 64-69%, DSp: 97.5%)	Balseiro *et al.,* 2006
	Surveillance	Flat oysters from the 3 main production sites in France representative of three different levels of *B. ostreae* prevalence (very low, low, high)	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	82.8% (349)	98.7% (349)	Real-time PCR (DSe 77.5%, DSp 98.4%). Bayesian latent class analysis	Canier *et al.,* 2020
Taqman real-time PCR *Bonamia* sp.	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA,	Heart	*Ostrea edulis* (1-2.5 years)	88% (607)	99% (607)	Combination histology and real-time PCR.	Marty *et al.,* 2006

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
		where *B. ostreae* is endemic). Low prevalence populations					Histology (DSe: 56%, DSp: 100%)	
Taqman real-time PCR *Bonamia* sp. (Corbeil *et al.,* 2006)	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Mantle, gill, heart (DNA tested pure and 1/10 diluted)	*Ostrea angasi*	69% (400)	93% (400)	Histology (DSe: 76%, DSp: 93%) and heart smear (DSe: 61%, DSp: 60%). Bayesian latent class analysis	Buss *et al.,* 2019
Taqman real-time PCR *Bonamia* sp.	Surveillance	Flat oysters from the three main production sites in France representative of three different levels of *B. ostreae* prevalence (very low, low, high)	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	77.5% (349)	98.4% (349)	Conventional PCR (DSe: 82.8%, DSp: 98.7%). Bayesian latent class analysis	Canier *et al.,* 2020
SYBR Green real-time PCR *B. ostreae*	Surveillance	Flat oysters produced in hatchery derived from five origins, deployed in the field, in a *B. ostreae* & *B. exitiosa* endemic area (Galicia, Spain). High prevalence populations	Gills tissues	*Ostrea edulis* (2–3 years)	99% (137)	72% (137)	Histology (DSe: 64%, DSp: 98%) and conventional PCR). Maximum likelihood latent class (TAGS)	Ramilo *et al.,* 2013

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study,
PCR: = polymerase chain reaction.
(TAGS programme, Pouillot *et al.,* 2002)

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* *

NB: There is a WOAH Reference Laboratory for infection with *Bonamia ostreae*
(please consult the WOAH web site:
https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3).
Please contact WOAH Reference Laboratories for any further information on infection with *Bonamia ostreae*

NB: FIRST ADOPTED IN 1995 AS BONAMIOSIS. MOST RECENT UPDATES ADOPTED IN 2021 (SECTIONS 2.2.1 AND 2.2.2).

Annex 24. Item 8.3.3. – 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*

[…]

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	no common name ~~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 shell ~~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
	Polititapes aureus	golden carpet shell
	Venus verrucosa	warty venus ~~clam~~

[…]

Annex 25. Item 8.3.4. – Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *X. californiensis*'

CHAPTER 2.4.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

[…]

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Haliotidae	*Haliotis corrugata*	pink abalone
	Haliotis cracherodii	black abalone
	Haliotis discus discus	Japanese abalone
	Haliotis diversicolor	small abalone
	Haliotis fulgens	green abalone
	Haliotis kamtschatkana	pinto abalone
	Haliotis rufescens	red abalone
	Haliotis rufescens X *Haliotis discus hannai* hybrid	hybrid red and Japanese abalone
	Haliotis sorenseni	white abalone
	Haliotis tuberculata	tuberculate abalone

~~*Xenohaliotis californiensis* infects members of the genus *Haliotis* and natural infections have been observed in black abalones (*H. cracherodii*), white abalones (*H. sorenseni*), red abalones (*H. rufescens*), pink abalones (*H. corrugata*), green abalones (*H. fulgens*), the small abalone (*H. diversicolor supertexta;* (Wetchateng, 2008; Wetchateng *et al.*, 2010), the European abalone (*H. tuberculata*) (Balseiro *et al.*, 2006) in the wild or culture facilities, as well as flat (*H. wallalensis*) and Japanese abalones (*H. discus hannai*) in laboratory challenges (Friedman, unpublished observations). Other abalone species have not been tested. Temperature is important in both pathogen transmission and disease expression (Braid *et al.*, 2005; Friedman *et al.*, 1997; Raimondi *et al.*, 2002; Rosenblum *et al.*, 2008).~~

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

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

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

~~While all post-larval life stages have been demonstrated susceptible to infection with *X. californiensis*, clinical disease is typically observed in animals >1 years of age in farmed abalones (Friedman, unpublished observations) and all abalone~~

~~size classes observed in wild populations surveyed to date (e.g. Balseiro *et al.*, 2006; Braid *et al.*, 2005; Friedman *et al.*, 1997; Haaker *et al.*, 1992; Steinbeck *et al.*, 1992; Van Blaricom *et al.*, 1993).~~

[…]