Report of the Meeting of WOAH Aquatic Animal Health Standards Commission

Original: English (EN)

12 to 19 February 2025

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 12 to 19 February 2025.

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 Republic of), Chinese Taipei, Colombia, Ecuador, Korea (Republic of), Mexico, New Zealand, Norway, Peru, Singapore, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), the African Union – Interafrican Bureau for Animal Resources (AU-IBAR), Members of the WOAH Americas Region (the Americas) and 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 originally 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.

The first step in this process was the publication on the Delegates' website of comments submitted by WOAH Members and partners that were considered by the Commission at its February 2024 meeting. This step was implemented in April 2024 when comments were uploaded onto the Delegates' website at the same time as the publication of the Commission's report.

The second step in this process was the publication on the Delegates' and public WOAH websites of comments considered by the Commission with the Commission's responses in October 2024. These were published as part of the Commission's September 2024 report in a specific annex (Annex 3) for information only. The Commission's responses were presented in English, French or Spanish according to the language of the report and comments were presented in the language in which they were submitted. Comments and the Commission's responses were embedded in the English version of the text that was circulated for comment in September 2024, irrespective of the language version due to resource constraints. As a consequence of presenting all the Commission's responses to comments considered in Annex 3, the text of the body of the Commission's September 2024 report focused on providing a short background summary for each agenda item as well as key points discussed and agreed by the Commission.

The Director General has agreed to implement the final step of this process in March 2026 which is to publish the name of the Member or partner who submitted the comment in the Commission's report published on both the public and the Delegates' website.

The Director General hopes that these new processes to improve transparency, together with the guidance documents for submitting comments and a more user-friendly report will encourage more Members to engage in the process for the elaboration of WOAH Standards.

Annexes

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

Texts in Annexes 5 to 18 and 22 to 27 are proposed for adoption at the 92nd General Session in May 2025.

Texts in Annexes 4, 19 to 21 and 28 to 29 are presented for comment.

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 4 July 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: 17 to 24 September 2025.

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

1.1. WOAH Director General

Dr Emmanuelle Soubeyran, the Director General of WOAH met virtually with the Aquatic Animals Commission on 13 February 2025. Dr Soubeyran congratulated the Commission on the importance of its work and remarked on the volume of work being completed. She noted that there are many significant areas in which the Commission is working together with experts including with the Collaborating Centre networks.

Dr Soubeyran updated the Commission on the development of the Eighth Strategic Plan which will be adopted by the General Assembly in 2026. She outlined the three phases to develop the plan and that the Specialist Commissions will be included in the consultation phase. The goal will be to have clarity on the values and priorities for WOAH to be included in the Strategic Plan. Further, Dr Soubeyran informed the Commission on the work for the WOAH Governance review that will occur over three years. She indicated that input from the Commission will be a valuable input as the Governance Review will include consideration of the standard-setting process.

Dr Soubeyran notified the Commission about upcoming changes to the WOAH organogram. She indicated that these changes would address WOAH Directorate imbalance and would not have an impact on Commission work.

Dr Soubeyran informed the Commission that the topic of the Animal Health Forum at the 92nd General Session will be 'Policy to Action: Vaccine and vaccination. Reflections to change'. The forum will create a platform to generate dialogue between WOAH Delegates, subject matter experts, civil society and private sector on the barriers impeding the development and use of vaccines for disease prevention and control.

Dr Soubeyran highlighted the new WOAH communication tool called the *Animal Echo*. The *Animal Echo* is a collaborative knowledge-sharing space offering insights on some of the world's most pressing challenges through the lens of animal health. It will serve as a resource for stakeholders committed to advancing animal health and welfare, and its connection to global health.

The Commission expressed their appreciation for her updates and offered its congratulations on ongoing work and initiatives at WOAH.

1.2. WOAH Deputy Director General, International Standards and Science

Dr Montserrat Arroyo, WOAH Deputy Director General for International Standards and Science (DDG-ISS) met with the Aquatic Animals Commission on 13 February 2025. Dr Arroyo thanked the Commission for their commitment and congratulated them on their ambitious agenda.

Dr Arroyo highlighted the work on the Governance Review and the importance of defining roles and responsibilities. She emphasised that the Commission's feedback and leadership in this review will be important for a successful outcome.

Dr Arroyo thanked the Commission for the inclusion of Section 6 'Antimicrobial use in aquatic animals' in its work programme. She informed the Commission that in September 2024 the United Nations General Assembly made a political declaration to combat antimicrobial resistance, and that WOAH holds a responsibility to provide tools to Members to allow them to make effective decisions.

Dr Arroyo updated the Commission on the transparency of elaboration of the standard-setting process. Positive feedback had been received from Members on changes to the report and publishing of comments, and that the process is to encourage greater participation in the standard-setting process. She informed the Commission that comments will be published with Member names starting in the February 2026 report.

The Commission thanked Dr Arroyo for her updates. The Commission noted that it is currently the final year of the WOAH Aquatic Animal Health Strategy and outlined the commitments which had been met and those on which work remained. The Commission noted that barriers to implementation of standards for aquatic animal health remains a concern and urged WOAH to continue work to address these barriers.

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 Biological Standards Commission

The Bureaux of the Aquatic Animals Commission and the Biological Standards Commission met on 13 February 2025, 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 Bureaux meetings at least annually to ensure enhanced coordination.

The Bureaux discussed issues of mutual interest notably:

- Meaning of equivalent quality management system
- Procedures of designation
- 5-year workplan report
- Satisfaction questionnaire for Collaborating Centres
- General Session kiosk

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 September 2024, new activities underway, communication initiatives and key priorities. The Commission was informed about planned and ongoing activities and the Commission confirmed their support for continued work on Strategy activities which impact the standards.

The Commission noted that the Aquatic Animal Health Strategy was to be completed between 2021 to 2025 and is thus in its final year. The Commission highlighted the commitments made in objective 1 ‘Standards’ and the Commission work to meet these commitments. This included:

- Activity 1.1. aimed to develop new WOAH standards that support risk management, and this was proposed to be met by the creation of five new chapters. In Section 4. ‘Disease prevention and control’ Chapter 4.1 adopted in 2021 and the three new draft chapters to be proposed for adoption in May 2025 including 4.X. ‘Emergency disease preparedness’, 4.Y. ‘Disease outbreak management’, 4.Z. ‘Control of pathogenic agents in traded gametes and fertilised eggs of fish’. Further, in Section 5. ‘Trade measures, importation/exportation procedures and health certification’, new Chapter 5.X. ‘Movement of ornamental aquatic animals’ is proposed for adoption in May 2025.

- Activity 1.2. was to revise existing *Aquatic Code* standards to provide up-to-date recommendations which are scientifically sound and responsive to the needs of Members. Prioritizing revision of the methodology for the self-declaration of freedom from aquatic animal diseases, which was met with the adoption of revised Chapter 1.4. in 2022. Another priority in this activity was the ongoing work to update Section 4 of the *Aquatic Code*, which is in its final stages. Finally, the revision of the lists of susceptible aquatic animal species for each listed disease has been ongoing with the completion of assessments of susceptible species for 27 of the listed diseases (see item 8.1.5.).

- Activity 1.3. was to review the scientific basis of existing aquatic animal welfare standards. Work has commenced and a review of current evidence is expected to be reviewed at the Commission's September 2025 meeting (see item 8.1.4.)

- Activity 1.4. revised existing *Aquatic Manual* standards has been met with the update of each chapter using the new template and including updated scientific information for each disease-specific chapter. 23 chapters have been revised and adopted, five chapters have been revised and are pending adoption, and only three chapters remain to be revised.

- Activity 1.5. was to identify barriers to the implementation of standards. Ongoing work includes the development of a WOAH Aquatic Animal Diseases Field Guide Phone Application and production of training materials for self-declaration of disease freedom for aquatic animal diseases.

5. Work programme and priorities

5.1. Comments received on the Work Programme

Comments were received from Australia, Canada, Ecuador, Peru and the EU.

The Aquatic Animals Commission noted comments expressing support for the Commission's work programme. Comments proposing new work are addressed in section 8.2. 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 considered are presented in Annex 3.

5.2. Overview of the Work Programme

The Aquatic Animals Commission reviewed the status of existing work and proposed a work programme 2025-2027 and prioritised work programme items after considering factors including the expected improvement of the standards, benefit to Members, Member comments, WOAH Aquatic Animal Health Strategy, capacity constraints, Headquarters' comments and progress on the previous Commission's work programme.

The Commission reminded Members that the work programme outlines the current and planned work to be undertaken. The Commission 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.

The WOAH Aquatic Animal Health Code

6. *Aquatic Code* texts that will be proposed for adoption in May 2025

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. The Commission noted that the draft chapters were consistent with other global emergency frameworks.

At its February 2024 meeting the Commission considered comments received and made edits for clarity. Further at its September 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 three times 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 report (Item 6.1., page 11).

February 2025 meeting

Comments were received from Australia, Canada, Chile, China (People's Rep. of), Mexico, New Zealand, the USA, AU-IBAR, 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 some suggestions for clarity and some proposals for content to consider.

The Commission noted that Chapter 4.6. 'Contingency planning' would become obsolete once the draft new Chapters 4.X. and 4.Y. are adopted, and Chapter 4.6. will be proposed for deletion.

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

Texts to be proposed for adoption

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, and will be proposed for adoption at the 92nd General Session in May 2025.

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'. The draft new chapter 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 in accordance with Chapter 1.4.

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.

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’.

At its February 2024 meeting the Commission agreed that it would ask industry experts to draft a new article for the draft new Chapter 4.Z. 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 Articles 10.X.10. and 10.X.15. to 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’.

At its September 2024 meeting the Commission considered comments received and noted that Members were generally supportive of the proposed changes to the draft new Chapter 4.Z. It considered the new article on biosecurity and added it to the chapter being circulated (Article 4.Z.6.).

The draft new chapter, model articles and new and revised glossary terms have been circulated three times 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 report (Item 6.2., page 12).

February 2025 meeting

Comments were received from Australia, Canada, Chile, China (People’s Rep. of), Korea (Rep. of), Norway, Thailand, the USA, AU-IBAR, 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 some suggestions for clarity and some proposals for content to consider.

The Commission’s responses to comments considered are presented in Annex 3.

The Commission noted that the new chapter is related to Activity 1.1 of the Aquatic Animal Health Strategy (see item 4) that WOAH Members had prioritised the creation of standards to support risk management and to facilitate the safe trade of aquatic animal genetic materials, such as gametes and eggs. The Commission reiterated that the purpose of the new Chapter 4.Z. ‘Control of pathogenic agents in traded gametes and fertilised eggs of fish’ is to provide an improvement to risk management over the current measures for the importation of disinfected eggs for aquaculture outlined in 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’. The new chapter and proposed changes to articles in the salmonid disease-specific chapters provide a mechanism for safe trade where no mechanism would otherwise exist.

The Commission reviewed the usage of the updated glossary definitions for ‘gametes’ and ‘fertilised eggs’ in other chapters of the *Aquatic Code*. The Commission agreed to remove the cross-references in other chapters to the glossary terms as usage in other chapters usually includes explanatory text now included in the definition. When the chapters that use these terms are revised in the future links to the revised glossary terms will be considered.

Texts to be proposed for adoption

The draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' is presented as Annex 7, and will be proposed for adoption at the 92nd General Session in May 2025.

The revised model Article 10.X.10. of Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Article 10.4.15. of Chapter 10.4. 'Infection with ISAV' are presented as Annex 8, and will be proposed for adoption at the 92nd General Session in May 2025.

The revised model Article 10.X.15. of Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Article 10.4.20. of Chapter 10.4. 'Infection with ISAV' are presented as Annex 9, and will be proposed for adoption at the 92nd General Session in May 2025.

The new glossary term for 'collection and incubation centre' and revised glossary terms for 'fertilised eggs' and 'gametes' are presented as Annex 10, and will be proposed for adoption at the 92nd General Session in May 2025.

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

Background

At its September 2023 meeting, 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 proposed edits. At its September 2024 meeting the Commission considered comments received and noted that Members were generally supportive of the proposed changes with some proposed edits.

The draft new chapter and new glossary term have been circulated three times 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 (Item 6.3., page 13).

February 2025 meeting

Comments were received from Australia, Canada, Chile, China (People's Rep. of), Korea (Rep. of), New Zealand, Singapore, the USA, AU-IBAR 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 some suggestions for clarity and some proposals for additional content.

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

The Commission reiterated that the development of draft new Chapter 5.X. 'Movement of ornamental aquatic animals is in response to one of the recommendations from the '4th OIE Global Conference on

Aquatic Animal Health: Collaboration, sustainability – our future' in Santiago, Chile in 2019. In addition, this chapter is related to Activity 1.1 of the Aquatic Animal Health Strategy (See item 4) to create a new standard to support risk management and to facilitate safe trade of ornamental aquatic animals.

Texts to be proposed for adoption

The draft new Chapter 5.X. 'Movement of ornamental aquatic animals', is presented as Annex 11, and will be proposed for adoption at the 92nd General Session in May 2025.

The new glossary term for 'ornamental aquatic animal' is presented as Annex 10, and will be proposed for adoption at the 92nd General Session in May 2025.

6.4. Assessment of periods of basic biosecurity conditions and targeted surveillance in Articles X.X.5. – X.X.7. 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 Aquatic Animals 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 Commission considered the assessments completed at the request of the Commission by a WOAH Collaborating Centre expert, and presented the assessments for Member comment.

At its September 2024 meeting, the Commission considered comments received and noted that Members were generally supportive of the proposed approach. The Commission updated the assessment to clarify the BBC and TS periods for 'infection with infectious salmon anaemia virus' (ISAV) as it applied to two categories of disease-free status: freedom from ISAV (including HPR0 and HPR-deleted ISAV) and freedom from HPR-deleted ISAV (but not HPR0 ISAV). The two categories of ISAV disease freedom are consistent with the relevant articles in the ISAV chapter and the articles on freedom at a country, zone and compartment level. The Commission also added assessments for 'infection with decapod iridescent virus 1' and 'infection with *Megalocytivirus pagrus1*'. Further, the Commission noted that for certain diseases some pathways should not be included and made these changes in the assessment document and in the relevant articles in the disease-specific chapters. The assessments were applied to Articles X.X.5. to X.X.7. (and 10.4.5. to 10.4.10.) in all disease-specific chapters.

The updated assessments of the BBC and TS periods in Articles X.X.5. to X.X.7. for all listed diseases were presented in the document 'Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the *Aquatic Animal Health Code*' which was circulated for comment along with the associated articles from the disease-specific chapters.

The assessment of the periods for BBC and TS in Articles X.X.5. – X.X.7. has been circulated twice for comment.

Previous Commission reports where this item was discussed

February 2024 (Item 7.4., page 36); September 2024 (Item 6.4., page 14).

February 2025 meeting

Comments were received from Australia, Canada, Chinese Taipei, Colombia, Mexico, Thailand, the UK, the Americas, AU-IBAR and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amended Articles X.X.5. – X.X.7. (and Articles 10.4.5. to 10.4.10.) in all disease-specific chapters.

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

The Commission reminded Members that the assessment of the periods ('Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of the *Aquatic Animal Health Code*') was included in its February 2024 and September 2024 reports to support Members to understand the approach taken to determine the periods for basic biosecurity condition (BBC) and targeted surveillance (TS).

The Commission reminded Members that the application of the assessments of the BBC and TS periods can be found in revised Articles X.X.5. to X.X.7. (and Articles 10.4.5. to 10.4.10.) for each disease-specific chapter. In addition, the Commission advised that the periods for BBC and TS in disease-specific chapters should be utilised in conjunction with relevant recommendations in Chapter 1.4. 'Aquatic animal disease surveillance'.

The Commission reminded Members that it had agreed to assess and update all periods when the revised Chapter 1.4. was adopted in 2022 and the application of periods is a completion of this work.

In response to comments requesting that revision of the periods for compartments be delayed until the revision of Chapter 4.3. 'Application of compartmentalisation' has been finalised, the Commission reminded Members that the amended periods in these articles are based on the current Chapter 4.3. The Commission highlighted that currently Articles X.X.7. (and Articles 10.4.9. and 10.4.10) on free compartments are 'under study' and the proposed revisions will not change the periods for these compartments.

The revised Chapter 4.3. 'Application of compartmentalisation' is being circulated for the first time for comment in this report (see item 7.1.). The Commission reminded Members that the proposed amendments in the revised Chapter 4.3. will not be applicable until that chapter is adopted. When the revised Chapter 4.3. is adopted, the Commission will review Chapter 1.4. and the articles in disease-specific chapters for declaration of compartment freedom and propose any revisions that may be required to align with the recommendations in Chapter 4.3.

In response to comments, the Commission agreed that for infection with *Gyrodactylus salaris,* pathway 2 (historical freedom) was not suitable as given scientific evidence available clinical disease is not seen in all susceptible species.

For ISAV (including HPR0 and HPR-deleted) the Commission agreed to change the ranking to a '3' and make the associated change in basic biosecurity conditions and targeted surveillance in relevant articles. The change in rank was due to factors including unknown rate of spread, low prevalence and environmental persistence for HPR0 ISAV. The Commission encouraged Members to refer to Annex 3 for more details on Commission responses to these comments.

The assessment of default periods 'Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-specific chapters of WOAH *Aquatic Animal Health Code*' can be found on the WOAH website.

Texts to be proposed for adoption

The revised Articles X.X.5. to X.X.7. (and Articles 10.4.5. to 10.4.10.) for all disease-specific chapters, are presented as Annex 12, and will be proposed for adoption at the 92nd General Session in May 2025.

6.5. 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) which had not been updated since 2016.

At its February 2024 meeting, the Aquatic Animals Commission considered the *ad hoc* Group report and 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.

At its September 2024 meeting, the Commission considered comments received and noted that Members were generally supportive of the proposed changes with some proposed edits. The Commission assessed the application of Article 1.5.9. utilising a list of considerations (outlined in its September 2024 meeting report Item 6.5.1., page 16) to ensure a balanced approach. The Commission determined that Penaeidae and Portunidae should remain listed at the family level and that *Panulirus spp.* should remain listed at the genus level. However, the Commission determined *Procambarus* species and *Palaemon* species should be listed at the species level.

The Commission requested that the *ad hoc* Group review its assessment of Oriental river prawn (*Macrobrachium nipponense*), and following this revised assessment, the Commission agreed to add *Macrobrachium nipponense* to Article 9.9.2. of Chapter 9.9. 'Infection with WSSV'.

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 9.1.1.).

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

Previous Commission reports where this item was discussed

February 2024 (Item 7.5., page 39); September 2024 (Item 6.5.2., page 16).

February 2025 meeting

Comments were received from Australia, Canada, Mexico, AU-IBAR 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'.

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

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 to be proposed for adoption

The revised Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus', is presented as Annex 13, and will be proposed for adoption at the 92nd General Session in May 2025.

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' for the assessments for susceptibility of fish species to infection with *Aphanomyces invadans* (epizootic ulcerative syndrome).

At its September 2024 meeting the Aquatic Animals Commission considered the *ad hoc* Group report and 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 its recommendations. The Commission also agreed with the recommendations of the *ad hoc* Group 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 its September 2024 meeting report (Item 6.5.1., page 16) to guide the application of Article 1.5.9. to the susceptible species for infection with *A. invadans*. The Commission agreed that *Channa spp.* should be listed at the genus level.

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 9.2.1.).

The amended Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with *Aphanomyces invadans* (Epizootic ulcerative syndrome)' have been circulated once for comment.

Previous Commission reports where this item was discussed

September 2024 (Item 6.6., page 18).

February 2025 Meeting

Comments were received from Canada, China (People's Rep. of), Mexico, Thailand, AU-IBAR and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with *A. invadans* (epizootic ulcerative syndrome)'.

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

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

Texts to be proposed for adoption

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 14, and will be proposed for adoption at the 92nd General Session in May 2025.

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

Background

At its 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*. The Commission proposed amendments to the relevant articles for alignment of the articles in English, Spanish and French.

The amended Articles 10.4.11. and 10.4.12. of Chapter 10.4. have been circulated once for comment.

Previous Commission reports where this item was discussed

September 2024 (Item 6.7., page 20).

February 2025 Meeting

Comments were received from Canada, China (People's Rep. of), Mexico, Thailand, AU-IBAR and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were supportive of the amendments to Articles 10.4.11. and 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia', while proposing some suggestions for clarity to consider.

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

Texts to be proposed for adoption

The revised Articles 10.4.11. and 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia virus', are presented as Annex 15, and will be proposed for adoption at the 92nd General Session in May 2025.

6.8. Draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus1*'

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 pagrus1*'. The Commission reminded Members that infection with *Megalocytivirus pagrus1* includes infection with the genogroups, red sea bream iridovirus (RSIV), infectious spleen and kidney necrosis virus (ISKNV) and turbot reddish body iridovirus (TRBIV).

At its September 2024 meeting, the Aquatic Animals Commission drafted a new Chapter 10.X. 'Infection with *M. pagrus1*' based on the model for disease-specific chapters. The Commission considered the report of the *ad hoc* Group on Susceptibility of Fish Species to Infection with WOAH Listed Diseases to determine the proposed list of susceptible species in Article 10.X.2. The Commission also used considerations outlined in its September 2024 meeting report (Item 6.5.1., page 16) to guide the application of Article 1.5.9. to the susceptible species for infection with *M. pagrus1*. The Commission agreed to list all species within the genera *Lethrinus*, *Poecilia*, *Seriola*, *Trachinotus*, *Pterophyllum*, *Opelgnathus, Trichopodus* and *Xiphophorus* as susceptible.

The Commission agreed to use the time-temperature combination assessed for RSIV genogroup for *M. pagrus1* as per the 2023 'Safe Commodity Assessments for Listed Aquatic Anima Diseases' due to the close taxonomic relatedness between genogroups. Further, the Commission updated the 'Recommendations for periods of basic biosecurity conditions and targeted surveillance for the disease-

specific chapters of the *Aquatic Code*' (see Item 6.4.) to reflect the basic biosecurity conditions and targeted surveillance for *M. pagrus1*.

The draft new Chapter 10.X. has been circulated once for comment.

Previous Commission reports where this item was discussed

September 2024 (Item 6.8., page 20).

February 2025 meeting

Comments were received from Australia, Canada, China (People's Rep. of), Chinese Taipei, Singapore, Thailand, the USA, AU-IBAR and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus1*', while proposing some suggestions for clarity and some proposals for additional content.

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

The Commission noted that the name of the virus as recorded by the International Committee on Taxonomy of Viruses (ICTV) does not have a space between the word '*pagrus*' and the number '*1*', and agreed to amend the disease name to reflect this.

In response to comments requesting additions to the list of susceptible species in Article 10.X.2., the Commission noted that some of the papers provided had been previously reviewed by the *ad hoc* Group on Susceptibility of fish species to infection with WOAH listed diseases, and that information on the assessment of those species is presented in the *ad hoc* Group's November 2022 report. The papers provided, which had not been previously reviewed were provided to the *ad hoc* Group who undertook relevant assessments .

The assessments of the *ad hoc* Group are presented in the table below:

Family	Scientific name	Common name	Stage 1: Route of infection	Stage 2: Pathogen Identification	Stage 3: Evidence of Infection				Outcome (paper)	Outcome (species)	References	Assessed for:
					A	B	C	D				
Cichliformes	*Orechromis niloticus x Orechromis mossambicus*	N/A	N	NO[1]	ND	ND	NO	YES	NS	NS	Suebsing *et al*. 2016	ISKNV
Lateolabracidae	*Lateolabrax japonicus*	Japanese seabass	N	PCR and sequencing	ND	YES	YES	YES	1	1[2]	Kim *et al.* 2019	RSIV
Percichthyidae	*Macquaria ambigua*	golden perch	E	qPCR and sequencing	ND	ND	YES	YES	1	2	Rimmer *et al*. 2017	ISKNV
	Macquaria australasica	Macquarie perch	E	qPCR and sequencing	ND	ND	YES	YES	1	2	Rimmer *et al*. 2017	ISKNV
Percalatidae	*Percalates novemaculeata*	Australian bass	E	qPCR and sequencing	YES	ND	YES	YES	1	1	Go & Whittington, 2019a	ISKNV
			E	qPCR and sequencing	YES	ND	YES	YES	1		Go & Whittington, 2019b	ISKNV

[1] LAMP positives, and all PCR results were negative thus stage 2 pathogen identification is not considered met.
[2] This species was scored as a '2' in the 2022 *ad hoc* Group report, taking into account this previous assessment this species was assessed as '1'.

As described in the *ad hoc* Group's November 2022 report the 'ideal situation to categorise a fish species as susceptible was the presence of two papers with a score of '1', a single strong study scoring '1' was also sufficient to conclude susceptibility of a species in the absence of conflicting evidence'; this was applied to these assessments.

The Commission reviewed the new assessments (presented in the table above) and agreed to include Australian bass (*Percalates novemaculeata*) and Japanese seabass (*Lateolabrax japonicus*) in the list of susceptible species in Article 10.X.2. of the draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus1*' of the *Aquatic Code* and in Section 2.2.1. of Chapter 2.3.Y. 'Infection with *Megalocytivirus pagrus1*' of the *Aquatic Manual*.

The Commission also agreed to include golden perch (*Macquaria ambigua*) and Macquarie perch (*Macquaria australasica*) in Section 2.2.2. 'Species with incomplete evidence for susceptibility' of Chapter 2.3.Y. 'Infection with *Megalocytivirus pagrus1*' in the *Aquatic Manual*.

The Commission agreed with the *ad hoc* Group conclusion that *Orechromis niloticus x Orechromis mossambicus* hybrid did not meet the criteria to be listed as a susceptible species.

The Commission noted that Chapter 10.8. 'Infection with red sea bream iridovirus' would become obsolete once the draft new Chapter 10.X. is adopted, and Chapter 10.8. will be proposed for deletion.

Texts to be proposed for adoption

The draft new Chapter 10.X. 'Infection with *M. pagrus1*', is presented as Annex 16, and will be proposed for adoption at the 92nd General Session in May 2025.

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 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' and conducted 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. of Chapter 11.6. 'Infection with *Perkinsus olseni*' in line with the recommendations of the *ad hoc* Group. The Commission also agreed to add the Family in Article 11.6.1. for consistency with other disease-specific chapters.

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 9.3.3.).

At its September 2024 meeting, the Commission considered comments and noted that Members were generally supportive of the proposed amendments.

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

Previous Commission reports where this item was discussed

February 2024 (Item 7.6., page 40); September 2024 (Item 6.9., page 23).

February 2025 meeting

Comments were received from Canada, Mexico, New Zealand 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*'.

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

In response to a comment that suggested there is evidence to list rainbow abalone (*Haliotis iris*) as a susceptible species, the Commission requested that the *ad hoc* Group review its assessment for this species.

The *ad hoc* Group reviewed the WOAH-WAHIS event #5889 from 2014 and re-assessed the susceptibility of rainbow abalone against the criteria in Chapter 1.5. The revised assessment is presented in the table below.

Re-assessment of rainbow abalone (*Haliotis iris*):

Stage 1: Route of infection	Stage 2: Pathogen Identification	Stage 3: Evidence of Infection				Outcome	References
		A	B	C	D		
N	PCR and sequencing	ND	ND	YES	YES	1	WOAH-WAHIS event 5889, 2014
N	NO[1]	YES	ND	YES	YES	NS[2]	Muznebin *et al*., 2023

[1] Did not meet the pathogen identification criteria because it relied only on the ISH probe published by Moss *et al*., 2006.

The *ad hoc* Group concluded that rainbow abalone met the criteria to be listed as a susceptible species. The Commission reviewed the revised assessment and agreed with the conclusion of the *ad hoc* Group that rainbow abalone met the criteria to be listed as a susceptible species.

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

Texts to be proposed for adoption

The revised Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *P. olseni*', are presented as Annex 17, and will be proposed for adoption at the 92nd General Session in May 2025.

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' and conducted the assessments for susceptibility of mollusc species to infection with *Xenohaliotis californiensis*.

At its September 2024 meeting, the Aquatic Animals Commission considered the *ad hoc* Group report and amended the list of susceptible species in Article 11.7.2. of Chapter 11.7. 'Infection with *X. californiensis*' in line with its recommendations.

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 9.3.4.).

The amended articles 11.7.1. and 11.7.2. of Chapter 11.7. have been circulated once for comment.

Previous Commission reports where this item was discussed

September 2024 (Item 6.10., page 24).

February 2025 Meeting

Comments were received from Canada, Mexico, AU-IBAR and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to Articles 11.7.1. and 11.7.2. of Chapter 11.7. 'Infection with *X. californiensis*'.

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

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

Texts to be proposed for adoption

The revised Articles 11.7.1. and 11.7.2. of Chapter 11.7. 'Infection with *X. californiensis*', are presented as Annex 18, and will be proposed for adoption at the 92nd General Session in May 2025

7. *Aquatic Code* items for Member comment

7.1. 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 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 some Regional Aquatic Animal 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.

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.

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

At its September 2024 meeting, the Commission agreed to use the final version of the discussion paper circulated in its February 2024 report to guide the revision of Chapter 4.3. 'Application of compartmentalisation' and started the drafting of a revised chapter.

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 (Item 7.1.2., page 27).

February 2025 meeting

The Aquatic Animals Commission finalised the draft Chapter 4.3. 'Application of compartmentalisation'. The Commission also reviewed the Glossary definition for 'compartment' and developed a revised definition to be consistent with usage in the draft text.

The Commission noted that changes in the revised draft Chapter 4.3. when adopted may have implications on other chapters in the *Aquatic Code* including surveillance requirements for compartments in Chapter 1.4. 'Aquatic animal disease surveillance' and articles on compartments in the disease-specific chapters. Consequently, the Commission highlighted that when the revised Chapter 4.3. is adopted the Commission will review other relevant articles and chapters, and revise as necessary for consistency with the revised Chapter 4.3. The Commission noted that any Member that declares freedom for a compartment before the adoption of the revised Chapter 4.3., i.e. based on the current standards in the *Aquatic Code* should retain the status of the compartment when the revised Chapter 4.3. is adopted but would need to meet any new requirements for maintenance of status.

The Commission agreed to circulate a clean version of the revised draft Chapter 4.3.

Texts for comment

The revised Chapter 4.3. 'Application of compartmentalisation' is presented as Annex 19 for comment.

The revised glossary term for 'compartment' is presented as Annex 20 for comment.

7.2. Chapter 4.7. 'Fallowing in aquaculture'

Background

At its September 2024 meeting, the Aquatic Animals Commission noted that Chapter 4.7. 'Fallowing in aquaculture', required a review as a consequence of the development of draft new Chapters 4.X. 'Emergency disease preparedness' and 4.Y. 'Disease outbreak management'.

Previous Commission reports where this item was discussed

September 2024 (Item 7.1.3., page 28).

February 2025 meeting

The Aquatic Animals Commission reviewed Chapter 4.7. 'Fallowing in aquaculture' and proposed amendments to align with draft new Chapters 4.X. 'Emergency disease preparedness' and 4.Y. 'Disease outbreak management'.

Texts for comment

The revised Chapter 4.7. 'Fallowing in aquaculture' is presented as Annex 21 for comment.

7.3. 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 meets the WOAH definition for 'emerging disease' and therefore 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.* Should the Commission determine that a disease meets the WOAH definition for an emerging disease 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,
- prevent spread at country, regional or global levels, and
- gather information on the criteria relevant to listing.

The Commission 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 related to the impact of these diseases to aquaculture production and trade so that the Commission can consider this information when reviewing emerging diseases.

7.3.1. 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 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.

At its September 2024 meeting, the Commission noted that there had been no notifications of infection with CMNV reported in the World Animal Health Information System (WAHIS) since September 2022. The Commission requested Members to share information regarding the impact of infection with CMNV to determine the global impact of disease.

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 report (Item 6.11.1., page 25).

February 2025 meeting

The Aquatic Animals Commission noted that there had been no notifications of infection with covert mortality nodavirus (CMNV) in WAHIS since the previous Commission meeting. The Commission considered recent scientific information on the impact of infection with CMNV and agreed that additional information would be needed for infection with CMNV to continue to be considered an emerging disease.

The Commission requested that Members provide feedback and evidence on the importance of infection with CMNV in their country ahead of its September 2025 meeting. If no feedback is received from Members on the impact of infection with CMNV then it will no longer be considered to be an emerging disease by the Commission.

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/.

7.3.2. 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 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.

At its September 2024 meeting, the Commission noted that there had been no notifications of infection with EHP in WAHIS since September 2021. The Commission requested Members to share information regarding the impact of infection with EHP to determine the global impact of disease.

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 (Item 6.11.2., page 26).

February 2025 meeting

The Aquatic Animals Commission noted there had been no notifications for infection with Enterocytozoon hepatopenaei (EHP) since its September 2024 meeting. The Commission considered recent scientific information on the impact of infection with EHP and agreed that additional information would be needed for infection with EHP to continue to be considered an emerging disease.

The Commission requested that Members provide feedback and evidence on the importance of infection with EHP in their country and the ability to declare freedom in a country, zone or compartment, ahead of its September 2025 meeting. If no feedback is received from Members on the impact of infection with EHP then it will no longer be considered to be an emerging disease by the Commission.

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

8. *Aquatic Code* Items for Member Information

8.1. *Aquatic Code* Ongoing work items

8.1.1. Chapter 4.2. 'Zoning and compartmentalisation'

February 2025

The Aquatic Animals Commission agreed that work to revise Chapter 4.2. 'Zoning and compartmentalisation' will commence following the revision of Chapter 4.3. 'Application of compartmentalisation'.

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

Background

At its September 2022 meeting, 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 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 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 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 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.

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.

At its September 2024 meeting, the Secretariat updated the Commission on progress on the creation of WOAH data models and data standards for electronic certificates to meet the criteria included in the *Aquatic Code*. The Commission reviewed the draft Terms of Reference for an *ad hoc* Group to update relevant chapters in the *Aquatic Code* and *Terrestrial Code* on certification procedures.

Previous Commission reports where this item was discussed

September 2024 report (Item 7.1.4., page 28).

February 2025 meeting

The Secretariat reported to the Aquatic Animals Commission that electronic data models and data standards corresponding to the model health certificates listed in Chapters 5.10. and 5.13. were completed in December 2024 and published on the WOAH website (see item 13.1.). In addition, the Secretariat noted updates that had been made to the draft certification *ad hoc* Group Terms of Reference to include suggestions from the Code Commission, Aquatic Animals Commission and the *ad hoc* Group reviewing Chapters 5.4.-5.7.

The Secretariat reported that the Terrestrial Animal Health Standards Commission ('Code Commission') had considered the status of Chapters 5.10. to 5.13. in the *Terrestrial Code* and noted that they have not been updated in over 10 years. With increasing reliance on electronic

certification and digital passports, this information on model passports and certificates could possibly be maintained outside of the *Terrestrial Code*. The Code Commission instructed their Secretariat to consult with experts to determine the need to update these chapters and whether the information should remain in the *Terrestrial Code* or at another location as reference information. The Code Commission requested the Secretariat to update the draft certification *ad hoc* group Terms of Reference accordingly.

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

Background

The WOAH Working Group on Antimicrobial Resistance (AMR Working Group) developed the revised Chapter 6.10 'Responsible and prudent use of antimicrobial agents in veterinary medicine' of the *Terrestrial Code* that was adopted at the 91st General Session in May 2024. Key amendments included 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 AMR Working Group recommended that chapters on the responsible use of antimicrobials in aquatic animals in the *Aquatic Code* be revised to reflect current scientific information and alignment, as relevant, with Chapter 6.10. of the *Terrestrial Code*.

At its September 2024 meeting, the Commission agreed that Chapter 6.2. 'Principles for responsible and prudent use of antimicrobial agents in aquatic animals' of the Aquatic Code is 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 agreed that revision of the chapters on Section 6. 'Antimicrobial Use in Aquatic Animals' of the *Aquatic Code* should be added to the Commission's work programme and requested a gap analysis of the section.

Previous Commission reports where this item was discussed

September 2024 (Item 7.1.4., page 28).

February 2025 meeting

A gap analysis of the points that require attention in the Section 6. 'Antimicrobial Use in Aquatic Animals', with particular attention to Chapter 6.2. was prepared in collaboration with the Collaborating Centre for Antimicrobial Stewardship on Aquaculture and submitted to the Aquatics Animal Commission. The Commission reviewed the gap analysis and agreed to start the update of Section 6 with Chapter 6.2. with the creation of an *ad hoc* Group to update the chapters. The *ad hoc* Group will be composed of appropriate experts representing geographic diversity, complemented by a member of the AMR Working Group and potentially a member of the Commission. The Commission requested an update on the progress of the *ad hoc* Group at its September 2025 meeting.

8.1.4. Section 7. 'Welfare of farmed fish'

Background

At its September 2024 meeting, the Aquatic Animals 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 Commission noted that this work was aligned with Activity 1.3. 'Review the scientific basis of existing animal welfare standards' of the WOAH Aquatic Animal Health Strategy. The Commission also agreed that they will use this review to inform a revision of chapters in Section 7 'Welfare of farmed fish'.

February 2025

The Aquatic Animals Commission was updated that a procurement process would be launched in March 2025 to review the scientific basis for welfare of farmed fish and that this review should be available for the Commission's consideration at its September 2025 meeting.

8.1.5. Assessments of 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 the eleven fish and the seven mollusc listed diseases as well as nine of the ten crustacean diseases.

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 April 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 dependent on availability of resources. This *ad hoc* Group will assess susceptible species to all three amphibian listed diseases.

8.2. *Aquatic Code* New work items

8.2.1. Section 5. 'Trade measures, importation/exportation procedures and health certification'

Background

In September 2024, 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 articles in disease-specific chapters. 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.

Previous Commission reports where this item was discussed

September 2024 report (Item 5.2.2., page 10).

February 2025 meeting

The Aquatic Animals Commission agreed that the work programme regarding Section 5. 'Trade measures, importation/exportation procedures and health certification' should focus on providing a clear understanding of how trade should occur and identifying barriers to the implementation of these standards. The objective of this revision would be to improve transparency and overall confidence between trading partners when implemented.

The intention is to work together with the Terrestrial Animal Health Standards Commission (Code Commission) and commit to joint work on horizontal chapters such as a new introductory chapter to Section 5. The Aquatic Animals Commission work plan for Section 5 will be finalised in September 2025 following the Bureaux meeting between the Aquatic Animals Commission and the Code Commission.

8.2.2. ICTV changes

February 2025 meeting

The Aquatic Animals Commission noted that a number of the viral pathogenic agents for WOAH listed aquatic animal diseases have been updated by the International Committee on Taxonomy of Viruses (ICTV). The Commission agreed to review the taxonomy and names of the viral agents of WOAH listed diseases and propose revisions for the usage of these names in its September 2025 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).

9. *Aquatic Manual* texts that will be proposed for adoption in May 2025

9.1. Section 2.2. 'Diseases of crustaceans'

9.1.1. Sections 2.2.1. and 2.2.2. of Chapter 2.2.9. '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 Section 2.2.1. in line with the recommendations of the *ad hoc* Group.

At its September 2024 meeting, the Commission considered comments received and noted that Members were generally supportive of the proposed changes with some proposed edits. The Commission assessed the application of Article 1.5.9. utilising a list of considerations (outlined in September 2024 meeting report Item 6.5.1., page 16) to ensure a balanced approach. The Commission determined that Penaeidae and Portunidae should remain listed at the family level and that and *Panulirus spp.* should remain listed at the genus level. However, the Commission determined *Procambarus spp.* and *Palaemon spp.* should be listed at the species level.

The Commission requested that the *ad hoc* Group review its assessment of Oriental river prawn (*Macrobrachium nipponense*), and 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 2.2.9. '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.).

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

Previous Commission reports where this item was discussed

February 2024 (Item 10.1.1., page 54); September 2024 (Item 8.1., page 30).

February 2025 meeting

Comments were received from Australia, Canada, Chinese Taipei, Mexico, AU-IBAR, and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to Sections 2.2.1. and 2.2.2. of Chapter 2.2.9. 'Infection with white spot syndrome virus'.

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

In response to a comment received that suggested there is evidence to include carpenter prawn (*Palaemon serrifer*) and *Palaemon serenus* under Section 2.2.2. 'Species where pathogen-specific positive PCR results have been reported' of Chapter 2.2.8. 'Infection with WSSV' in the *Aquatic Manual*, the Commission requested that the *ad hoc* Group perform an assessment of these species.

The *ad hoc* Group reviewed the publication provided (Diggles, 2020) and assessed the susceptibility of carpenter prawn (*Palaemon serrifer*) and *Palaemon serenus* against the criteria in Chapter 1.5. The revised assessment is presented in the tables below.

Assessment of carpenter prawn (*Palaemon serrifer*):

Stage 1: Route of infection	Stage 2: Pathogen Identification	Stage 3: Evidence of Infection				Outcome	References
		A	B	C	D		
N	qPCR	ND	ND	ND	ND	3	Diggles *et al*., 2020

Assessment of *Palaemon serenus*:

Stage 1: Route of infection	Stage 2: Pathogen Identification	Stage 3: Evidence of Infection				Outcome	References
		A	B	C	D		
N	qPCR	ND	ND	ND	ND	3	Diggles *et al*., 2020

The *ad hoc* Group concluded that both carpenter prawn (*Palaemon serrifer*) and *Palaemon serenus* meet the criteria to be included in Section 2.2.2. 'Species where pathogen-specific positive PCR results have been reported' of Chapter 2.2.8. 'Infection with WSSV' in the *Aquatic Manual*.

The Commission reviewed the assessments and agreed to add carpenter prawn (*Palaemon serrifer*) and *Palaemon serenus* to Section 2.2.2. 'Species where pathogen-specific positive PCR results have been reported' of Chapter 2.2.9. '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 proposed for adoption

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.2.9. 'Infection with white spot syndrome virus', are presented as Annex 22, and will be proposed for adoption at the 92nd General Session in May 2025.

9.2. Section 2.3. 'Diseases of fish'

9.2.1. 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).

At its September 2024 meeting the Aquatic Animals Commission considered the *ad hoc* Group report on Susceptibility of Fish Species to Infection with *A. invadans* and 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 their recommendations. 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 the September 2024 meeting report (Item 6.5.1., page 16) to guide the application of Article 1.5.9. to the susceptible species for infection with *A. invadans*. The Commission agreed that *Channa spp.* should be listed at the genus level.

The amended Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome) have been circulated once for comment.

Previous Commission reports where this item was discussed

September 2024 (Item 8.2.1., page 31).

February 2025 meeting

Comments were received from Canada, Thailand, AU-IBAR and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *A. invadans* (epizootic ulcerative syndrome)'.

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

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.

Texts proposed for adoption

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 23, and will be proposed for adoption at the 92nd General Session in May 2025.

9.3. Section 2.4. 'Diseases of molluscs'

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

Comments were received from Australia, Canada, China (People's Rep. of), Chinese Taipei, Mexico, New Zealand, Switzerland, the UK, AU-IBAR and the EU.

Background

At its September 2024 meeting the Aquatic Animals Commission amended Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' which had been updated by the WOAH Reference Laboratory expert and reformatted using the new disease chapter template.

Previous Commission reports where this item was discussed

September 2024 report (Item 8.2.1., pages 31–32).

February 2025 meeting

The Aquatic Animals Commission addressed Member comments received prior to the deadline and supported by a rationale. In accordance with WOAH's new transparency policy, the Commission's responses to comments considered are presented in Annex 3.

Texts proposed for adoption

The revised Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' is presented as Annex 24 and will be proposed for adoption at the 92nd General Session in May 2025.

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

Comments were received from Australia, Canada, China (People's Rep. of), Chinese Taipei, Mexico, New Zealand, Switzerland, Thailand and the UK, AU-IBAR and the EU.

Background

At its September 2024 meeting the Aquatic Animals Commission amended Chapter 2.4.3. 'Infection with *Bonamia ostreae*' which had been updated by the WOAH Reference Laboratory expert and reformatted using the new disease chapter template.

Previous Commission reports where this item was discussed

September 2024 report (Item 8.2.2., pages 32–33).

February 2025 meeting

The Aquatic Animals Commission addressed Member comments received prior to the deadline and supported by a rationale. In accordance with WOAH's new transparency policy, the Commission's responses to comments considered are presented in Annex 3.

Texts proposed for adoption

The revised Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' is presented as Annex 25 and will be proposed for adoption at the 92nd General Session in May 2025.

9.3.3. 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.

At its September 2024 meeting, the Commission considered comments received and noted that Members were generally supportive of the proposed amendments.

The amended Sections 2.2.1. and 2.2.2. of Chapter 2.4.4. 'Infection with *Perkinsus olseni*' have been circulated twice for comment.

Previous Commission reports where this item was discussed

February 2024 (Item 10.2.1., page 55); September 2024 (Item 8.3.3., page 33).

February 2025 meeting

Comments were received from Canada, New Zealand, AU-IBAR 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 considered are presented in Annex 3.

Texts proposed for adoption

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *Perkinsus olseni*', are presented as Annex 26, and will be proposed for adoption at the 92nd General Session in May 2025.

9.3.4. 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*.

At its September 2024 meeting, the Aquatic Animals Commission considered the *ad hoc* Group report and amended the list of susceptible species in Article 11.7.2. of Chapter 11.7. 'Infection with *X. californiensis*' in line with its recommendations.

The amended Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*' have been circulated once for comment.

Previous Commission reports where this item was discussed

September 2024 (Item 8.3.4., page 33).

February 2025 Meeting

Comments were received from AU-IBAR and the EU.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the amendments to Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*'.

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

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.

Texts proposed for adoption

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*', are presented as Annex 27, and will be proposed for adoption at the 92nd General Session in May 2025.

10. *Aquatic Manual* Items for Member comment

10.1. Section 2.4. 'Diseases of molluscs'

10.1.1. Chapter 2.4.6. 'Infection with *Perkinsus olseni*'

February 2025 meeting

The Aquatic Animals Commission reviewed Chapter 2.4.6. 'Infection with *Perkinsus olseni*, which had been updated by a WOAH Reference Laboratory expert and reformatted using the new disease-specific chapter template.

The main amendments include:

Section/paragraph	Change
2.1.1. 'Aetiological agent'	Expanded the text to include information on morphology, structure and genomic characterisation
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.
7. 'References'	Updated the references.

Texts for comment

The revised Chapter 2.4.6. 'Infection with *Perkinsus olseni*, is presented as Annex 28 for comment.

NB: Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *Perkinsus olseni*' are not presented for comment. They are presented for adoption (see item 9.3.3. above).

10.1.2. Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*'

February 2025 meeting

The Aquatic Animals Commission reviewed Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*', which had been updated by the ad hoc Group and reformatted using the new disease-specific chapter template.

The main amendments include:

Section/paragraph	Change
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'	Completed the table in this section.
7. 'References'	Updated the references.

Texts for comment

The revised Chapter 2.4.5. 'Infection with *Xenohaliotis californiensis*', is presented as Annex 29 for comment.

NB: Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*' are not presented for comment. They are presented for adoption (see item 9.3.4. above).

11. *Aquatic Manual Items* for Member information

11.1. *Aquatic Manual* ongoing work items

11.1.1. *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 February 2025, only four of 31 disease-specific chapters are yet to be reformatted and comprehensively revised: infection with *Batrachochytrium dendrobatidis*, infection with *Ranavirus* species, infection with tilapia lake virus and infection with *Megalocytivirus pagrus1*.

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

Background

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.

Previous Commission report where this item was discussed

September 2024 (Item 9.1.1., page 34)

February 2025 meeting

The Aquatic Animals Commission reviewed the replies received from the Reference Laboratory experts, which highlighted the complexity of the issue. If initial screening using PCR (either conventional or real-time) yields positive results, laboratories need to undertake multiple tests to confirm infection with IHHNV. The Commission agreed to convene an expert consultation comprising the two WOAH Reference Laboratory experts and some other internationally recognised experts to review the current scientific knowledge on EVEs and provide an informed opinion on approaches to confirmatory diagnosis in relevant aquatic species.

11.1.3. Draft new Chapter 2.3.Y. 'Infection with *Megalocytivirus pagrus1*'

Background

Following the listing change of 'infection with red sea bream iridovirus' to 'infection with *Megalocytivirus pagrus1'* at the 91st General Session in May 2024, a new disease-specific chapter for the *Aquatic Manual* 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).

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).

Previous Commission report where this item was discussed

September 2024 (Item 9.1.2., page 34)

February 2025 meeting

The chair of the Group reported on all the progress the Group has made since the first electronic meeting in November 2024. Of the six actions the Group was charged with addressing, three are complete or almost complete: the review the available literature regarding detection methods for *Megalocytivirus pagrus*1; the establishment of an initial short-list of the most appropriate methods of detection of all three genogroups of *Megalocytivirus pagrus*1; and the development of a technical disease card providing preliminary guidance on diagnostic methods for Members. This card is available on the Aquatic Animals Commission's website at: Technical disease card: Megalocytivirus pagrus1.

The inter-laboratory comparability (ILC) study will now be undertaken to determine the performance of the assays identified above. Those assays that perform the best will be incorporated into the updated *Aquatic Manual* chapter along with details of the three genogroups. The chapter will be reviewed by the Aquatic Animals Commission at the September 2025 meeting.

12. Reference centres or change of experts

12.1. 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* Aphanomyces invadans (*epizootic ulcerative syndrome*)
Aquatic Animal Health Laboratory, Exotic & Aquatic Animal Health Division, ICAR-National Bureau of Fish Genetic Resources, Canal Ring Road, P.O. Dilkusha, Lucknow 226 002, INDIA
Tel.: (+522) 244.1735 / 244.0145
E-mail: director.nbfgr@icar.gov.in
Website: http://www.nbfgr.res.in/en
Designated expert: Dr Pravata Kumar

12.2. Evaluation of annual reports for activities in 2024

The Aquatic Animals Commission reviewed the performance of the aquatic WOAH Reference Centres (comprising 36 Reference Laboratories and all six Collaborating Centres) by analysing their 2024 annual reports. This assessment aimed to ensure that each Reference Centre is fulfilling the Terms of Reference (ToRs) and maintaining the scientific excellence of the network: the evaluation is based on 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). By assessing the annual reports, the Commission also seeks to strengthen the network by identifying key areas of excellence to further develop, exploring opportunities for targeted support, and gathering insights from Reference Centres experts to help shape future research priorities.

The Aquatic Animals Commission acknowledged the high level of performance demonstrated by the Reference Centre network, particularly their contributions to the *Aquatic Manual* and *Aquatic Code,* which are highly valued by WOAH and its Members. The Commission also recognised the diverse challenges faced by some Centres, noting that national circumstances can impact their ability to fully meet all the ToRs. Nonetheless, the Aquatic Animals Commission remains committed to supporting the work and fostering continuing collaboration within the network.

During the review, the Aquatic Animals Commission identified some Reference Laboratories that, while complying with the ToRs, have areas for improvement, primarily in strengthening their activities at the international level. The Aquatic Animals Commission also identified some Reference Laboratories and Collaborating Centres for their outstanding performance in providing diagnostic testing facilities, scientific and technical advice on disease control measures and training, organising and participating in scientific meetings, coordinating or participating in proficiency testing among other activities.

Finally, the Aquatic Animals Commission expressed its appreciation to the aquatic WOAH Reference Centres for their timely submission of annual reports and their continued adherence to the ToRs. It acknowledged the significant contributions made by the Reference Centres and extended its gratitude to the designated experts for their dedication to the WOAH mission.

12.3. Accreditation to ISO 17025 or equivalent quality management system

The requirement to maintain a quality management system (QMS) was included in the Basic Texts adopted in 2011. At the Global Reference Centre Conference in Seoul in 2014 it was announced that WOAH Reference Laboratories should be accredited to ISO 17025 or equivalent by the end of December 2017, and since that date the obligation is included in Procedures for Designation of Reference Laboratories and the Guidelines for applicants for WOAH Reference Laboratory status. In both documents the requirement is to “Provide documented proof (certificates) of accreditation to the ISO 17025 or equivalent quality management system, ideally with relevant tests included in the scope

of the accreditation" This obligation is monitored through the annual reports where Reference Laboratories are asked if they have a QMS and is it accredited.

This requirement was discussed at the meeting of the Bureaux of the Biological Standards and Aquatic Animals Standards Commission (see Item 3.3.). Both Commissions also agreed that as Reference Laboratories are designated for a specific disease, they must hold accreditation for the disease's frontline diagnostic test. However, recognising that some laboratories would not currently meet that criterion, the Commissions agreed to give a 3-year deadline (by end December 2027) before introducing the new requirement. From January 2028, the criterion will be as follows:

"Provide documented proof (certificates) of accreditation to the ISO 17025 or equivalent quality management system, with relevant tests (at least one of the tests described in the relevant *Aquatic Manual* chapter) included in the scope of the accreditation."

In the meantime, the annual report questionnaire will be amended to gather information on current QMS systems operating in the WOAH Reference Laboratories and whether the QMS is accredited to ISO 17025 or to an equivalent system. For those laboratories reporting an equivalent system a more detailed description of their equivalent QMS will be requested.

12.4. Evaluation of the Collaborating Centres 5-year workplans

Half of the current aquatic Collaborating Centres reached the end of their 5-year designation at the close of 2024. Each Centre was invited to indicate whether it wished to renew its designation for an additional 5 years and, if so, to submit a self-assessment detailing its activities over the past 5 years in relation to the original 5-year work plan. These self-assessments were expected to provide evidence of the Centre's impacts, achievements, and contributions.

All the Collaborating Centres did wish to renew their designation. Upon evaluation, the Aquatic Animals Commission accepted their self-assessments, which not only demonstrated their technical capacity and global authority in their respective fields but also reaffirmed their commitment to supporting WOAH. These Centres will be formally notified of their designation renewal, along with a request to submit a new 5-year work plan for review at the September meeting. The next designation period will cover 2026–2030.

The Commission commends the Collaborating Centres for their valuable contributions over the past five years to the WOAH Aquatic Animal Health Strategy. Their active participation has been instrumental in ensuring the development and implementation of standards and other activities related to the Strategy.

12.5. Update on the Aquatic Collaborating Centres Network

The Aquatic Animals Commission was updated on the recent activities undertaken by the Aquatic Collaborating Centres Network, which met after the last Commission meeting. During the December session, the network discussed the updates regarding the principal activities for 2024 from each Collaborating Centre, presented information on "Discontools" (www.discontools.eu), and were introduced to the Aquaculture Research Workshop (WOAH Headquarters, 20–21 February 2025). Additionally, the network considered the potential inclusion of experts from Aquatic Reference Laboratories into the network. The proposal received a positive response, and the network will explore the most effective approach for their inclusion.

The Aquatic Animals Commission further discussed and agreed on the necessity for a more structured framework and a list of expected outcomes within a specified timeframe to guide the Aquatic Collaborating Centres Network. Consequently, it was decided that the Collaborating Centre leading the network will collaborate with the Secretariat of the Aquatic Animals Commission to develop ToRs and a comprehensive work plan for the network.

Lastly, it was announced that the next network meeting will be held at the end of March 2025, where the network will continue to discuss potential activities for incorporation into the workplan.

13. Updates from WOAH Headquarters

13.1. Electronic data models and data standards

The Secretariat updated the Aquatic Animals Commission on the work of the WOAH expert consultation Group convened in 2024 to develop electronic data models and data standards to facilitate international trade. The Group used model certificates from Chapter 5.10. 'Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin' and Chapter 5.13. 'Model veterinary certificates for international trade in laboratory animals' of the *Terrestrial Code* as reference documents for developing these data models. Chapter 5.11. 'Model health certificates for international trade in live aquatic animals and aquatic animal products' of the *Aquatic Code* was also used as a reference.

The data models and standards follow UN/CEFACT SPS standardised language (global international standard) and are consistent with the work already done by Codex Alimentarius. These outputs will facilitate paperless certification between Competent Authorities where export/import certification is required to facilitate entry of a commodity.

The final documents produced include a guidance document in English, Spanish and French, an excel spreadsheet detailing the data models and standards in XML language, and a visual reference e-certification model that details how the WOAH model veterinary certificates are organised and how data elements relate to one another. These documents can be found on the WOAH website.

13.2. WOAH *ad hoc* Group on emergency management

The Aquatic Animals Commission was updated by the Preparedness and Resilience Department on the development of emergency management standards by the *ad hoc* Group on Veterinary Emergencies for the *Terrestrial Animal Health Code.* Two meetings were held in 2024: the first to define the scope of the proposed content, and the second to begin drafting a chapter. The Commission noted that this chapter follows an all-hazards approach, whereas the two upcoming chapters for adoption for the *Aquatic Code* are disease focused. As a result, this new chapter could be used by Aquatic Animal Health Services. The Commission noted potential differences in terminology and recommended that the WOAH Secretariat consider feedback from Members on the two related *Aquatic Code* chapters as well as ensure review and linkages with other relevant chapters.

13.3. WOAH Global Conference on Biological Threat Reduction

WOAH is hosting its 3rd WOAH Global Conference on Biological Threat Reduction scheduled for 28-30 October 2025 in Geneva, Switzerland. The Conference will address the dynamic landscape of biological threats by reflecting on historical experiences, discussing current challenges and anticipating future risks. Bringing together participants from diverse sectors, it aims to catalyse actionable commitments and strengthen cross-sectoral collaboration to tackle biological threats. The Aquatic Animals Commission was invited to nominate a representative to attend the Conference on behalf of the Commission.

13.4. WOAH Incident Management System

The Aquatic Animals Commission was updated by the Preparedness and Resilience Department on the development of a WOAH incident management system. At the 89th General Session, the development of an incident management system (IMS) was recommended by the Technical Item and its accompanying Resolution (No. 28). WOAH is committed to strengthening its institutional response to global and regional incidents affecting animal health and welfare. The IMS will enhance internal coordination, clarify roles during incidents, and improve collaboration with partners such as FAO and WHO, while fostering a stronger emergency management culture within the organisation. The IMS will align with and respect WOAH's mandate, expectations of Members and role of other organisations, whilst integrating a health-security function. The initiative was commended for its potential benefits, particularly in aquatic animal health emergencies, where it could position WOAH as a key coordination

leader, working alongside the WOAH Aquatic Collaborating Centre Network and partner organisations such as FAO. The Commission also provided examples of scenarios which could trigger activation of the IMS and the WOAH Secretariat will use these to guide future training and simulation exercises.

13.5. Update on WAHIAD activities and WAHIS platform updates in 2025

The Aquatic Animals Commission was informed of the 2024 WAHIS platform updates and the relevant updates of the WAHIS Reference Tables done in December 2024 which included the addition of the newly listed disease 'infection with *Megalocytivirus pagrus1*'. The objective of this work was to align with the changes adopted in the *Aquatic Code* at the 91st General Session. The Commission commended this work and the good communication between the Secretariat and WAHIAD during the process.

WAHIAD informed the Commission that the list of susceptible hosts for 'infection with *Megalocytivirus pagrus1*' will be reviewed and updated accordingly when the disease-specific chapter is adopted. The Commission acknowledged the request by WAHIAD that the case definition and other information to support Members in their reporting is provided in relevant Commission meeting reports for newly listed diseases that do not have an adopted disease-specific chapter.

13.6. WOAH Governance Review Committee

Dr François Caya, WOAH Deputy Director General for Institutional Affairs & Regional Activities, updated the Aquatic Animals Commission on the work of the Governance Review Committee (GRC), which was established in December 2024 following a nomination process led by the five Regional Commissions. The objective of GRC is to analyse and evaluate WOAH's legal framework, institutional, regional, technical and financial governance for improvement following the findings from an independent assessment that was presented at the WOAH 91st General Session. The GRC comprises representatives from 16 Members and is an anticipated three-year project that will conclude at the General Session in 2027. Dr Caya highlighted key issues to be reviewed by the GRC included formalising WOAH's standard-setting procedures and streamlining other technical decision-making processes, transparency in statutory contributions from Members and improving institutional and regional consultation processes.

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…/Annexes

Annex 1. Item 2. – Adopted Agenda

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

12 – 19 February 2025

Agenda

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 Biological Standards Commission Bureaux meeting

3.2. Code Commission updates (Secretariat)

4. WORK PROGRAMME OF THE AQUATIC ANIMALS COMMISSION

4.1. Proposed work

5. Chapter 6.2. 'Monitoring the quantities and usage patterns of antimicrobial agents in aquatic animals in aquatic animals' and progressive updates on Section 6 'Antimicrobial Use in Aquatic Animals' (WOAH AMR Department)

5.1.1. Introductory chapter for Section 5 (collaborative work with the Terrestrial Animal Health Code)

5.1.2. Usability of the *Aquatic Code* for trade purposes (AAHSC)

6. AQUATIC ANIMAL HEALTH STRATEGY

6.1. Status report on the implementation of the Aquatic Animal Health Strategy (Gillian Mylrea)

7. AQUATIC CODE

7.1. **Texts to be proposed for adoption May 2025**

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

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

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

7.1.3.1. Model Article 10.X.10. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Article 10.4.15. for Chapter 10.4. 'Infection with ISAV'

7.1.3.2. 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’

7.1.3.3. New Glossary terms

- Usage of new Glossary terms in Aquatic Code

7.1.4. Draft new Chapter 5.X. ‘Movement of ornamental aquatic animals’

7.1.5. Revised articles X.X.4.-X.X.7. (and 10.4.5. to 10.4.10.) for disease-specific chapters

7.1.6. Article 9.9.2. of Chapter 9.9. ‘Infection with white spot syndrome virus’

7.1.7. Article 10.2.2. of Chapter 10.2. ‘Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)’

7.1.8. Articles 10.4.11. and 10.4.12. of Chapter 10.4. ‘Infection with infectious salmon anaemia virus’

7.1.9. Draft new Chapter 10.X. ‘Infection with *Megalocytivirus pagrus1*’

7.1.10. Articles 11.6.1. and 11.6.2. of Chapter 11.6. ‘Infection with *Perkinsus olseni*’

7.1.11. Article 11.7.1. and 11.7.2. of Chapter 11.7. ‘Infection with *Xenohaliotis californiensis*’

7.2. **Items for Member comment**

7.2.1. Article 1.1.4. of Chapter 1.1. ‘Notification of disease and provision of epidemiological information’

7.2.1.1. Definition of emerging disease

7.2.2. New Chapter 4.3. ‘Application of compartmentalisation’

7.2.3. Chapter 4.7. ‘Fallowing in aquaculture’

7.3. **Items for consideration**

7.3.1. Consideration of emerging diseases

7.3.1.1. Covert mortality nodavirus (CMNV) in zebrafish

7.3.1.2. Infection with *Enterocytozoon hepatopenaei*

7.3.1.3. Other diseases

7.3.2. Other items for consideration

7.3.2.1. Review ICTV for changes in phylogenetic organisation for pathogens and accuracy in the *Aquatic Code*.

8. AQUATIC MANUAL

8.1. **Texts to be proposed for adoption May 2025**

8.1.1. Section 2.2. ‘Diseases of crustaceans’

8.1.1.1. Section 2.2.1. and 2.2.2. of Chapter 2.2.8. ‘Infection with white spot syndrome virus’

8.1.2. Section 2.3. ‘Diseases of fish’

8.1.2.1. Section 2.2.1. and 2.2.2. of Chapter 2.3.1. ‘Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)’

8.1.3. Section 2.4. ‘Diseases of molluscs’

8.1.3.1. Chapter 2.4.2. ‘Infection with *Bonamia exitiosa’*

8.1.3.2. Chapter 2.4.3. ‘Infection with *Bonamia ostreae’*

8.1.3.3. Section 2.2.1. and 2.2.2. of Chapter 2.4.6. ‘Infection with *Perkinsus olseni’*

8.1.3.4. Section 2.2.1. and 2.2.2. of Chapter 2.4.7. ‘Infection with *Xenohaliotis californiensis’*

8.2. **Items for Member comment**

8.2.1. Section 1.1. ‘Introductory chapters’

8.2.1.1. Chapter 1.2. ‘Validation of diagnostic assays for infectious diseases of aquatic animals’

8.2.2. Section 2.3. ‘Diseases of fish’

8.2.2.1. New draft chapter ‘infection with tilapia lake virus’

8.2.3. Section 2.4. ‘Diseases of molluscs’

8.2.3.1. Chapter 2.4.5. ‘Infection with *Perkinsus marinus*

8.2.3.2. Chapter 2.4.6. ‘Infection with *Perkinsus olseni’*

8.3. **Items for consideration**

8.3.1. Follow-up from September 2024: Member question on Chapter 2.2.5. ‘Infection with infectious hypodermal and haematopoietic necrosis virus’

8.3.2. Chapter 2.4.7. ‘Infection with *Xenohaliotis californiensis*’

9. *AD HOC* GROUPS

9.1. Report of the a*d hoc G*roup on Susceptibility of mollusc species to infection with WOAH listed diseases

9.2. Report of the a*d hoc G*roup on Susceptibility of fish species to infection with WOAH listed diseaseS

9.3. Report of the a*d hoc G*roup on Susceptibility of crustacean species to infection with WOAH listed diseases

9.4. Update on the electronic *ad hoc* Group on *Megalocytivirus pagrus*1

10. REFERENCE CENTRES OR CHANGE OF EXPERTS

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

10.2. Evaluation of annual reports for activities in 2024

10.3. Evaluation of the Collaborating Centres 5-year workplans

10.4. Update on the Aquatic Collaborating Centres Network

10.5. Support of Reference Centres

11. OTHER ISSUES

11.1. For decision

11.1.1. Update on the *ad hoc* Group to revise Chapter 5.1. and 5.2. and terms of reference (WOAH Standards Department)

11.1.2. Publication of Reference data models for e-certification (WOAH Standards)

11.1.3. Global Conference on Biological Threat Reduction request for member attendance (WOAH Preparedness and Resilience Department)

11.2. For discussion

11.2.1. Follow-up Observatory consideration on monitoring implementation of the standards on aquatic animal health (WOAH Observatory)

11.2.2. Emergency management ad hoc Group (WOAH Preparedness and Resilience Department)

11.3. For information

11.3.1. Standards Online Navigation Tool Update (WOAH Standards Department)

11.3.2. Update on WAHIAD activities and WAHIS platform updates in 2025 (WAHIAD)

11.3.3. WOAH Governance Review Committee

12. Meeting review

13. Next meeting: 17–24 SEPTEMBER 2025

Annex 2. Item 2. – List of Participants

MEETING OF THE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

12 to 19 February 2025

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MEMBERS OF THE COMMISSION

Dr Alicia Gallardo Lagno
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Dr Mariana Delgado
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Science Department

Dr Kathleen Frisch
Scientific Coordinator for Aquatic Animal Health
Standards Department

Dr Patricia Kelly
Scientific Coordinator for Aquatic Animal Health
Standards Department

Ms Sara Linnane
Senior Scientific Officer
International Standards
Science Department

Annex 3 (for information) – Aquatic Animals Commission's responses to comments considered

Work Programme for the Aquatic Animal Health Standards Commission – September 2024

General comments

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
General_1	The Member thanks the WOAH for the opportunity to comment on the report of the September 2024 meeting of the Aquatic Animal Health Standards Commission. The Member supports the work programme and the proposed changes to all presented chapters. We do not have any specific comments.	Noted

Comments on the work programme

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Work_1	**Category:** General comment **Proposed amended text:** To include a definition of an "official control programme" in the newly developed trade section of the Code. **Rationale:** The Member acknowledges the Commission's ongoing efforts to enhance the usability of the Aquatic Code for trade purposes, aligning it with the terrestrial animal health standards set by the Terrestrial Animal Health Standards Commission. However, the Member requests that the Commission prepare a clear definition of 'official control programme' as referenced in Article 5.1.2. It appears that some member countries misunderstand the application of Article 5.1.2. as the Aquatic Code does not provide a clear definition, unlike the Terrestrial Code. The concept of an official control program within the Aquatic Code should be explicitly outlined to help countries demonstrate ongoing freedom from specific diseases in certain populations, areas or regions to minimise impact of the disease. In some cases, countries call an official control program through implementing limited surveillance programs to assess the distribution of a pathogen within the country but lack ongoing biosecurity measures to reduce the likelihood of pathogen re-introduction.	The Commission discussed the lack of clear definition for 'official control programme' in the *Aquatic Code* and agreed that this item should be added to the work programme under the revision and restructure of Section 5 (see item 8.2.1. of the February 2025 report).

Not for comment

	An official control program should clearly define the necessary measures a member country must implement, including accurately identifying the distribution of the pathogen of concern and maintaining ongoing monitoring programs. These programs should focus on monitoring the boundaries of infected zones or populations. For example, the Member has implemented nationally consistent surveillance programs to demonstrate freedom from specific WOAH-listed diseases in certain populations, regions, or industries within the country, as well as ongoing domestic biosecurity measures to reduce spread of pathogens from infected areas to free areas. These domestic biosecurity controls and surveillance programs are essential for protecting our industries and maintaining import requirements that protect disease-free populations or disease-free areas of the Member state. We seek alignment of these surveillance programs with international standards to ensure recognition and acceptance by our trading partners.	
Work_2	**Proposal/Comment:** The Member recommends the commission consider adding wording to Article 1.5.9. to ensure consistent application as to what was done for Infection with WSSV. Specific wording that could be added would be: For *pathogenic agents* that have a low host species specificity, a decision to conclude susceptibility of species at a taxonomic ranking of Genus or higher should only be made where: a) after application of Article 1.5.7., a significant proportion of the genus has been found to be susceptible ~~within the taxonomic ranking has been found to be susceptible~~; **Rationale:** The Member agrees with the Commission's rationale in Item 6.5.2. that *Procambarus* and *Palaemon* should be listed at the species level and not the genus level for WSSV, but noted that guidance on this type of judgement is not included in Article 1.5.9. and have concerns about consistent application for other diseases where Article 1.5.9. will be applied in the future. Large genus size is not currently a consideration of Article 1.5.9 but the Member, other members and the commission appear to agree that it should based on the September 2024 Commission report. The Member agrees that it not reasonable to list at the genus level based on 2 species meeting Article 1.5.7. when the genus has almost 100 species. The Member recommends the commission consider adding wording to Article 1.5.9. as outlined above.	The Commission noted that the application of Article 1.5.9. is currently ongoing and may continue to be applied where appropriate as the assessments of susceptible species to listed diseases are completed. Article 1.5.9. was created through extensive consultation with Members and the rationale for the criteria can be found in the AAC reports from September 2016 to in February 2019. A revision of Article 1.5.9. at this time would create confusion and should not be considered until the first round of assessments of susceptible species to listed diseases have been completed and any potential applications of Article 1.5.9. have occurred.
Work_3	**Proposal/Comment:** The Member respectfully requests that the AAC to work with WAHIAD to highlight the importance to include the ability to view country health status at the genogroup level in WAHIS, specifically for listed diseases *Megalocytivirus pagrus 1* and ISA. **Rationale:** Member countries may control imports based on genogroup for *Megalocytivirus pagrus 1* (e.g. control for RSIV, but not ISKNV, TRBIV) and for ISA (ISA HPR-deleted but not ISA HPR0). WAHIS is a critical source for viewing country health status. Displaying health status by genogroup will allow member countries to mitigate the risk of introduction of each genogroup separately.	Currently Members can notify *Megalocytivirus pagrus1* and infectious salmon anaemia at the genogroup levels during immediate notification and this information can be found on WAHIS under 'animal disease events'. The Commission agreed that in other areas of WAHIS it would be beneficial to display the genogroup; for

Not for comment

	The Member understands that there are currently some limitations to do this in WAHIS and requests the AAC to highlight the importance of this to support system upgrades.	example, to easily determine the animal health situation at the genogroup level of a country or region. This feedback has been shared with WOAH Information and Analysis Department for consideration during future developments of WAHIS.
Work_4	**Proposal/Comment:** The Member supports the efforts of WOAH and the Aquatic Animals Commission on the implementation of the WOAH Aquatic Animal Health Strategy; specifically, the efforts to hold a global workshop to identify high priority research areas that will impact the WOAH international standards for aquatic animal health. The Member supports the Quads Alliance submission which identifies several scientific gaps which should be prioritized as critical for the management of aquatic animal diseases at the workshop to be held in February 2025.	Noted
Work_5	**Propuesta/Comentario:** El Miembro, coincide con el problema planteado y los argumentos expuestos por el país miembro respecto al problema relacionado con la especificidad de los métodos moleculares que figuran en el Capítulo 2.2.5. "Infección por el virus de la necrosis hipodérmica y hematopoyética infecciosa" **Justificación**: En adición a la justificación planteada por el país miembro, se precisa que en el reporte de la comisión de setiembre 2020, se realizó la evaluación del deslistado de la enfermedad, evidenciando en el criterio N°3, la necesidad de actualizar la definición de caso, y el Manual Acuático, a fin de incorporar métodos con una mejor sensibilidad y especificidad. **Evidencia documentada, si corresponde:** Anexo 9: Item 4.6 Assessment of the infection with infectious hypodermal and hematopoietic necrosis virus (IHHNV) for delisting in the Aquatic Code. REPORT OF THE MEETING OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION. Paris, 26 August to 2 September 2020. Junto con saludarlo, me permito compartir la siguiente solicitud dirigida a la Comisión de Normas para los Animales Acuáticos de la Organización Mundial de Sanidad Animal (OMSA), con la finalidad de que, la Agencia de Regulación y Control Fito y Zoosanitario AGROCALIDAD; punto focal del Miembro, traslade la presente: 9. Ítems del Manual Acuático para Información de los Miembros 9.1. Nuevos ítems de trabajo del Manual Acuático 9.1.1. Capítulo 2.2.5. Infección por el virus de la necrosis hipodérmica y hematopoyética infecciosa	The Commission supported the formation of an *ad hoc* Group representing a wide geographic distribution to review the new scientific information on diagnostic methods for IHHNV (see item 11.2.1. of the February 2025 report). Any further decisions regarding this disease will need to wait for the outcomes of this work.

Not for comment

	Resumen de septiembre de 2024 Un miembro solicita a la Comisión para los Animales Acuáticos orientaciones sobre un problema relacionado con la especificidad de los métodos moleculares que figuran en el Capítulo 2.2.5. “Infección por virus de la necrosis hipodérmica y hematopoyética infecciosa”. La falta de especificidad puede dificultar la diferenciación clara entre las secuencias genéticas del virus de la necrosis hipodérmica y hematopoyética infecciosa y los elementos virales endógenos dentro del genoma de los camarones *P. monodon y P. vananamei.* La Comisión consultó a los dos expertos del laboratorio de referencia de la OMSA sobre la infección por el virus de la necrosis hipodérmica y hematopoyética infecciosa y les pidió que trabajaran juntos para proporcionar una recomendación sobre cómo abordar esta cuestión. La Comisión examinará la propuesta en su reunión de febrero de 2025. En este contexto, el informe adjunto respalda la propuesta de modificación del Artículo 1.3.3 del Capítulo 1.3. "Enfermedades de la lista de la OIE", para el deslistado del agente patógeno *Virus de la Necrosis Hipodérmica y Hematopoyética Infecciosa* (IHHNV, por sus siglas en inglés). Esta propuesta se fundamenta en los criterios establecidos en el Artículo 1.2.2 del Código Acuático. Adicionalmente, el Miembro, al igual que otros países, considera que el IHHNV ya no representa un riesgo significativo de propagación internacional debido a su amplia distribución mundial. Además, no se han reportado pérdidas económicas relevantes relacionadas con esta enfermedad en cultivos de camarón en el estado miembro ni en otros países. Estas conclusiones están sustentadas en evidencia científica y productiva, misma que puede ser compartida a la Comisión de considerarlo pertinente. Agradecemos de antemano que esta información sea considerada en la reunión de la Comisión, programada para febrero del presente año.	
Work_6	**Propuesta/Comentario:** El Miembro, solicita a la comisión la realización de un nuevo trabajo; dirigido hacia la revisión del Título 5.3, Capítulo 16.3. Procedimientos de la OMSA relacionados con el Acuerdo sobre Medidas Sanitarias y Fitosanitarias de la Organización Mundial del Comercio, a fin de diferenciar técnicamente las consideraciones entre animales acuáticos y productos de animales acuáticos. **Justificación:** El Miembro, como otros países de América latina son exportadores de productos de animales acuáticos, cumpliendo con el Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias (Acuerdo MSF). Sin embargo, ciertas mercancías son evaluadas por los países importadores utilizando la rigurosidad que se aplica para el análisis de riesgo de importación (ARI) de animales acuáticos (vivos). En esa línea, se evidencia que la interpretación del título 5.3 entre los países miembros no es homogénea, lo cual estaría generando medidas restrictivas para el comercio.	Agreed to add the revision and restructure of Section 5 to the work programme (see item 8.2.1. of the February 2025 report). This work will include collaboration with the Terrestrial Animal Health Standards Commission on the revision of horizontal chapters.

Not for comment

	El Miembro, en el año 2024 tuvo varios rechazos de contenedores de productos de animales acuáticos en puertos internacionales, frente a la detección de agente patógenos listado por la OMSA, lo cual hasta la actualidad represente un perjuicio socioeconómico para la industria acuícola y para el país. Por lo que, se requiere que el Código Acuático brinde consideraciones diferenciadas para ambas mercancías (animales vivos y producto de animales acuáticos), considerando la finalidad y el nivel de riesgo que representa para los países importadores.	
Work_7	**Propuesta/Comentario:** El miembro, coincide con el problema planteado y los argumentos expuestos por el país miembro respecto al problema relacionado con la especificidad de los métodos moleculares que figuran en el Capítulo 2.2.5. "Infección por el virus de la necrosis hipodérmica y hematopoyética infecciosa" **Justificación:** En adición a la justificación planteada por el país miembro, se precisa que en el reporte de la comisión de setiembre 2020, se realizó la evaluación del deslistado de la enfermedad, evidenciando en el criterio N°3, la necesidad de actualizar la definición de caso, y el Manual Acuático, a fin de incorporar métodos con una mejor sensibilidad y especificidad. **Evidencia documentada, si corresponde:** Anexo 9: Item 4.6 Assessment of the infection with infectious hypodermal and hematopoietic necrosis virus (IHHNV) for delisting in the Aquatic Code. REPORT OF THE MEETING OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION. Paris, 26 August to 2 September 2020.	See response for comment Work_5
Work_8	**Propuesta/Comentario:** El Miembro, solicita a la comisión la realización de un nuevo trabajo; dirigido hacia la revisión del Título 5.3, Capítulo 16.3. Procedimientos de la OMSA relacionados con el Acuerdo sobre Medidas Sanitarias y Fitosanitarias de la Organización Mundial del Comercio, a fin de diferenciar técnicamente las consideraciones entre animales acuáticos y productos de animales acuáticos. **Justificación:** El Miembro, como otros países de América latina son exportadores de productos de animales acuáticos, cumpliendo con el Acuerdo sobre la Aplicación de Medidas Sanitarias y Fitosanitarias (Acuerdo MSF). Sin embargo, ciertas mercancías son evaluadas por los países importadores utilizando la rigurosidad que se aplica para el análisis de riesgo de importación (ARI) de animales acuáticos (vivos). En esa línea, se evidencia que la interpretación del título 5.3 entre los países miembros no es homogéneas lo cual estaría generando medidas restrictivas para el comercio.	See response for comment Work_6

Information

	El Miembro, en el año 2020 logró la aprobación del PPG 767 (https://standardsfacility.org/es/PPG-767), para desarrollar el "Estudio de factibilidad para la aplicación de la zonificación como herramienta de control de enfermedades infecciosas para el desarrollo social y económico de la acuicultura del langostino blanco (*Penaeus vannamei*)", como parte de la justificación del proyecto se consideraron los rechazos de contenedores de productos de animales acuáticos frente a la detección de agente patógenos del listado de la OMSA, lo cual hasta la actualidad represente un perjuicio socioeconómico para la industria acuícola y para el país. Si bien, se estima dar continuidad a la hoja de ruta proporcionada por el PPG, se requiere que el Código Acuático brinde consideraciones diferenciadas para ambas mercancías, considerando la finalidad y el nivel de riesgo que representa para los países importadores.	
Work_9	**Category:** General The Members agree with the proposed work programme.	Noted

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**

Not for comment

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.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**
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**

Not for comment

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 *
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**
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**
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**

Not to be commented

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. 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**
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**

Not for comment

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. 2.1.1.	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**
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**

Not to comment

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**
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**

Not for comment

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. 2.4.6.	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**

Not for comment

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

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X._1	**Category:** General The Member supports the proposed changes in this Chapter for the purposes of improving clarity, understanding and member country emergency disease preparedness. The Member has developed strongly coordinated systems for emergency disease preparedness, although there is always room for improvement. Simulation exercises play an important role in the continual improvement of the disease preparedness and response framework.	Noted
4.X._2	**Category:** General The Member supports the changes proposed and has inserted comments within the text.	Noted
4.X._3	**Category:** editorial Inconsistent use of 'disease-free' vs 'disease free' throughout this document. **Rationale:** Either term is correct, but we should be consistent throughout this chapter with hyphenating (or not) this term.	Based on the WOAH style's guide, the correct form is 'disease-free' with the hyphen which will be applied throughout this chapter. In cases where the sentence read 'disease free zone' or 'disease free compartment', the word disease was deleted as free zone and free compartment are glossary terms which as defined mean freedom from disease.
4.X._4	**Category:** General The Members thank the Code Commission for considering its earlier comments and supports this new chapter.	Noted

Not for comment

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 (in language submitted)	Aquatic Animals Commission Response
4.X.1._1	**Category:** Deletion **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:** Suggest removing additional words as they are unnecessary to achieve the intended meaning.	Did not agree to remove 'a suitable path to'. In a given situation there may be multiple alternative paths to recovery. This chapter should guide the Competent Authority and Aquatic Animal Health Services, towards the most appropriate 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 outbreaks*~~.~~ The specific actions which are necessary to operationalise the framework in the event of a *disease outbreak* are described in Chapter 4.Y.

Article 4.X.3.

Introduction

~~*Aquatic animal 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 disease*s which are important to a country, *zone* or *compartment*, are identified in advance (i.e. in peacetime) by the *Competent Authority*, and that their future control is supported by adequate legislative and funding measures. The ~~statutory~~ list of important *disease*s that is developed after conducting a *risk analysis* as described in 4.X.6.*,* may include *aquatic animal disease*s which are listed in Chapter 1.3., as well as other *disease*s which have been identified as being of importance to the country, *zone* or *compartment*. 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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.3._1	**Category:** change **Proposed amended text:** When developing the framework, it is of fundamental importance to ensure that the *aquatic animal disease*s which are important to a country, *zone* or *compartment*, are identified in advance (i.e. in peacetime) by the *Competent Authority*, and that their future control is supported by adequate legislative and funding measures.	Did not agree to remove the sentence describing the development of the list of important diseases. This point includes the use of risk analysis, and expands the concept to include that the importance of a disease may be at a country, zone or compartment level.

Not for comment

	~~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:** Paragraph 2 of Article 4.X.1. has already give definition of important diseases.Repeat here.	
4.X.3._2	**Category:** editorial **Proposed amended text:** In addition to the *diseases* ~~which~~ that 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. **Rationale:** Correct grammar. This should be consistently corrected throughout the text, for example, in Articles: 4.X.6, 4.X.7.7, 4.X.8.2, 4.Y.4.1(a), 4.Y.9.3(b), 4.Z.3.5, 4.Z.4.2,	Did not agree, WOAH uses British English and either 'which' or 'that' is correct.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.3._3	**Categoría:** Cambio **Propuesta modificación de texto:** También en tiempos de paz, la *autoridad competente* deberá adoptar un enfoque sistemático para planificar cada elemento del marco que se aplicará desde el momento en que se sospecha una *enfermedad* importante durante la fase de alerta, pasando por la activación del *plan de* ~~*emergencia*~~ contingencia en la fase de emergencia ~~fase operativa~~, hasta el momento en que comienza la fase de recuperación y en que, oficialmente, finaliza la emergencia. **Justificación:** Los conceptos de los capítulos 4.X. y 4.Y. deben ser concordantes. En el capítulo 4.Y. no se indica articulo o referencia a "fase operativa", siendo el artículo 4.Y.5 referente a "fase de emergencia"	Agreed, the Spanish versions of Chapters 4.X. and 4.Y. will be amended for correct use of 'fase de emergencia'.

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.

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.4._1	**Category:** change **Proposed amended text:** ~~case~~ definitions for suspect and confirmed cases should be established for all important *diseases* which are subject to the emergency disease preparedness framework. ... **Rationale:** Typing error. Please see disease-specific chapter, normally, definitions for a suspect case or definitions for confirmed cases.	Agreed with removing the word 'case' for consistency with the *Aquatic Manual*.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.4._2	**Category:** revision **Proposed amended text:** *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 relevant industry stakeholders; **Rationale:** For consistency between Articles (ex. 4.X.4) and Chapters (4.X.Y)	Agreed to add 'relevant' before 'industry stakeholders' for consistency with other articles in this chapter.

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';

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.4._3	**Categoría:** Cambio **Propuesta modificación de texto:** b) completamente, de conformidad con el Artículo 4.Y.5. ~~Capítulo 4.Y.~~, una vez que la emergencia en caso de *enfermedad* se haya iniciado en el marco de la "fase de emergencia". ~~"fase operativa".~~ **Justificación:** Los conceptos de los capítulos 4.X. y 4.Y. deben ser concordantes. En el capítulo 4.Y. no se indica articulo o referencia a "fase operativa", siendo el artículo 4.Y.5 referente a "fase de emergencia"	Agreed, see response for comment 4.X.3._3.

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.*;*

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.5._1	**Category:** addition **Proposed amended text:** 1) seeking fundraising to enable recourse to and implementation of *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. **Rationale:** In many countries, there is no insurance for aquaculture projects	Did not agree to add seeking of funds to point 1 as it describes the requirement for legislation which underlies all the elements and actions that are necessary to manage the suspicion and confirmation of an outbreak. The seeking of funds is included in point 2 of Article 4.X.5.

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.

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.5._2	**Category:** addition **Proposed amended text:** 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 incentives for reporting and the operational measures which are set out in Chapter 4.Y. **Rationale:** Funding ensures compensation to affected farmers for culled or quarantined stocks, encouraging transparency.	Did not agree to add incentives for reporting to point 2. Notification of disease is a legal obligation as described in Article 1.4.7. that an early detection system requires that 'veterinarians, aquatic animal health professionals and others with an occupational role with aquatic animals have a legal obligation to report suspicion of the occurrence of listed disease or emerging diseases to the Competent Authority'. Further, as legislation is covered in point 1 of this article, the legal obligation for reporting is included within that point.

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.5._3	**Category:** editorial **Proposed amended text:** Identification of *aquatic animal diseases* ~~which~~ that will be subject to emergency measures **Rationale:** Grammar	Did not agree, see response for comment 4.X.3._2.

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.

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.6._4	**Category:** editorial **Proposed amended text:** Such *risk analysis* should also include information on the most important routes of introduction, transmission pathways, life cycle stages, persistence in the environment, and likelihood of eradication, which will inform *disease* control strategies and response options which are referred to in Article 4.X.10.	Agreed, editorial change.

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.*

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.6._5	**Category:** addition **Proposed amended text:** … Changes in the species or strains farmed, and in the distribution or virulence of known *pathogenic agents* should inform changes in national *disease* listings **Rationale:** Strains of the same species generated from breeding programs may vary in susceptibility to diseases.	Agreed to add 'strains' as strains of the same species generated in breeding programmes may vary in susceptibility to disease.

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.~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.6._6	**Category:** change **Proposed amended text:** *Surveillance* and reporting activities Suspicion of an *outbreak* of an important *aquatic animal disease*, which is subject to statutory control, often results from *surveillance* and reporting activities. **Rationale:** Reporting of suspicion of an disease and unexplained mortality is very important for the emergency disease preparedness.	Changes were made as proposed in comment 4.X.6._7 which covers the same concept.
4.X.6._7	**Category:** Addition **Proposed amended text:**	Agreed to reference the 'early detection system' as its purpose is to ensure the rapid recognition of signs of an important disease in aquatic animals, allowing rapid

Not for comment

	Suspicion of an *outbreak* of an important *aquatic animal disease*, which is subject to statutory control, often results from *surveillance* activities, including an *early detection system*. Therefore, emergency *disease* preparedness systems and the outcomes from those systems are heavily reliant on the quality of the *surveillance*, *early detection system* 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:** Suggest including *early detection system* as its specific purpose is to ensure the rapid recognition of signs that are suspicious of an important *aquatic animal disease,* so that an investigation can be activated by the *Competent* Authority and decisions be made on response actions.	communication to the Competent Authority and activation an investigation with minimal delay.

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 (in language submitted)	Aquatic Animals Commission Response
4.X.6._8	**Category:** Deletion **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 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*. **Rationale:** The way this sentence reads, it is not clear whether "On-growing stock on an infected establishment to slaughter weight" is an example of a protocol that should be developed or a disease control option (and it would not be a good example of the latter). Suggest deleting this example to avoid confusion.	Did not agree to remove the example of a disease control option. This is an important example, as on-growing of stock on an infected aquaculture establishment may be possible under certain circumstances. The situation would be subject to risk analysis and would only proceed if deemed to be an acceptable option.

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*~~*t* 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

Not for comment

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 (in language submitted)	Aquatic Animals Commission Response
4.X.7._1	**Category:** change **Proposed amended text :** The Competent Authority may refer to 4.6. and ~~should~~ decide whether the *contingency plan* applies either to a specific *aquatic animal disease* or to a group of such *diseases* which, ... **Rationale:** Principles of CHAPTER 4.6.of the Aquatic Code may be applied to this article.	Did not agree to reference Chapter 4.6. 'Contingency planning' as this chapter will become obsolete once draft new Chapters 4.X. and 4.Y. are adopted. As described in item 6.1. of the Aquatic Animals Commission February 2025 report, Chapter 4.6. will be proposed for deletion at the 92nd General Session.
4.X.7._2	**Category:** general **Proposed amended text:** We suggest that this section should consider including an explanation on how a *contingency plan* may differ and interact with individual *biosecurity plans*. **Rationale:** Both types of plans may build on the same types on information for managing and mitigating the risk of a pathogenic agent, however the way management and mitigation is applied will differ as the purpose of each plan is different –a *biosecurity plan* is to prevent the introduction and spread of a pathogenic agent, and should operate during in "peace time", whereas a *contingency plan* is only triggered once a disease is detected to bring the outbreak under control.	Did not agree to include an explanation of how a contingency plan may be different from biosecurity plans. A contingency plan is a defined glossary term which includes all needed actions, requirements and resources to eradicate or control outbreaks of diseases of aquatic animals. As such the contingency plan includes the biosecurity elements. As well, point 4 of this article references Chapter 4.1. 'Biosecurity for aquaculture establishments' which provides further details on biosecurity plans.

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 (in language submitted)	Aquatic Animals Commission Response
4.X.7._3	**Category:** Addition **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 *Contingency plans* could also be developed for specific *aquaculture* or fishery sectors. Sector-specific *contingency plans* could identify common pathways, practices and risks, and the potential measures that could be applied to those sector-specific activities to mitigate the *risk* of a *disease*. As with *contingency plans* for *emerging diseases*, sector-specific *contingency plans*	Agreed to addition of text that contingency plans should be developed for specific aquaculture or fishery sectors as it can identify key points of contacts, common pathways, activities and practices for mitigation measures.

Not for comment

	would require rapid and effective fine-tuning once the details of the *disease* are known. **Rationale:** *Contingency plans* that are specific to particular aquaculture (or fishery) sectors are useful starting points during an emergency disease outbreak, in the absence of a disease-specific contingency plan, as they should identify key points of contact within those sectors, common pathways, activities and practices to target for mitigation measures, which can be fine-tuned.	

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.7._4	**Category:** deletion **Proposed amended texts:** 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; **Rationale:** We suggest removing this text because the definition of a Competent Authority already includes those authorities at the national or regional level.	Did not agree to remove text indicating chain of command is from central to regional and local levels. This text provides additional detail and clarity on chain of command inclusive of Competent Authorities and the Aquatic Animal Health Services.

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, producers~~'~~ group, mental health and psychological support group.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.7._5	**Category:** addition **Proposed amended texts:** ii) specialist sub-groups which will provide specific advice to the emergency management group~~Emergency Task Force~~ for	Agreed to add welfare group to the list of examples. However did not agree to add insurance group as this is not considered an exhaustive list and groups are intended to be

Not for comment

	consideration e.g. epidemiology group, laboratory group, logistics group, insurance groups, welfare groups, communications group, environmental group, producers' group, mental health and psychological support group. **Rationale:** Insurance groups help aquaculture operations to manage risks of production loss from biological hazards (i.e. diseases). Welfare groups provide guidelines production of healthier animals that are less susceptible to disease, and less reliant on antibiotics.	functional; insurance may be included in a logistics or finance 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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.7._6	**Category:** addition **Proposed amended texts:** 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 or vectors. ~~The *risk assessment* should also inform the need for synchronised~~Synchronised *fallowing* of a	Agreed that vectors should be considered when determining the duration of a fallowing period as vectors may play a role in the risk that a pathogenic agent is present and maintained in the environment.

Not for comment

	number of *aquaculture establishments*, should be considered in certain circumstances; **Rationale:** We suggest including vectors in this list because for some pathogens, vectors play a critical and significant role and risk in pathogen presence and duration in an environment. Fallowing and basic biosecurity conditions should take into account the presence (and absence) of vectors (which may be seasonal etc.) when developing control measures.	
4.X.7._7	**Category:** deletion **Proposed amended text:** 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~~, taking~~e~~ 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. **Rationale:** Reduce redundancy in repeating reference to the duration of the fallowing period	Agreed to editorial change to reduce redundancy.

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.

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.8._1	**Category :** addition **Proposed amended text** A simulation exercise should be designed upon realistic scenarios that reflect actual risks, with operational feasibility and 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. **Rationale:** Exercises should take in considerations specific pathogens affecting local aquaculture, consider the resources, infrastructure, and capabilities of the participating organizations, and incorporate local environmental and industry conditions into the simulation.	Agreed to the addition that a simulation exercise should be designed on realistic scenarios; however added the point at the end of the paragraph rather than in the first sentence.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.8._2	**Category :** addition **Proposed amended text** 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 in addition to communication protocols; **Rationale:** It is very important to simulate communication with the public and media as part of the exercise, include public awareness campaigns to test crisis messaging strategies.	Did not agree. Communication protocols are a component of the emergency disease preparedness framework as mentioned in point 4 and does not need to be repeated.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response

Not for comment

4.X.8._3	**Category :** revision **Proposed amended text** b) the readiness and capacity of the *Competent Authority*, ~~and~~ the *Aquatic Animal Health Services*, and relevant industry stakeholders to respond to the elements of the emergency disease preparedness framework, that were tested during the exercise. **Rationale:** For consistency between Articles (ex. 4.X.4), within the Article (point 3) and Chapters (4.X.Y)	Agreed, see response to comment 4.X.4._2.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.X.9._1	**Category :** revision **Proposed amended text** All revisions which are made as a result of the review process described above should be communicated to the *Aquatic Animal Health Services* and relevant industry stakeholders within an agreed timeframe. **Rationale:** For consistency between Articles (ex. 4.X.4, 4.X9.)	Agreed, see response to comment 4.X.4._2.

Article 4.X.10.

Response Options

Not for comment

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;

Not for comment

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.

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y._1	**Category:** General The Member supports the proposed changes in this Chapter for the purposes of improving clarity, understanding and member country disease outbreak management.	Noted
4.Y._2	**Category:** General The Member supports the changes proposed and has inserted comments within the text.	Noted
4.Y._3	**Category:** general The Member supports and appreciates the development of this new chapter by the Aquatic Animal Health Standards Committee. The new chapter is an important part of the section 4. It has important guiding significance for the prevention and control of specific and important diseases in aquatic animals. It is of great significance to maintain or restore the free status of the country and zone, promote the sustainable development of aquaculture, and ensure the safe and sustainable development of international trade.	Noted
4.Y._4	**Category:** General The Members support this new chapter.	Noted

Not for comment

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.3._1	**Category:** change **Proposed amended text :** 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~~free status. However, should the progression of the *outbreak* prevent this objective from being achieved, other actions should be described, which will assist the *Competent Authority* and the *Aquatic Animal Health Services* to pursue an alternative pathway to recovery; **Rationale:** Free status instead of freedom demonstrated the end of a changing process, from not free to free. The process includes not only Competent authority, but also aquatic animal health services.	Did not agree to change 'disease freedom' to 'disease free status'. As in Chapter 1.4. either term can be used. Will continue to use 'disease freedom' for consistency of usage within draft new Chapters 4.X. and 4.Y. Agreed to add 'Aquatic Animal Health Services' as activities towards recovery require them to work with the Competent Authority.
4.Y.3._2	**Category:** editorial **Proposed amended text:** 3) the ~~preferred~~~~initial response~~ objective following an infectious *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; **Rationale:** We recommend simplifying this sentence further to just read that the objective following a disease outbreak is to eradicate the pathogenic agent.	Did not agree to remove preferred objective because while the initial response objective is to eradicate this may not always be possible and other objectives may be required. Did not agree to add 'infectious' as this is inherent within the glossary definition of 'disease' (means clinical or non-clinical infection with one or more pathogenic agents).

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*.

Not for comment

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.4._1	**Category:** change **Proposed amended text :** 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*~~ *important diseases* as described in Article 4.X.1.6., 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; **Rationale:** Just in align with the previous articles.	Did not agree, the text distinguishes between the approach to be taken for listed and non-listed disease compared to emerging diseases. Important diseases may include those that are listed, non-listed or emerging.

~~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~~) 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;~~.~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.4._2	**Category:** change **Proposed amended text:** b~~c~~) gather information to determine the potential ~~if the~~ for *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	Did not agree Amendments were made to 1c in the Aquatic Animals Commission's September 2024 report to address a comment that information gathering may occur in the alert phase but activities will not fully

Not for comment

	surveillance as described in point 2 a), and contact tracing once the disease is confirmed. ~~which may commence during the alert phase and become fully applicable during the emergency phase, if the *disease* is 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).'	apply until the disease is confirmed. The text reflects this intent and is considered clear as written.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.4._3	**Category:** Deletion **Proposed amended text:** 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; **Rationale:** The qualification "highly" is not needed here. This section, 3)a), indicates that members should be evaluating risk when conducting surveillance, tracing, etc. In this example, all potential "connections" should be evaluated and inspected/sampled based on risk.	Agreed to remove the word 'highly' as it is not needed as the intent of this point is to evaluate the connections and associated risk.

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 (in language submitted)	Aquatic Animals Commission Response

Not for comment

4.Y.4._4	**Category:** change **Proposed amended text :** 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~~ with suitable capacity to produce reliable results in the shortest possible timeframe. **Rationale:** Equipped and staffed suitable is not enough to describe the laboratories identified in the Contingency plan. It is better to use 'suitable capacity' to cover all of the necessary elements of the laboratories.	Agreed to change for clarity.

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

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

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

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

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

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

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

5~~6~~) whilst confirmation of the presence of the *disease* in question is ongoing, the *Competent Authority* should communicate with relevant personnel, 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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.4._5	**Category:** Editorial **Proposed amended text:** 5) whilst confirmation of the *disease* in question is ongoing, the *Competent Authority* should communicate with relevant personnel, ~~relevant~~ industry stakeholders, diagnostic laboratories…" **Rationale:** unnecessary repetition	Agreed that 'relevant' does not need to be repeated as it is already indicated at the start of the list.
4.Y.4._6	**Category:** Revision **Proposed amended text:** 5) whilst confirmation of the presence of the *disease* in question is ongoing, the *Competent Authority* should communicate with the *Aquatic Animal Health Services* including relevant personnel, relevant industry ~~industry~~ stakeholders, diagnostic laboratories,	Agreed to include that the Aquatic Animal Health Services as communication on disease response should be communicated broadly. Also agreed to specify

Not for comment

	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.; **Rationale:** Communication of ongoing disease efforts should be communicated broadly to ensure awareness therefore inclusion of Aquatic Animal Health Services would cover off all applicable groups as all of the groups included within point 5 are part of the Aquatic Animal Health Services. In addition, 'industry' stakeholders should be reintroduced for consistency between articles (ex. Article 4.X.4), for the explicit addition of relevant industry stakeholders and as it could be argued that diagnostic laboratories, personnel and contractors could also be considered stakeholders. Inclusion of industry makes this reference more specific.	industry stakeholders for consistency between articles. Relevant was removed before industry to reduce redundancy as it is stated at the start of the list.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.4._7	**Category:** Change **Proposed amended text:** 7) should the suspicion not be confirmed, the alert phase is terminated by the Competent Authority, relevant ~~actors~~ stakeholders are informed that the situation is moving back to ~~peacetime~~ readiness. **Rationale:** Suggest replacing "actors" with "participants" or "stakeholders" here and elsewhere (use search tool), and in view of current world events, strongly consider replacing the word "peacetime" with "readiness" or "standby" status not only here, but throughout. Alternatively, if the term peacetime is considered appropriate and has been used from the very start in the context of development and preparation of the entire chapter, then keep the word, but add it to a glossary of definitions to define what the word actually means in this context.	Agreed to change 'actors' to 'stakeholders' for consistency in text. Did not agree to use an alternative word rather than 'peacetime'. Peacetime is a term that is widely used in disease preparedness and outbreak management including in other partner organisations. Amendments were made in Article 4.X.3. to clarify the use of the term 'peacetime'.

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:

Not for comment

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;

Not for comment

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~~;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.6._1	**Category:** Revision **Proposed amended text:** 5) agreed messages, format ~~for~~, and timing of, communications with the *Aquatic Animal Health Services* and other relevant industry 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~~; **Rationale:** For consistency of terminology between chapters for the explicit addition of industry stakeholders.	Did not agree to specify industry stakeholders. Stakeholders beyond the industry will need to receive relevant communications.

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.7._1	**Category:** change **Proposed amended text:** Appropriate facilities, skills, resources, personnel and skills. **Rationale:** Keep the context consistent.	Did not agree to add 'personnel and skills'. Skills are already included within the current title and is understood to mean skilled personnel.

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;

Not for comment

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:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.7._2	**Category:** Addition and editorial **Proposed amended text:** a) During the emergency, the Aquatic Animal Health Services and industry should submit samples to the accredited laboratories ~~which~~ that have been identified in the Contingency Plan". ~~Those~~ These laboratories… **Rationale:** Editorial for clarity. Laboratories diagnosing notifiable disease outbreaks should have minimum accreditations	Did not agree to specify that laboratories used during an emergency should be accredited. Information around the access to appropriate laboratories is adequately covered 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. As well, point 2) of Article 4.Y.7. goes into further detail on laboratories during an emergency outbreak.

Not for comment

		The Commission noted that appropriate laboratories must be identified by the Competent Authority, however accredited laboratories may not always be available during an emergency.
4.Y.7._3	**Category:** Revision **Proposed amended text:** a) During the emergency, the *Aquatic Animal Health Services* and relevant industry stakeholders 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: **Rationale:** For consistency between chapters for the explicit addition of industry stakeholders.	Agreed to specify relevant industry stakeholders for consistency between chapters.

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

Not for comment

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

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.7._4	**Category:** Addition and Editorial **Proposed amended text:** "c) predatory animal, vermin and bird control specialists" … "h) providers of vaccines/ veterinary medicines, ~~who~~ which can supply an appropriate number of doses and have a suitable lead-in time for delivery" **Rationale:** Vermin also a potential vector in need of control during an emergency response.	Agreed that rodents can be a potential vector along with other pest animals. Point c was modified to include 'pest' and bird control specialists.

ijg) 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;

jkh) 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 jkh) 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;

32) 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*;

43) 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;

54) specifying relevant *biosecurity* and other specific *disease* control measures including:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.8._1	**Category:** addition **Proposed amended text:**	Did not agree as 'relevant biosecurity measures' indicates that the measures put in place are

Not for comment

	5) specifying relevant biosecurity and dynamic other specific disease control measures including: **Rationale:** To better adapt plans and actions as the situation evolves, ensuring the response remains effective.	suitable for the situation even if it is dynamic and may change.

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.

Not for comment

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:

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Y.9._1	**Category:** Addition and editorial **Proposed amended text:** e) ongoing communication with Aquatic Animal Health Services and industry stakeholders to explain relevant details of the recovery plan and to reinforce the role the Aquatic Animal Health Services and industry stakeholders play in future disease prevention and control." **Rationale:** Suggest adding the word 'stakeholders' for consistency with previous text for clarity.	Agreed, the Commission specified relevant industry stakeholders for consistency in the chapter. The Commission also removed repetitive wording in the sentence.
4.Y.9._2	**Category:** Revision **Proposed amended text:** e) ongoing communication with *Aquatic Animal Health Services* and relevant industry stakeholders to explain relevant details of the recovery plan and to reinforce the role the *Aquatic Animal Health Services* and relevant industry stakeholders play in future *disease* prevention and control. **Rationale:** For consistency between chapters for the explicit addition of industry stakeholders.	Agreed, see response to comment 4.Y.9._1.

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z._1	**Category:** General The Member supports the changes proposed and has inserted comments within the text.	Noted
4.Z._2	**Category:** General The Member supports the proposed changes to this Chapter. We consider it a significant improvement compared to the current Aquatic Code. The farming of salmonids is a growing industry, with production in many countries and a growing market for trade in both fertilised eggs and gametes. It is therefore of great importance to have standards in place that are relevant to the framework under which the industry operates. The new chapter may also provide a framework for the development of similar standards for other farmed fish species.	Noted
4.Z._3	**Category:** General The Members' policy approach is to promote the achievement of disease-free status for countries, zones or compartments to facilitate trade between areas with a similar health status. The Members do not understand the rationale behind this chapter as it seems to discourage the achievement of the disease-free status for countries, zones or compartments, promoting the trade of gametes and fertilised eggs of fish from non free areas. The Members cannot support this new approach until it is confident that it provides an equivalent level of protection as the current system does. For this purpose, the European Food Safety Authority (EFSA) is currently working on a mandate from the European Commission for a scientific opinion on a risk assessment of viral haemorrhagic septicaemia (VHS), infectious haematopoietic necrosis (IHN) and infection with HPR-deleted infectious salmon anaemia virus (HPR deleted ISAV) introduction in areas declared free of those diseases related to the introduction of eggs, sperm and gametes of listed species originating from areas which are not free of those diseases. (https://open.efsa.europa.eu/questions/EFSA-Q-2024-00668). Therefore, the Members may not be in a position to support the adoption of this chapter at the next General Session, keeping it under scrutiny until the EFSA delivers the scientific opinion (currently planned for 30 November 2025). In addition, the Members invite the WOAH Aquatic Animals Commission to consider deleting the Articles on importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from certain diseases (Article 10.4.20 for infection from ISAV, 10.5.15 for infection with SAV, 10.6.15 for infection with IHNV and 10.10.15 for infection with VHSV) from the relevant disease specific chapters of the Aquatic Code concurrently with the adoption of this new chapter, as those	Noted See response in item 6.2. of the February 2025 report.

Not for comment

	provisions will be superseded by this new chapter and thus become superfluous.	

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*~~;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.1._1	**Categoría:** editorial / general **Propuesta modificación de texto:** Objetivo Brindar recomendaciones sobre el comercio de *gametos* ~~lecha~~ y *ovas fecundadas* ~~huevos fecundados~~ de peces destinados a ~~para~~ la *acuicultura* y definir la ~~mitigación~~ gestión del *riesgo* para su comercio a un *país*, una *zona* o un *compartimento libre* cuando: 1) la intención es el crecimiento y cosecha ~~la cría captura~~ de peces provenientes de *gametos* y *ovas fecundadas* ~~que han sido comercializados~~ ~~*animales acuáticos* importados~~; o **Justificación**: si bien se propone un cambio en la redacción, esto es solamente para hacer congruente este texto con la versión en inglés. Sin perjuicio de lo anterior, se sugiere eliminar este numeral pues las exigencias zoosanitarias serían las mismas que se aplicarían en ambos casos, no siendo necesario especificar entonces, el destino final de los productos importados. Es quizás importante que se considere igualmente como propósito final en repoblamiento de cuerpos de agua, lo que no está en el ámbito de la acuicultura.	Agreed, change made in the Spanish version of the chapter to improve the translation.

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~~.

Not for comment

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.2._1	**Categoría:** editorial **Propuesta modificación de texto:** Ámbito de aplicación Este capítulo describe las recomendaciones generales para el comercio seguro de *gametos* ~~lecha~~ y *ovas fecundadas* ~~huevos fecundados~~ de peces procedentes de un área distinta ~~que no sea un~~ *de un país*, una *zona*, ~~*país*~~ o un *compartimento libres* de *enfermedad*. En su conjunto, estas recomendaciones incluyen las medidas detalladas en el Artículo 4.Z.3. que disminuyen progresivamente el *riesgo* de transferencia de la infección a las *poblaciones de animales acuáticos* de un *país*, *zona*, ~~*país*~~ o *compartimento* libres de *enfermedad*. **Justificación**: coherencia con el texto en inglés.	Agreed, change made in the Spanish version of the chapter to improve the translation.

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:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.3._1	**Categoría:** cambio **Propuesta modificación de texto:** El comercio de *gametos* ~~lecha~~ y *ovas fecundadas* ~~huevos fecundados~~ de peces procedentes de un *país*, una *zona* o *compartimento* que no hayan sido declarados libres de infección por las *enfermedades* ~~de preocupación~~ *de la lista de la OMSA* deberá cumplir con los siguientes requisitos: **Justificación:** No existe definición para "*enfermedades de preocupación*". Este concepto genera incertidumbre respecto del ámbito de las recomendaciones establecidas en estos documentos.	Did not agree, 'listed disease' is a glossary term and its definition refers to the list in Chapter 1.3. By adding 'of concern' this sentence is referring to the listed disease(s) that are being controlled through the specific measures described.

Not for comment

1) the health status of the broodstock at the *aquaculture establishment* of origin mustshould 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 movementsupply to *collection and incubation centres*, as described in Article 4.Z.4.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.3._2	**Categoría:** cambio **Propuesta modificación de texto:** 1) deberá determinarse el estatus sanitario de la población reproductora en el *establecimiento de acuicultura* de origen deberá determinarse. Solo las poblaciones reproductoras que demostraron demuestren estar libres de *agentes patógenos* de la lista de la OMSA de preocupación, tal como se describe en el apartado 3 del Artículo 4.Z.4., serán aptas para el movimiento a suministro de los *centros de recolección e incubación*, tal como se describe en el Artículo 4.Z.4.; **Justificación:** No existe definición para "agentes patógenos *de preocupación*". Este concepto genera incertidumbre respecto del ámbito de las recomendaciones establecidas en estos documentos. Para mejorar la redacción se propone modificar demostraron por demuestren.	Did not agree. See response to 4.Z.3._1.
4.Z.3._3	**Category:** addition **Proposed amended text:** 1) the health status of the broodstock at the *aquaculture establishment* of origin must be determined (health records and batch-specific testing results for pathogen of concern). **Rationale:** For clarity	Did not agree to add details to this point as the requirement for health records and testing results are covered in Article 4.Z.4.

2) *gametes*milt and *fertilised eggs* mustshould originatecome 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;

43) the *fertilised eggs* mustshould behave 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);

54) when intended for *international trade*, the consignment mustshould be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* statingwhich should state that the *gametes*milt and the *fertilised eggs* originatecome from parents which have been individually tested and are negative for tested free from the relevant *pathogenic agentdisease*, and which meet the requirements in points 1, and 2 and 4.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.3_4	**Category:** addition **Proposed Amended Text:**	Agreed to add text that the Competent Authority of the importing country requires the accompaniment of a health

Not for comment

	when intended for *international trade*, the Competent Authority of the importing country should require that the consignment ~~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. **Rationale:** For consistency with the wording in the disease specific chapters that the onus for requiring an export certificate is on the importing country. While it may be the opinion of The Member that every consignment of gametes and fertilised eggs must require an export certificate, this decision should be made by each importing Competent Authority.	certificate to be consistent with wording in disease-specific chapters.
4.Z.3._5	**Category:** deletion **Proposed amended text:** 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. **Rationale:** While it is important that the gametes/fertilized eggs originate from parents that are negative for pathogens of concern, testing (via lethal methods in many cases) of each individual may not be the only way to determine the health status of a given broodstock population.	Did not agree. Individual testing is important to determine health status of the broodstock population.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.4_1	**Category:** Amendment **Proposed Amended text:** 1) the *aquaculture establishment* ~~it~~ ~~should~~ must be approved for that purpose by the *Competent Authority* and be under its official control; **Rationale:** For consistency with Article 4.Z.3. point 2 which indicates gametes and fertilised eggs must originate from a	Agreed to change 'should' to 'must' for consistency with Article 4.Z.3. point 2.

Not for comment

	collection and incubation centre which has been approved for that purpose	

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.4._2	**Categoría:** editorial **Propuesta modificación de texto:** a) 1) ~~los establecimientos de acuicultura~~ deberán estar aprobados a tal efecto por la *autoridad competente* y estar bajo su control oficial; b) 2) ~~deberán implementar contar con~~ contar con *plan de bioseguridad* implementado ~~deberá implementarse,~~ elaborado de conformidad con lo previsto en el Capítulo 4.1.; **Justificación:** optimización de redacción en español	Agreed, change made in the Spanish version of the chapter to improve the translation.

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*;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.4_3	**Category: General/change** **Proposed amended text:** 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%,~~ freedom as described in Article 1.4.16. 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 for very small populations of high value broodstock, where no non-lethal, pre-collection sampling is available, broodstock should be isolated for the length of the incubation period for the diseases of concern, and remain health, before movement to a collection and incubation centre. **Rationale and supporting evidence:** 1st change: Considerations for design prevalence are presented in Article *1.4.16.* In the case of diseases that are transient or less contagious, these diseases may require a lower design prevalence at the establishment-level. For ISAV HPR0, a design prevalence of 1% may be more appropriate given the transient nature of ISAV HPR0 (Aamelfot et al., 2016; Christiansen et al., 2011; Pietrak et al., 2024) and the annual low-level sampling	1st proposed change: Agreed to add text to point 3 to reflect that if justified by epidemiological evidence a lower design prevalence should be used. 2nd proposed change: Did not agree, testing is essential before the movement of animals. For high-value broodstock where non-lethal testing methods are not available, compartments can be utilised to facilitate trade. Point 3 does not exclude non-lethal testing therefore if a validated non-lethal test was added to the *Aquatic Manual* in the future, the test could be covered by this point.

Not for comment

	prevalence detected in some facilities reported in the literature (Christiansen et al., 2021; Jónsson, 2023). This may be a consideration until more disease-specific evidence on the required surveillance design to detect and the consequence of occurrence of low-level ISAV-HPR0 infections supports an alternative strategy. 2nd change: Point 3 of Article 4.Z.4 does not allow for sampling of high values small populations. It requires testing of broodstocks before movement to a collection and incubation centre. For some diseases there are no validated non-lethal sampling method or the only validated non-lethal tests are on ovarian fluid or milt (making the animal useless for collection) included within the Aquatic Manual. Therefore point 3 Article 4.Z.4 implies that lethal testing of the broodstock population is required before movement to a collection and incubation centre. Some broodstock are high value with small population sizes, therefore lethal sampling at a 2% prevalence and 95% confidence would require lethal testing of the entire population. Aamelfot 2016 - Localised infection of Christense 2011 - a low path variant of IS Christensen 2021 - No Evidence of the V aquaculture-surveillance-program-disease Pietrak 2024 - Intermittent Detectio	

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;~~

Not for comment

~~c) milt testing and storage;~~

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

~~eb) an incubation ofcentre 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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.6._1	**Category:** change **Proposed amended text:** 1) … c) ~~milt~~ gametes testing and storage; **Rationale:** For clarity	Did not agree, this point refers specifically to milt as disinfection and incubation is reflected in points 1(d) and 1(e). Storage was changed to cryopreservation to more specifically reflect the intention of the word.

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;

Not for comment

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.6._2	**Category:** Change **Proposed amended text:** 7) After removal of eggs or after the last collection of milt, each broodstock should be either euthanized or returned to the aquaculture establishment ~~after removal of eggs or after the last collection of milt~~; **Rationale:** It may be preferred that the fish are not killed after gamete collection. For example, sturgeon take at least 7 years to reproduce and non-lethal gamete collection occurs.	Did not agree, the purpose is to know the health status of each individual broodstock. However, point 7 was removed from this article as it does not fit with the focus of the article and is covered by point 2 of Article 4.Z.7.
4.Z.6._3	**Category:** Addition **Proposed amended text:** 7) each broodstock should be euthanized after removal of eggs or after the last collection of milt or immediately returned to the broodstock aquaculture establishment (if repeat spawners) **Rationale:** This, as written, does not allow for high value repeat spawners. Recommend changing wording to allow for survival of broodstock as necessary.	Did not agree. See response to comment 4.Z.6._2.
4.Z.6._4	**Categoría:** eliminación **Propuesta modificación de texto:** ~~7) cada reproductor deberá ser sacrificado tras la extracción de las ovas o tras la última recolección de *gametos*;~~ **Justificación:** no se justifica la eliminación de los reproductores salvo por la eventual positividad a alguna de las enfermedades de la OMSA o de aquellas que cada país tenga bajo programa de control.	Did not agree. See response to comment 4.Z.6._2.
4.Z.6._5	**Category:** addition **Proposed amended text:** 7) each broodstock should be euthanized after removal of eggs or after the last collection of milt~~;~~. Proper disposal of euthanized broodstock should follow guidelines outlined in the International Aquatic Animal Health Code or relevant national and local regulations. **Rationale:** For clarity	Did not agree, point 7 was removed. See response to comment 4.Z.6._2.

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;

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.6._6	**Category:** editorial **Proposed amended text:** 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~~ disposed of in biosecure manners in accordance with Chapter 4.8. **Rationale**: In order to minimize the risk that pathogenic agents released from infected and discarded fertilised eggs may be transmitted to aquatic animals, it is necessary to dispose of the infected fertilised eggs in a biosecure manner in accordance with Chapter 4.8.	Agreed to replace 'discarded' with a link to Chapter 4.8.

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*;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.7._1	**Category:** addition **Proposed amended text:** 1) stripping or pressing milt from dissected testes and sampling should be carried out **Rationale:** Stripping cannot be done for many fish species. For example, the males of the African catfish cannot be stripped and the sperm can only be obtained by sacrificing (not stripping). The male is killed and the body surface thoroughly dried after which the testis is dissected and placed in a mortar. The testis is rapidly cut into small pieces using a scissor and finally the milt is pressed out with a pestle or a teaspoon (https://www.fao.org/4/w3595e/w3595e05.htm).	Agreed, changed the wording of point 1 and used 'extraction of gametes' instead of stripping as stripping cannot be done for all fish species.

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 (in language submitted)	Aquatic Animals Commission Response

Not for comment

4.Z.7._2	**Categoría: cambio** **Propuesta modificación de texto:** 1) En el momento de la extracción, se tomarán muestras individuales de las poblaciones reproductoras y se les someterá a pruebas de detección de las enfermedades listadas ~~de los peces de la lista de enfermedades de la OMSA~~, de conformidad con los métodos de diagnóstico descritos en el *Manual Acuático*, en un laboratorio autorizado por la *autoridad competente*. **Justificación:** coherencia con texto en inglés	Agreed, change made in the Spanish version of the chapter to improve the translation.

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.7._3	**Category:** Addition **Proposed amended text:** 32) fish that test positive, and any *gametes* or *fertilised eggs*~~milt or eggs~~ derived from them should not be traded; and the importing country may consider further risk mitigation measure for any gametes or fertilized eggs that are epidemiologically linked to the fish that test positive **Rationale:** Depending on the disease, species, level of contamination and efficacy of egg disinfection, member countries should be able to apply additional mitigations measure for trade for any fish, gametes or fertilized eggs that are epidemiological link to positive animals.	Did not agree, this is already addressed in Article 4.Z.3. point 3 indicating that the Competent Authority of the importing country should assess the risks associated and take all relevant factors into account in regards to the trade of gametes and fertilised eggs of fish.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.7._4	**Category:** General comment **Rationale:** There could be a scenario where the disease detected is established in - or endemic to - the country or zone where it is detected, but may be a disease of concern to an importing country, in which case the disease detection may simply prevent export to one country and not another so the destruction of gametes and broodstock may not be required.	Did not agree, the purpose of collection and incubation centres is to produce gametes that are free of disease. As such, any positive broodstock and the gametes linked to positive broodstock should be destroyed.

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.~~

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.7._5	**Category:** change **Proposed amended text :** 6) *fertilised eggs* should be surface disinfected using a method proven to ~~inactive~~inactivate *pathogenic agents*, for salmonid eggs in accordance with the protocol ~~as~~ described in Article 4.5.2.;~~Chapter 4.5.~~ **Rationale:** We recommend this sentence as revising the word "inactive" to “inactivate”.	Agreed, editorial change.
4.Z.7._6	**Category:** change **Proposed amended text :** 6) fertilised eggs should be surface disinfected using a method proven to ~~inactive~~inactivate pathogenic agents, for salmonid eggs in accordance with the protocol ~~as~~ described in Article 4.5.2.;~~Chapter 4.5.~~ **Rationale:** We recommend this sentence as revising the word "inactive" to “inactivate”. **Supporting evidence:** not relevant	Agreed, see response to comment 4.2.7._5.
4.Z.7._7	**Category:** change **Proposed amended text:** 6) *fertilised eggs* should be surface disinfected using a method proven to ~~inactive~~ inactivate *pathogenic agents*, for salmonid eggs in accordance with the protocol ~~as~~ described in Article 4.5.2.;~~Chapter 4.5.~~ **Rationale:** editorial suggestion	Agreed, see response to comment 4.2.7._5.
4.Z.7._8	Commission suggestion **Category:** deletion **Proposed amended text:** deletion of point 7 **Rationale:** The requirement of surface disinfection of fertilized eggs is covered by point 4 of Article 4.Z.3. and does not fit with the content of the rest of Article 4.Z.7 which focuses on testing of broodstock.	The Commission proposed to remove point 7 as it is already covered by point 4 of Article 4.Z.3.

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*~~;

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.Z.8._1	**Category:** change **Proposed amended text:** 4) frozen milt should be stored in hermetically sealed containers at ~~a~~ species-specific optimal temperatures to maintain their viability in a separate room. **Rationale:** Matching noun-verb tenses.	Agreed, editorial change.

Not for comment

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 (in language submitted)	Aquatic Animals Commission Response
10.X.10._1	**Category:** General Pending the outcome of the risk assessment already mentioned in the Members comments *to Annex 7. Item 6.2. – Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'*, the Members may not be in a position to support the adoption of these articles at the next General Session, keeping them under scrutiny until the EFSA delivers the scientific opinion (currently planned for 30 November 2025).	See response in item 6.2. of the February 2025 report.

Not for comment

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~~ point~~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 *fertilised*~~*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 fertilised~~*fertilized eggs*~~.

[…]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.10_2	**Category:** Change **Proposed change:** **1)** If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following: Either~~Either~~ [---] Or~~Or~~ d)~~d) apply the requirements of Chapter 4.Z.~~apply the requirements of Chapter 4.Z. regarding *gametes* or *fertilized eggs*.~~ **OR**	Agreed to the rationale that with points 1(d) and 2(c) of 10.X.10 referring to Chapter 4.Z., an alternative option to 10.X.15. is provided, which has a different level of risk mitigation. Point 1(d) and 2(c) were changed to refer to Article 10.X.15. to avoid this unintended choice.

Not for comment

	2) If the intention is to establish a new stock for *aquaculture*, consider applying the following: ~~Either~~Either [---] ~~Or~~Or c)~~c) apply the requirements of Chapter 4.Z.~~ apply the requirements of Chapter 4.Z. regarding ~~*gametes*~~ or ~~*fertilized eggs.*~~ **Rationale:** The Member agrees that gametes and fertilized eggs should have 2 options for import into a country, into a life long quarantine (10.X.10) or in compliance with the new chapter 4.Z. However, the Member is of the opinion that import control of gametes and fertilized egg not destined into quarantine (in compliance with 4.Z) should not be listed in two locations in the within each disease specific chapter with different levels of risk mitigation. Therefore the Member proposes to delete the OR options for Point 1 and 2. Point 1) d) and point 2) c) refer to chapter 4.Z. which does not describe what member countries should do with packaging water, effluent, packaging material and equipment which is described in points 2, 3, 4 and additional wording from 10.X.15. The trade requirements when in compliance with Chapter 4.Z, as proposed in 10.X.10 is less stringent than the requirements listed in 10.X.15. This adds inconsistency to the Aquatic code and allows for member countries to hold other members to different trade restrictions.	

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.15._1	**Category:** addition **Proposed amended text:** In this article, all statements referring to infection with ISAV are for any detectable ISAV strain, including HPR0 ISAV. **Rationale:** Clarity	Did not agree, for consistency with the rest of the chapter, the word 'strain' should not be added.

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 fertlised*~~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;

Not for comment

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 fertilised~~*fertilized* eggs.~~

[…]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.15_2	**Category:** Change **Proposed change:** **1)** If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following: Either~~Either~~ [---] 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 [---] Or~~Or~~ c)~~c) apply the requirements of Chapter 4.Z.~~ apply the requirements of Chapter 4.Z. regarding *gametes* or ~~*fertilized eggs.*~~ **Rationale:** The Member agrees that gametes and fertilized eggs should have 2 options for import into a country, into a life long quarantine (10.X.10) or in compliance with the new chapter 4.Z.	Agreed to the rationale that with points 1(d) and 2(c) of 10.4.15 referring to Chapter 4.Z., an alternative option to 10.4.20. is provided, which has a different level of risk mitigation. Point 1(d) and 2(c) were changed to refer to Article 10.4.20. to avoid this unintended choice.

Not for comment

	However, The Member is of the opinion that import control of gametes and fertilized egg not destined into quarantine (in compliance with 4.Z) should not be listed in two locations in the within each disease specific chapter with different levels of risk mitigation. Therefore the Member proposes to delete the OR options for Point 1 and 2. Point 1) d) and point 2) c) refer to chapter 4.Z. which does not describe what member countries should do with packaging water, effluent, packaging material and equipment which is described in points 2, 3, 4 and additional wording from 10.X.15. The trade requirements when in compliance with Chapter 4.Z, as proposed in 10.X.10 is less stringent than the requirements listed in 10.X.15. This adds inconsistency to the Aquatic code and allows for member countries to hold other members to different trade restrictions.	

_____

Not for comment

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 (in language submitted)	Aquatic Animals Commission Response
10.X.15._1	**Category:** General The Member supports the changes proposed and has inserted comments within the text.	Noted
10.X.15._2	**Category:** General The Members support all modifications made on Annex 9	Noted
10.X.15._3	**Category:** General Pending the outcome of the risk assessment already mentioned in the Members comments *to Annex 7. Item 6.2. – Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'*, the Members may not be in a position to support the adoption of these Articles at the next General Session, keeping them under scrutiny until the EFSA delivers the scientific opinion (currently planned for 30 November 2025). In addition, the Members invite the WOAH Aquatic Animals Commission to consider deleting the Articles on importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from certain diseases (Article 10.4.20 for infection from ISAV, 10.5.15 for infection with SAV, 10.6.15 for infection with IHNV and 10.10.15 for infection with VHSV) from the relevant disease specific chapters of the Aquatic Code concurrently with the adoption of this new chapter, as those provisions will be superseded by this new chapter and thus become superfluous.	See response in item 6.2. of the February 2025 report.

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:

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.15._2	**Category:** addition **Proposed Amended text:** The Competent Authority of the importing country should require that the consignment be accompanied by ~~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. **Rationale:** For consistency with the wording in the other articles of the disease specific chapters that the onus for requiring an export certificate is on the importing country. While it may be the opinion of the Member that every consignment of gametes and fertilised eggs must require an export certificate, this decision should be made by each importing Competent Authority.	Agreed to the addition for consistency with the wording in other articles of the disease-specific chapters.
10.X.15._3	**Category:** Clarification Is there any specific recommendation available in the Aquatic Code on the disinfection of gametes? **Rationale:** The title of Article 10.X.15 covers both gametes and fertilised eggs; however, only the recommendation on the surface disinfection of salmonid eggs (Chapter 4.5) is referred to in point 2.	No, there are no specific recommendations on the disinfection of gametes available in the *Aquatic Code*. Gametes are covered by other measures, including the new chapter and other articles in the disease-specific chapters.

~~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~~

Not for comment

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.

[…]

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.20_1	**Category:** change **Proposed amended text :** In this article, all statements referring to infection with ISAV ~~includes~~ include HPR-deleted ISAV and HPR0 ISAV. **Rationale:** We recommend this sentence as revising the word " includes" to “include”.	Agreed, editorial change.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.20._2	**Category:** addition **Proposed Amended text:** The Competent Authority of the importing country should require that the consignment be accompanied by ~~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.	Agreed, see response to comment 10.X.15._2

Not for comment

	Rationale: For consistency with the wording in the other articles of the disease specific chapters that the onus for requiring an export certificate is on the importing country. While it may be the opinion of the Member that every consignment of gametes and fertilised eggs must require an export certificate, this decision should be made by each importing Competent Authority.	
10.4.20_3	**Category:** Clarification and Editorial change **Clarification**: Is there any specific recommendation available in the Aquatic Code on the disinfection of gametes? The title of Article 10.4.20 covers both gametes and fertilised eggs; however, only the recommendation on the surface disinfection of salmonid eggs (Chapter 4.5) is referred to in point 2. **Proposed amended text:** Editorial change (numbering): "point 4, 5 and 6" should be changed to "point 2, 3 and 4" **Rationale:** to improve a logical order	See response to comment 10.X.15_3. Agreed to the editorial change

~~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.~~

[…]

Not for comment

Glossary

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Glossary_1	**Category:** General The Member supports the changes proposed and has inserted comments within the text.	Noted
Glossary_2	**Category:** General The Members support the revised definitions.	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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Glossary_3	**Category:** addition **Proposed amended text:** means a facility approved by the *Competent Authority* in conformity with the provisions of Chapter 4.Z. for holding and potential grow out of broodstock, the collection of eggs, fertilisation and incubation, and the collection, processing, and storage of milt. **Rationale and supporting evidence:** Some aquaculture premises may identify replacement brood stock at early production stages (i.e. smolt) and transfer them to a brood facility or collection and incubation centre. The intention is that these fish will be raised and grown out for a couple years within that dedicated facility before reaching spawning age. Removing these fish early from the commercial production system and raising them in a designated facility will reduce the likelihood for exposure to diseases.	Did not agree, the purpose of a collection and incubation centre is for bring broodstock in for the purpose of extracting gametes, and not for grow-out. However, the current definition does not prohibit the potential for grow-out of broodstock.

[...]

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.

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Glossary_4	**Category:** support The Member supports this change as green eggs has different meanings in different regions. This amendment will provide clarity for Members.	Noted
Glossary_5	**Categoría:** editorial **Texto modificado propuesto:** ~~*HUEVO*~~ *OVA FECUNDADA* designa un óvulo fecundado y viable de *animal acuático*. La expresión «ovas sin ojos ~~huevos verdes~~» se aplica a los óvulos de peces recién fecundados. La expresión «ovas embrionadas ~~huevos embrionados~~» designa las ~~los~~ ~~*huevos*~~ *ovas fecundadas* de peces ~~*fecundados*~~ en que son visibles los ojos del embrión y que pueden ser transportadas ~~transportados~~. **Justificación:** Mejorar la redacción	Agreed, change made in the Spanish version of the chapter to improve the translation.
Glossary_6	**Category:** deletion **Proposed amended text:** *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. **Rationale:** Repeated use of "*fertilized eggs*" in the same sentence is redundant and reduces clarity.	Agreed, removed the repetition of 'fertilised eggs' in the second half of the definition.

[...]

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Glossary_7	**Category:** Change **Proposed amended text:** ORNAMENTAL AQUATIC ANIMAL means an aquatic animal that is reared or kept in captivity for the production of any commercial aquatic animals intended for subsequent display, exhibition,	Agreed, text added to reflect this comment and clarify it is referring to aquatic animals supplied for sale as a pet and not include those aquatic animals kept as pets in an individual household.

Not for comment

	competition. or to be kept as a pet; or for breeding for these purposes. Ornamental aquatic animals kept exclusively as pets within a single household, with no direct or indirect contact with other *aquatic animal populations* or *aquaculture establishments* and not intended to enter the supply chain, are excluded from ornamental aquatic animals. **Rationale:** The definition of "ornamental aquatic animals" should not include aquatic animals kept as pets in individual households that do not enter the supply chain and have contact with other breeding or commercial facilities for aquatic animals. The definition should be modified to be analogous to the wording used in the definition of "poultry" specified in the glossary of the WOAH Terrestrial Animal Health Code where the definition is as follows: *poultry* means all birds reared or kept in captivity for the production of any commercial animal products or for breeding for this purpose, fighting cocks used for any purpose, and all birds used for restocking supplies of game or for breeding for this purpose, until they are released from captivity. Birds that are kept in a single household, the products of which are used within the same household exclusively, are not considered *poultry*, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities. Birds that are kept in captivity for other reasons, including those that are kept for shows, racing, exhibitions, zoological collections and competitions, and for breeding or selling for these purposes, as well as pet birds, are not considered *poultry*, provided that they have no direct or indirect contact with *poultry* or *poultry* facilities. **Supporting evidence:** WOAH Terrestrial Code	

[...]

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X._1	**Category:** General Ornamental aquatic animals are among the most highly traded live animal commodities, presenting significant biosecurity risks with limited risk mitigation measures available. These animals often carry pathogens asymptomatically, but when stressed, they can develop diseases, shed high pathogen loads, and transmit these pathogens to susceptible naïve populations, causing substantial economical and ecological impacts. The international supply chain for ornamental aquatic animals is extensive and complex, often involving the mixing of populations with varying health statuses on a large scale. Many member countries lack adequate risk management systems to address those challenges. They require clear, fundamental guidance on managing risks, rather than being directed to intricate risk analysis methodologies. The proposed chapter does not sufficiently address the unique nature of the management of biosecurity risks associated with the movement of ornamental aquatic animals through such complex supply chains. Moreover, the likelihood of emerging diseases, such as the case of koi herpesvirus, is high in expansive supply chains. Therefore, this chapter should include a focus on the risk associated with emerging diseases linked to the trade of ornament aquatic animals and suggest generic biosecurity measures member countries can take to prevent occurrence of emerging diseases. Additionally, specific guidance is needed for responding to pathogen detection in imported ornamental aquatic animals, particularly concerning the demarcation of response activities across pre-border, border, and post-border stages, as these boundaries are often unclear. Recommendations on the extent of necessary tracing, as part of responding to such a detection would be beneficial.	The Commission acknowledges that the supply chain for ornamental aquatic animals is complex. Addressing risk using risk assessment is referenced through Chapter 5.X. to address the biosecurity risks of movements of aquatic animals. This includes Article 5.X.7. on risk analysis of which risk assessment is an important component. As well as Article 5.X.9. on risk management measures in the importing country. In regards to emerging disease, the scope of the chapter includes emerging diseases and all recommendations in the chapter apply to emerging diseases. The scope can be found in Article 5.X.2. where it states 'other diseases identified as hazards'. Hazard is a defined term in the Glossary and includes a biological, chemical or physical agent with the potential to cause an adverse effect on aquatic animal health or public health. An emerging disease of concern would be considered a disease identified as a hazard. Specific guidance for emergency disease preparedness and outbreak management can be found in new draft chapters 4.X. and 4.Y. The recommendations in these chapters would apply to disease in ornamental aquatic animals.
5.X._2	**Category:** General The Member supports this new chapter and thanks the Commission for their efforts for its development.	Noted
5.X._3	**Category:** General The Members support this new chapter.	Noted

Not for comment

SECTION 5

TRADE MEASURES, IMPORTATION/EXPORTATION PROCEDURES AND HEALTH CERTIFICATION

CHAPTER 5.X.

MOVEMENT OF ORNAMENTAL AQUATIC ANIMALS

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X._4	**Category:** change **Proposed amended text :** International ~~M~~movement of ornamental aquatic animals. **Rationale:** Chapter 5.X Movement of ornamental aquatic animals mainly describes the international movement of ornamental aquatic animals involving disease risk analysis, risk management measures of exporting countries, ports of entry and importing countries, and aquatic animal welfare measures. In fact, movement can be divided into domestic and international movement. International movement includes entry,exit and transit. In view of the content of this chapter, it is recommended to change the title to International Movement of Ornamental Aquatic Animals.	Did not agree, the recommendations in this chapter are intended for international movements but may also be relevant for domestic movements of ornamental aquatic animals depending on the sanitary situation of a member and the presence of free zones or compartments.

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~~.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.1_1	**Category:** change **Proposed amended text:** 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*,excluding those non-artificially bred animals as specified in Appendix 1 of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). **Rationale:** According to the CITES Convention, specimens of an animal species listed in Appendix I, if bred in captivity for commercial purposes or of a plant species listed in Annex I, are artificially cultivated for commercial purposes, shall be regarded as specimens of the species listed in the appendix. Appendix I contains all species arising from and potentially vulnerable to extinction due to trade effects. The trade of these species	Did not agree, the scope of this chapter includes the new glossary definition which defines what is an ornamental aquatic animal.

Not for comment

	specimens must comply with very strict rules that do not further endanger their survival, and trade permits may be allowed only with some exceptions.	
5.X.1._2	**Category:** change **Proposed amended text:** This chapter provides recommendations to address the *risk* of pathogenic agent ~~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~~ **Rationale:** pathogenic agents cause infectious disease.	Agreed to use pathogenic agent as it is a defined glossary term in the Aquatic Code.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.1._3	**Categoría:** Cambio **Propuesta modificación de texto:** Los *animales acuáticos ornamentales* suelen provenir de un entorno silvestre o de *establecimientos de acuicultura*. Una vez que entran en la cadena de suministro, pueden estar epidemiológicamente separados de las poblaciones de cría o silvestres, pero también pueden destinarse a otros usos finales, distintos de los iniciales. Esto puede constituir una vía de transmisión ~~de la *enfermedad*~~ del patógeno y poner en *peligro* a otras poblaciones de *especies susceptibles*. **Justificación:** Se propone utilizar el concepto transmisión del patógeno en concordancia con el primer párrafo de este artículo.	Agreed, to change 'disease transmission' to 'transmission of pathogenic agents' for consistency within the article.
5.X.1._4	**Category:** addition **Proposed amended text:** Similar to other commodities, ~~O~~*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*. **Rationale:** We agree that in general "ornamental aquatic animals" may originate from the wild or an aquaculture establishment, and there may be a risk of a given commodity being diverted to an end use for which it was not intended, but these characteristics are not unique to just ornamental aquatic animals. This addition is intended to support the statements regarding potential challenges to the movement of ornamental aquatic animals, while also taking into consideration that members face similar challenges with other aquatic animal commodities/end uses.	Did not agree, the trade of live aquatic animals, the origin and end-use of ornamental aquatic animals are specific and not similar to other commodities. The specificity of this situation is why this chapter is required.
5.X.1._5	**Category:** change **Proposed amended text:** **…** This may provide a pathway for pathogen ~~*disease*~~ transmission and place other populations of *susceptible species* at *risk*.	Agreed, see response to comment 5.X.1._3.

Not for comment

	Rationale: The term “pathogen” highlights the movement of the infectious agent itself, independent of whether it causes disease in the new host. The term “disease” is less precise because it conflates pathogen spread with the outcome (disease). Not all transmission events result in disease, making this term potentially misleading in scientific discussions.	

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 (in language submitted)	Aquatic Animals Commission Response
5.X.1._6	**Category:** Change **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~~ pathogen 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~~ pathogen transmission. These characteristics of the movement of ornamental aquatic animals may present challenges for managing aquatic animal disease risks **Rationale:** For accuracy and consistency with the rest of the chapter.	Agreed, see comment 5.X.1._3.
5.X.1._7	**Category:** addition **Proposed amended text:** **…** Supply chains may involve the aggregation of animals from multiple sources and their dissemination through retail trade as pets or for display, providing opportunities for *disease* transmission. These characteristics of the movement of *ornamental aquatic animals* may present challenges for managing *aquatic animal disease risks*. **Rationale:** In the case of ornamental aquatic animal trade, the animals may be disseminated through retail trade either as pets, or for display. Both end uses/routes provide opportunities for disease transmission.	Agreed that ornamental aquatic animals may be used for display. Added ‘for competition’ to be inclusive of this use and to be consistent with glossary term.

Article 5.X.2.

Scope

Not for comment

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 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 (in language submitted)	Aquatic Animals Commission Response
5.X.3._1	**Category:** General comment **Proposed amended text:** n/a **Rationale:** Consider if the term 'importer' should be in the glossary.	Did not agree. Definitions are only included in the glossary of the *Aquatic Code* if the usage and definition of that word/term differs from the common definition of the word. As such, the commonly understood definition of importer is applicable for this term and does not need to be added to the glossary.
5.X.3._2	**Categoría:** Supresión **Propuesta modificación de texto:** Se propone eliminar el texto **Justificación:** Se propone eliminar el párrafo dado que el texto propuesto para la elegibilidad no es concordante con el ámbito sanitario al cual debe ser enfocado el capítulo.	Did not agree to delete point 1 as the eligibility of an import is an important factor that should be duly considered prior to the development of the import procedures.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.3._3	**Category:** Editorial **Proposed amended text:** 2) ornamental aquatic animals intended for international movement should be clinically healthy at the time of movement, not knowingly exposed to animals… **Rationale:** Consider addition for accuracy.	Did not agree, it is not necessary to include 'knowingly exposed animals', as this is a subjective measure. It is considered accurate as written.

Not for comment

5.X.3._4	**Categoría:** Editorial **Propuesta modificación de texto:** Los *animales acuáticos ornamentales* destinados a ser transportados en el marco de movimientos internacionales deberán estar clínicamente sanos ~~en el momento~~ desde el inicio del desplazamiento, no deberán estar expuestos a animales de un estatus sanitario inferior y no deberán provenir de un establecimiento en el que se registre o se haya registrado recientemente una *enfermedad* o mortalidad inexplicables ~~recientemente~~, tal como se describe en el Artículo 5.X.5. **Justificación:** Se propone modificar el texto a fin de mejorar el entendimiento de este en cuanto a que lo animales deben encontrarse clínicamente sanos desde el inicio del desplazamiento dado que en el momento se puede entender como durante el desplazamiento lo cual operativamente muchas veces no es factible de modificar.	Did not agree. The intent of point is that animals be healthy when they are moved. The time of movement is a distinct time period and changing to the beginning would create uncertainty.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.4_1	**Category:** change **Proposed amended text :** Prior to~~consulting the *Competent Authority* with responsibility for *aquatic animal* health concerning considering the *aquatic animal* health *risks* associated with~~ application for the import of a species of *ornamental aquatic animal*, an importer~~the *Competent Authority* of an *importing country*~~should first consult the Competent Authority and 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~~	Did not agree, it is the responsibility of the importer to determine that an import will be compliant with all requirements for import. This includes understanding the policies, practices and relevant legislation and international obligations prior to import.

Not for comment

	Rationale: An importer should consult the competent authorities before importing and confirm whether it complies with international and domestic regulations.	
5.X.4._2	**Category:** change **Proposed amended text:** 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 and exporter ~~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~~. **Rationale:** The exporter should equally ensure compliance to international obligations by providing evidence or proof that live ornamental species are free from notifiable diseases /pathogens or diseases of national interest of importing countries. This will reduce the risk of introductions	Agreed, added 'exporter' as the exporter also holds responsibility in ensuring that international obligations are met.

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 (in language submitted)	Aquatic Animals Commission Response
5.X.4._3	**Categoría:** Supresión **Propuesta modificación de texto:** Se propone eliminar el texto **Justificación:** Se propone eliminar el párrafo dado que el texto propuesto para la elegibilidad no es concordante con el ámbito sanitario al cual debe ser enfocado el capítulo.	Did not agree to delete text. See response to comment 5.X.3._2.
5.X.4._4	**Category:** general **Proposed amended text:** 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~~ from being traded, owned or farmed due to the risks (as informed by a *risk assessment*) they present to biodiversity, ecosystems, industry, ~~or~~ public amenity or public health in the *importing country*. **Rationale:** - Improved wording so it reads better - Risks should be informed by a risk assessment	Did not agree, legislation in a country may be informed by other factors other than risk assessment.

Article 5.X.5.

General health status of ornamental aquatic animals

Reference	Comment (in language submitted)	Aquatic Animals Commission Response

Not for comment

5.X.5_1	**Category:** change **Proposed amended text :** Maintenance of~~General~~ health status of ornamental aquatic animals **Rationale:** Revision according to the content.	Did not agree, this article is about the general health status of ornamental aquatic animals and does not focus only on maintenance of status.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.5_2	**Category:** change **Proposed amended text :** *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.and be equipped with appropriate *biosecurity* protection facilities and epidemic prevention management systems to prevent the spread of aquatic animal diseases. **Rationale:** The biosecurity protection facilities and epidemic prevention management system of Aquaculture establishments holding are crucial to preventing the spread of aquatic animal diseases, helping to ensure the safety of the breeding environment, improve the efficiency of breeding, protect public health, and promote the sustainable development of the breeding industry.	Did not agree, suggested text is not necessary as the article links to Chapter 4.1. 'Biosecurity for aquaculture establishments' in the third paragraph. Chapter 4.1. provides recommendations on the development and implementation of biosecurity measures, as well as the importance of biosecurity in preventing disease spread.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.5._3	**Category:** Addition **Proposed amended text:** Ornamental aquatic animals should not be moved or traded from an aquaculture establishment if they are exhibiting clinical signs of disease, are knowingly infected by a pathogen of concern to the importing country, or experiencing unexplained mortalities. **Rationale:** Added for accuracy given some diseases of concern have a carrier status and therefore infected fish will not exhibit clinical signs.	Did not agree, see response to comment 5.X.3._3.

Not for comment

5.X.5_4	**Category:** addition **Proposed amended text:** General health status of ornamental aquatic animals Ornamental aquatic animals should not be moved or traded from an aquaculture establishment if they are exhibiting clinical signs of disease ~~or~~, are experiencing unexplained mortalities or are being detected with pathogenic agent of disease regardless of clinical signs of disease. **Rationale:** Since pathogenic agents can be detected not only in aquatic animals showing clinical signs but also in aquatic animals without clinical signs (e.g. vectors), aquatic animals in which pathogenic agent has been detected should not be moved or traded from an aquaculture establishment.	Did not agree, the recommendations for movements when a pathogenic agent is detected regardless of clinical signs can be found in the disease-specific chapters of the *Aquatic Code*.

Article 5.X.6.

Application of measures for listed diseases

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.6_1	**Category:** change **Proposed amended text :** Application of sanitary measures for listed diseases **Rationale:** Revision according to the content.	Agreed, sanitary measures is a defined glossary term.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.6_2	**Categoría:** Cambio **Propuesta modificación de texto:** Las *medidas sanitarias* implementadas con la intención de gestionar el *riesgo* de transmisión de las *enfermedades listadas* asociadas a los movimientos de *animales acuáticos ornamentales* deberán ajustarse a lo dispuesto en los capítulos específicos de enfermedad. La *autoridad competente* de un *país importador* solo podrá exigir medidas específicas para una *enfermedad listada* si está libre de l~~a enfermedad de~~ preocupación ~~considerada~~ esta o si dicha enfermedad ~~la misma~~ está sometida a un programa oficial de control, tal y como se describe en el Capítulo 5.1. **Justificación:** El texto no es concordante con el título, ya que indica enfermedades listadas, pero luego indica enfermedades de preocupación, por lo que no queda claro cuáles son las enfermedades de preocupación, ya no se encuentran definidas en el glosario, y deben distinguirse aquellas enfermedades OMSA, de las que por análisis de riesgo son de preocupación para cada país importador.	Did not agree as the scope of the chapter does not only cover WOAH listed diseases, it also includes other diseases of concern.

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.7_1	**Category:** change **Proposed amended text :**Risk assessment ~~analysis~~ --- Entry assessment --- Exposure assessment **Rationale:** Consistent with Chapter 2.1 of Aquatic Code.	Did not agree to change to risk analysis as the glossary definition of risk analysis 'means the process composed of hazard identification, risk assessment, risk management and risk communication' all of which is covered in Article 5.X.7. Did not agree to change to 'entry assessment' and 'exposure assessment' as these sections are discussing more than assessment for entry and exposure.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.7._2	**Category:** Editorial **Proposed amended text:** 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 country chooses a level of protection requiring measures ~~are~~ more stringent than the standards of the Aquatic Code. **Rationale:** Consider edits to align with other chapter referencing a risk analysis (e.g. Article 5.1.2.) for consistency. **Supporting evidence:** WOAH Aquatic Code	Did not agree, considered clear as written.

No comment

5.X.7._3	**Categoría:** Supresión **Propuesta modificación de texto:** La *autoridad competente* de un *país importador* deberá recurrir al *análisis del riesgo* para justificar cualquier *medida sanitaria* relativa a las enfermedades no listadas asociadas a *animales acuáticos ornamentales* importados. ~~Asimismo, el *análisis del riesgo* deberá utilizarse para justificar cualquier *medida sanitaria* relativa a las *enfermedades listadas* si las medidas son más estrictas que las normas del *Código Acuático*.~~ La *autoridad competente* de un *país importador* solo podrá exigir *medidas sanitarias* específicas para un agente patógeno si el país está libre de la enfermedad de preocupación ~~en cuestión~~ o si dicha *enfermedad* ~~la misma~~ es objeto de un programa oficial de control, tal como se describe en el Capítulo 5.1. **Justificación:** El texto propuesto para supresión ya se encuentra mencionado en el último párrafo del capítulo Artículo 5.X.6. (La *autoridad competente* de un *país importador* solo podrá exigir *medidas sanitarias* para una *enfermedad listada* más estrictas que las normas del *Código Acuático* si dichas medidas están respaldadas por un *análisis del riesgo* conforme a lo previsto en el Capítulo 2.1.)	Did not agree, while this concept is mentioned in Article 5.X.6. it is important to reiterate here in the article on risk analysis that any measures more stringent than those included in the *Aquatic Code* need to be justified by a risk analysis.
5.X.7._4	**Category:** deletion **Proposed amended text:** **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. **Rationale:** The text is already mentioned in Article 5.X.6. (Application of measures for listed diseases).	Did not agree, see response to 5.X.7._3.

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 animals* 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*.

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.7._5	**Category:** Addition **Proposed amended text:** 4) The suitability of environmental conditions (e.g. temperature, salinity) for the *hazard* at the place of origin of the *ornamental aquatic animals* which support hazard viability and infection, transmission and clinical expression in susceptible species. **Rationale:** Consider updating the original text to provide further explanation, i.e. environmental conditions conducive to hazard viability (in the environment), and supporting infection/transmission and clinical expression in susceptible species. These other factors may be factored into risk management approaches such as verification testing for sub-clinical diseases. Some environmental parameters may be manageable to mask infection/disease.	Agreed. Text updated to provide further detail on the suitability of environmental conditions which support viability, transmission and infection should be considered.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.7._6	**Category:** Addition **Proposed amended text:** 7) The suitability of environmental conditions (e.g. temperature, salinity) for infection of the susceptible species ~~of imported ornamental aquatic animals~~ in the importing country. **Rationale:** This point was confusing since 8) discusses suitability of environmental conditions for the hazard. Edited for accuracy (assuming this is the intent of the point).	Did not agree. The intention of the point is the suitability for the susceptible species to live in the environment and is considered clear as written.

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.

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.7._7	**Category:** Editorial **Proposed amended text:** 11) Internal measures for disease prevention and control and to limit diversion to unintended ~~non-intended~~ end-uses. **Rationale:** For consistency in language and punctuation.	Agreed to editorial change.

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:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.9._1	**Category:** Editorial **Proposed amended text:**	Did not agree. The mechanism for communicating status in the *Aquatic Code* is self-declaration of

Not for comment

	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 or recognized by the importing country, as free from *diseases* of concern. **Rationale:** Prior language implies an importing country may not impose measures following a declaration of freedom (which may be a self-declaration). The recognition of the disease-free status by the importing country is critical and may or may not accompany a declaration of freedom.	freedom at a country, zone or compartment level as defined in the disease-specific chapters.

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);

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.9._2	**Category:** Addition **Proposed amended text:** 1) registration or approval by a Competent Authority of aquaculture establishments that collect from the wild, produce, hold or package ornamental aquatic animals for export. **Rationale:** Inclusion of 'collect' to be explicit on wild caught fish that may not be captured under produce, hold or package. For consideration – does the current 'aquaculture establishment' definition appropriately capture wild-caught ornamental fish which may only be held for a short and transient period before being exported or moved to other establishments.	Did not agree, the current wording of 'hold' covers the scenario where ornamental aquatic animals may have been collected in the wild. The intent of this point is the registration or approval of aquaculture establishments, not the origin of the aquatic animals.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.9._3	**Category:** insertion **Proposed amended text:** 2) confirmation that the exported *ornamental aquatic animals* are free from clinical 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.; **Rationale:** Add "clinical" to be consistent with other parts of the text.	Agreed, text amended for consistency.

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;

Not for comment

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*;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.9._4	**Categoría:** Adición **Propuesta modificación de texto:** 5) Sistemas de rastreabilidad y mantenimiento de registros para garantizar la transparencia del estatus sanitario de poblaciones o remesas específicas de *animales acuáticos ornamentales*. El sistema de rastreabilidad deberá permitir que la *autoridad competente* en el *país importador* pueda identificar cada *contenedor* (ejemplo: rotulación) que mantenga *animales acuáticos ornamentales* y verificar el contenido con los documentos presentados para la certificación. **Justificación:** Contar con la información permite facilitar que en destino la autoridad competente pueda verificar la remesa enviada y acotar los aforos, dirigirlos según riesgo y disminuir los tiempos de retención de animales en frontera, promoviendo el bienestar animal.	Did not agree. The intention of point 5 is to ensure appropriate traceability to have transparency of the health status. The point was modified to say 'specific populations and consignments' to reinforce this point.

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

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.9._5	**Category:** Editorial **Proposed amended text:** 7) A requirement that aquatic animals are not subject to unauthorised pharmacological therapies prior to export which could mask clinical signs of disease. **Rationale:** Consider edits to address situations where aquatic animals may undergo authorised chemical treatments (e.g. salt baths) prior to export to prevent parasite infestations, as part of export requirements. That is the case for Australia's import requirements for goldfish. **Supporting evidence:** WOAH Aquatic Code	Did not agree to add 'unauthorised' therapies. This addition would imply that authorised pharmaceutical therapies could be used to mask clinical signs of disease. The intent is not to prohibit pharmacological therapies used for preventative measures but only those that would mask clinical signs of disease. The word 'could' mask clinical signs was changed to 'may' to clarify the point.
5.X.9._6	**Category:** clarification Point 7 is acceptable as long as prophylactic treatment is still allowed to be administered in consignments and not considered a pharmacological therapy, since the intent is preventive rather than treating a known disease in the exported population. With regards to this clause: 7) A requirement that aquatic animals are not subject to	Did not agree, see response to comment 5.X.9._6.

Not for comment

	pharmacological therapies prior to export which could mask clinical signs of disease;" We would like to seek clarification as to what would be deemed to be a 'pharmacological' therapy. For example: would a chemical bath treatment of sodium chloride, acriflavine and formalin which are typically applied to the consignment of ornamental fish before export be considered "pharmacological", or does this term only apply to antibiotics and medication containing active pharmaceutical ingredients?	

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:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.10._1	**Category:** Addition **Proposed amended text:** 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 or recognized by the importing country, as free from *diseases* of concern. **Rationale:** Prior language implies an importing country may not impose measures following a declaration of freedom (which may be a self-declaration). The recognition of the disease-free status by the importing country is critical and may or may not accompany a declaration of freedom.	Did not agree, see response to comment 5.X.9._1.

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.;

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.10._2	**Category:** Addition **Proposed amended text:** 2) at border quarantine under the supervision of the Competent Authority. The length of quarantine and water quality conditions (water temperature) would be based on the risk assessment and may vary depending on the aquatic animal species and specific diseases of concern to optimise the health of the animal but also maximise the opportunity for the physiological expression of disease if the pathogen is present. Effluent and waste materials from the quarantine facilities should be treated or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8 **Rationale:** Within an imported aquatic animal quarantine facility, the environmental holding conditions (eg water temperature) should be conducive to maintaining the health and welfare of the aquatic animals held in these facilities, but also re-create conditions that provide the highest possible chance of detecting the physiological expression of the disease of concern if it is present in the imported animals.	Agreed with the rationale that within an imported aquatic animal quarantine facility, the environmental holding conditions (e.g. water temperature) should be conducive to maintaining the health and welfare of the aquatic animals held in these facilities, but also provide conditions that provide the possibility of detecting the disease of concern if it is present in the imported animals. Modifications to text were made to reflect the intention of this rationale.
5.X.10._3	**Category:** change **Proposed amended text:** 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 pathogens ~~diseases~~ of concern. **Rationale:** The term “pathogen” highlights the movement of the infectious agent itself, independent of whether it causes disease in the new host. The term “disease” is less precise because it conflates pathogen spread with the outcome (disease). Not all transmission events result in disease, making this term potentially misleading in scientific discussions.	Agreed, changed to pathogenic agent.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.10._4	**Category:** Editorial **Proposed amended text:** 4) destruction (as described in Chapter 7.4.) and biosecure disposal of ~~clinically affected~~ infected animals. **Rationale:** Should this be ‘infected animals’ as point 3) discusses testing and not all infected animals will show clinical signs.	Agreed to editorial change.

Not for comment

5.X.10._5	**Categoría:** Adición **Propuesta modificación de texto:** Se propone agregar numeral 5) Devolución de los animales acuáticos en caso que sea posible y no interfiera con el bienestar animal. **Justificación:** Se propone agregar la posibilidad que la autoridad competente en destino determine la devolución de los animales acuáticos que por hallazgos en inspección fronteriza no puedan ser importados. Esta medida deberá hacerse siempre y cuando el nuevo tiempo de viaje no afecte el bienestar animal.	Did not agree, it is high risk to move infected animals and could lead to disease transmission. Return of aquatic animals is not an option for clinically affected animals.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.11._1	**Category:** Editorial **Proposed amended text:** 1) prohibiting the diversion of ornamental aquatic animals for an ~~alternative~~ unintended end-use…. **Rationale:** For consistency with the rest of the article.	Agreed to change to unintended for consistency within the article.

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~~.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
5.X.11_2	**Category:** change **Proposed amended text :** 3) traceability of imported *ornamental aquatic animals* to commercial establishments~~through the commercial supply chain~~. 4) Before moving Ornamental aquatic animals, quarantine shall be carried out at places approved by the Competent Authorities of the exporting country or region. During the quarantine period, it shall have no contact with other aquatic animals. 5) The dead aquatic animals shall be treated harmless; disinfect the original packaging, loading water or ice and bedding materials. **Rationale:** Quarantine is an important measure to ensure the safety of ornamental aquatic animals into the importing country or region, and it is of great significance to prevent the spread of	Did not agree, the suggested added point 4 on quarantine is addressed in Article 5.X.9. and the suggested added point 5 on disinfection is addressed in Article 5.X.10.

Not for comment

	epidemic diseases and protect ecological security and human health. Harmless treatment and disinfection treatment are necessary measures to prevent the spread of pathogens, protect the environment and public health safety, observe laws and regulations, follow scientific principles and standardize the operation.	

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 (in language submitted)	Aquatic Animals Commission Response
5.X.12._1	**Category:** Editorial **Proposed amended text:** 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~~ pathogen transmission and morbidity or mortality of animals not related to disease. **Rationale:** For accuracy	Agreed, changed to pathogenic agent as a glossary term.

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.

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
X.X.5._1	We support this amendment.	Noted
X.X.5._2	**Category:** General The Member thanks the Commission for their efforts on amending the default periods for each disease specific chapter. The Member has inserted comments within the table below.	Noted
X.X.5._3	**Proposal/Comment: / Propuesta/Comentario:** We thank the Aquatic Animal Health Standards Commission (Aquatic Animals Commission) for their work in developing the new recommendations for periods for basic biosecurity conditions and targeted surveillance for Articles X.X.5.-X.X.7. of the disease specific chapters. The Members urge the AAHSC to reconsider the timing of the adoption of Articles X.X.7. (and 10.4.9. and 10.4.10 for infection with ISAV), Compartment free of Pathogen X, as we have concerns about the potential impacts with the revision of Chapter 4.3. Application of Compartmentalisation. We feel it is important for both articles/ chapters to be reviewed together in order to ensure consistency across members' recommendations and guidelines on the use of basic biosecurity conditions and targeted surveillance at the compartment level. Agradecemos a la Comisión de Normas Sanitarias para los Animales Acuáticos (Comisión de Animales Acuáticos) por su trabajo en el desarrollo de las nuevas recomendaciones para los períodos de condiciones básicas de bioseguridad y vigilancia específica para los Artículos X.X.5.-X.X.7. de los capítulos específicos de enfermedades. Los miembros instan a la Comisión de Normas Sanitarias para los Animales Acuáticos a que reconsidere el momento de la adopción de los Artículos X.X.7. (y 10.4.9. y 10.4.10 para la infección con ISAV), Compartimento libre del patógeno X, ya que nos preocupan los posibles impactos de la revisión del Capítulo 4.3. Aplicación de la compartimentación. Creemos que es importante que ambos artículos/capítulos se revisen juntos para garantizar la coherencia entre las recomendaciones y directrices de los miembros sobre el uso de condiciones básicas de bioseguridad y vigilancia específica a nivel de compartimento. **Rationale: / Razón fundamental** The Members are concerned about the timing of adoption of Articles X.X.7. (and 10.4.9. and 10.4.10 for infection with ISAV), Compartment free of [Pathogen X] in May 2025, as Members will not have an opportunity to review the new Chapter 4.3. Application of Compartmentalisation until after the February 2025 meeting. Since the new Chapter 4.3. Application of Compartmentalisation will be based on the February 2024 Discussion paper, it will likely include new concepts and approaches for compartmentalisation (such as dependent and independent compartments). Therefore, the new chapter for compartmentalisation needs to be taken into account so that Members can comprehensively understand the	The amendments circulated for comment are based on the current chapter on compartmentalisation in the *Aquatic Code*. Currently all periods for BBC and TS in articles X.X.7. (10.4.9. and 10.4.10 for ISAV) are under study in the *Aquatic Code.* The default periods are currently included in these articles and the proposed revisions will not change from these default periods. The Commission had agreed to assess and update the periods for BBC and TS for all listed diseases following adoption of Chapter 1.4. in 2022. During the intervening period, the default periods prescribed in Chapter 1.4 have been included in each of the disease specific chapters but "under study". The revised Chapter 4.3. 'Application of compartmentalisation' is being circulated for the first time for comment in the February 2024 report, and will not be considered for adoption for one to two years depending on comments received. The recommendations in the revised Chapter 4.3. will not be applicable until that chapter is adopted. When the revised Chapter 4.3. is adopted the Commission will review Chapter 1.4. and default periods in relation to compartments and make revisions as required to align with the recommendations in Chapter 4.3. When the new Chapter 4.3. is adopted any compartments which were declared free from disease using the recommendations in the old chapter should be considered a free compartment. They should not be required to submit any additional information to support their free

Not for Comment

	application and potential impacts of the periods for basic biosecurity conditions and targeted surveillance. As several countries have internationally recognised compartments consistent with the current Chapter 4.3. Application of Compartmentalisation and Zoning, both the new Chapter 4.3. Application of Compartmentalisation, and periods for basic biosecurity conditions and targeted surveillance in Articles X.X.7. (and 10.4.9. and 10.4.10 for infection with ISAV) have the potential to impact the recognition of these compartments, and consequently trade. The Members request the opportunity to review both items for comment at the same time to allow for comprehensive consideration of the interactions between these two items. Los Miembros están preocupados por el momento de la adopción de los Artículos X.X.7. (y 10.4.9. y 10.4.10 para la infección con ISAV), Compartimento libre de [Patógeno X] en mayo de 2025, ya que los Miembros no tendrán la oportunidad de revisar el nuevo Capítulo 4.3. Aplicación de la compartimentación hasta después de la reunión de febrero de 2025. Dado que el nuevo Capítulo 4.3. Aplicación de la compartimentación se basará en el documento de debate de febrero de 2024, es probable que incluya nuevos conceptos y enfoques para la compartimentación (como los compartimentos dependientes e independientes). Por lo tanto, el nuevo capítulo sobre compartimentación debe tenerse en cuenta para que los Miembros puedan comprender de manera integral la aplicación y los posibles impactos de los períodos para las condiciones básicas de bioseguridad y la vigilancia específica. Dado que varios países han reconocido internacionalmente compartimentos de conformidad con el actual Capítulo 4.3. Aplicación de la compartimentación y la zonificación, tanto el nuevo Capítulo 4.3. Aplicación de la compartimentación como los períodos para las condiciones básicas de bioseguridad y la vigilancia específica de los Artículos X.X.7 (y 10.4.9. y 10.4.10 para la infección con ISAV) tienen el potencial de afectar el reconocimiento de estos compartimentos y, en consecuencia, el comercio. Los Miembros solicitan la oportunidad de revisar ambos puntos para formular comentarios al mismo tiempo a fin de permitir una consideración integral de las interacciones entre estos dos puntos.	status. However, to maintain the freedom from disease they will have to meet the new standards on maintenance of status.
X.X.5._4	**Category:** General The Members support these revised articles provides the comment to Annex 12 is accepted.	Noted
X.X.5._5	**Category:** Deletion **Proposal:** Proposed remove section on compartments from assessment. **Rationale:** While compartments share a common biosecurity plan, that does not automatically include greater surveillance by those within the compartment or the Competent Authority. Furthermore, for those conditions where the disease is only seen in adults and can therefore take years to manifest, no amount of surveillance will speed up that biological process. Because of this, we cannot assume that, even if there is enhanced surveillance being undertaken within a compartment, that these diseases will be detected in a shorter period of time. We recommend that compartments not be treated any differently than other aquaculture establishments when making these assessments.	Did not agree to remove compartments from the assessment. As described in Chapter 1.4. 'Aquatic animal disease surveillance' a self-declaration of freedom from disease can be made at a country, zone or compartment level. It is required to have periods of BBC and TS for compartments so that Members have the information to make a declaration of freedom of disease for a compartment. As described in Article 1.4.10. 'Required periods for targeted surveillance', the shorter period of TS for compartments reflects the more clearly defined populations, the biosecurity required to maintain

Not for comment

		its population's health status and a likely narrower variation in environmental variables present in compartments.' Taking this into account, the periods are the minimum period required for either BBC and TS. However, any surveillance programme must take into account the guidance of Chapter 1.4. including Article 1.4.16. This article describes that surveillance must have 95% confidence to detect design prevalence (default 2%) and the surveillance must be planned in accordance with the conditions of the population. Thus, the periods of BBC and TS may be longer if determined necessary by the Competent Authority. As well, the *Aquatic Code* chapter on compartmentalisation is currently under revision by the Commission. When the revised chapter is adopted and becomes applicable any necessary changes to Chapter 1.4 and the disease-specific chapters will be considered.

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) […]

Not for comment

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 *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: […] 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

Not for comment

Article	Amended Text
	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 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:

Not for comment

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 *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 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]~~ 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 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:

Not for comment

Article	Amended Text
	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 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*.~~

Not for comment

Article	Amended Text
	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) […] 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

Not for comment

Article	Amended Text
	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: […] 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~~.

Not for comment

Article	Amended Text
	[…]
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 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;

Not for comment

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 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 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;

Not for Comment

Article	Amended Text
	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 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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
9.3.5._1	**Category:** Change **Proposed amended text:** ~~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 ~~[six]~~ months; **Rationale:** Article 9.3.2 does not list any susceptible species at a taxa higher than species (no genus or family level listings) therefore Pathway 1 should be permissible.	Did not agree, the Commission maintains that pathway 1 is not suitable for infection with DIV1. As per Article 1.4.11. pathway 1 'cannot be used for disease where there is uncertainty regarding the full range of susceptible species'. The pathogenic agent DIV1 is relatively newly identified and scientific publications to assess susceptible species were only available as early as 2016. Further the susceptible species identified cover a large taxonomic range in both fresh and salt water species. These factors were considered and until more research is completed the full range of susceptible species is uncertain.

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

Not for comment

	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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
9.3.6._1	**Category:** Change **Proposed amended text:** ~~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 ~~[six]~~ months; **Rationale:** Article 9.3.2 does not list any susceptible species at a taxa higher than species (no genus or family level listings) therefore Pathway 1 should be permissible.	Did not agree, see response to comment 9.3.5._1.

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) […]

Not for comment

	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: […] 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;

Not for comment

	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 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

Not for comment

	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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
9.5.5._1	**Category:** Change **Proposed amended text:** 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last ~~two~~ three ~~[two]~~ years without detection of IHHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least ~~one~~ 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: i) at least the last ~~two~~ three ~~[two]~~ years in wild and farmed *susceptible species* without detection of IHHNV; or ii) at least the last ~~one~~ two ~~[one]~~ year without detection of IHHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. **Rationale:** The Member proposes ranking IHHNV as a a level 3 (based on the assessment of default periods annex) and therefore would propose 2 years BBC and 3 years for TS. IHHNV can transit rapidly in P. stylirosris but in P. vannamei and P. monodon the rate of spread is low. The table in the assessment document indicates “low in *P. vannamei*, *P. monodon* (may go undetected for months)”. Additionally, early detection in *P. vannamei and P. monodon* is low and it has reduced replication at high temp. Overall this makes IHHNV freedom more difficult to substantiate in populations on cultured *P. vannamei and P. monodon* populations unless there are P. stylirosris sentineal	Did not agree to rank IHHNV as a 3. The table in attachment 3 of the assessment showing the ranking is for the duration of basic biosecurity conditions (BBC) preceding targeted surveillance to demonstrate freedom. In regards to BBC the period needs to be appropriate to reach design prevalence while measures are in place to prevent introduction of disease. It is considered that one year is an appropriate BBC period for IHHNV. For targeted surveillance the period needs to be long enough to detect disease. For BBC we are concerned with the period it would take for design prevalence to be reached (and while measures to prevent introduction are in place). For the period of surveillance, we just need long enough to detect it. IHHNV if present should be detected within two years of targeted surveillance. Even if there may not be severe clinical disease and mortality, there can be subclinical disease and circulating infection at a sufficient prevalence for detection.

Not for comment

	animals. Additionally, KHV, G. salaris and most of the mollusc pathogens have similar profiles to IHHNV and are ranked 3. The time frame for TS in 4 d) ii) should reflect compartments. See comment for 9.5.7.	

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 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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
9.5.6._1	**Category:** Change **Proposed amended text:** 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last ~~two~~ three ~~[two]~~ years without detection of IHHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least ~~one~~ two ~~[one]~~ year prior to commencement of *targeted surveillance*; OR	Did not agree, see response to comment 9.5.5._1.

Not for comment

	4) […] d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: i) at least the last ~~two~~ three ~~[two]~~ years in wild and farmed *susceptible species* without detection of IHHNV; or ii) at least the last ~~one~~ two ~~[one]~~ year without detection of IHHNV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. **Rationale:** The Member proposes ranking IHHNV as a 3 (based on the annex for assessment of default periods) and therefore would propose 2 years BBC and 3 years TS. IHHNV can transit rapidly in P. stylirosris but in P. vannamei and P. monodon the rate of spread is low. The table in the assessment document indicates "low in *P. vannamei*, *P. monodon* (may go undetected for months)". Additionally, early detection in *P. vannamei and P. monodon* is low and it has reduced replication at high temp. Overall this makes IHHNV freedom more difficult to substantiate in populations on cultured *P. vannamei and P. monodon* populations unless there are P. stylirosris sentinel animals. Additionally, KHV, G. salaris and most of the mollusc pathogens have similar profiles to IHHNV and are ranked 3. The time frame for TS in 4 d) ii) should reflect compartments. See comment for 9.5.7.	

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~~. […]

Reference	**Comment (in language submitted)**	**Aquatic Animals Commission Response**
9.5.7._1	**Category:** Change **Proposed amended text:** 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last ~~one~~ two~~[one]~~ year without detection of ~~*H. penaei*~~ IHHNV, and *basic biosecurity conditions* have been continuously met	Did not agree to change default periods applied to pathways 3 and 4 for 'compartments free from infection with IHHNV'. The text refers to targeted surveillance, not passive surveillance.

Not for comment

	and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*; OR 2) […] c) ~~one~~ two survey for infection with ~~*H. penaei*~~ IHHNV has been completed at least ~~six months~~ one year ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. **Rationale:** IHHNV in P. vannamei is a sub-clinical diseases and therefore cannot be detected by passive surveillance. A Competent Authorities authorising a compartment would not improve passive surveillance for these diseases. This applies to any disease where the strength of the passive surveillance will not be improved by increased oversight. Two years of TS should be considered if the pathogen require longer than 1 year to establish itself due to pathogen or host characteristics or if the pathogen has been show to persist in a closed populations at very low levels (e.g. ISA HPR0 prevalence of 0.2% or 0.3% in Christiansen et al. (2021)) 1. Christiansen DH, Petersen PE, Dahl MM, Vest N, Aamelfot M, Kristoffersen AB,[…] Falk K, 2021. No Evidence of the Vertical Transmission of Non-Virulent Infectious Salmon Anaemia Virus (ISAV-HPR0) in Farmed Atlantic Salmon [Internet]. *Viruses*. Also note the name change from *H. penaei* to IHHNV to reflect the specific disease.	As described in the *Aquatic Manual* prevalence in *P. vannamei* can range from 6 – 63% and with the prevalence of these levels the pathogenic agent would be expected to be detected within one year of targeted surveillance. Further, as several cycles of shrimp production can occur in one year it is expected that the pathogenic agent would be detected if present. Agreed with editorial change to address typos.
9.5.7._2	**Category:** Editorial change **Proposed amended text:** Point 1 and 2: change "*H. penaei*" to "IHHNV"	Agreed with editorial change to address typos

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

Not for comment

	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 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

Not for comment

	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 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: […]

Not for comment

	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 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;

Not for comment

	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 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*. […]

Not for comment

Article 9.8.7. 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.	[…]

Not for comment

Zone 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: […] 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; OR

Not for comment

	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 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~~.

Not for comment

	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) […] 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

Not for comment

	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 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~~. […]

Not for comment

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: […] 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*

Not for comment

	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 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*;

Not for comment

	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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.3.5._1	**Category:** change **Proposed amended text:** Proposed that G. salaris should be considered 'pathway not suitable' for pathway 2. **Rationale:** For G.*salaris,* it has only caused outbreaks with clinical disease in two WOAH members, although it is prevalent without clinical signs in a number of WOAH members. As clinical disease may not occur Pathway 2 Historical freedom' should not be considered appropriate to claim freedom for this disease.	Agreed that pathway 2 (historical freedom) is not suitable for *G. salaris* as clinical signs may not always be evident with infection. Text was amended to reflect that pathway 2 was not suitable.

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

Not for comment

	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 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) […]

Not for comment

	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 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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.5._1	**Category:** Change **Proposed amended text:** 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last ~~two~~ three ~~[two]~~ years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least ~~one~~ 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: i) at least the last ~~two~~ three ~~[two]~~ years in wild and farmed *susceptible species* without detection of ISAV; or ii) at least the last ~~one~~ two ~~[one]~~ year without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. **Rationale:** The Member proposes ranking ISAV (including HPR0 and HPR-deleted) as a 3 and therefore would move to 2 years BBC and 3 year TS in the table above. The "rate of spread" and "transmission period" of ISAV HPR0 is unknown. They are assumed to be the same as ISA HPR-deleted, yet tissue trophism, clinical signs (Christiansen et al., 2011), and epidemiological behaviours differ (Christiansen et al. (2011)). Prevalence of IAS HPR0 in land-based farmed fish may be low to very low (Christiansen et al., 2021; Jónsson, 2023) with possible house strains. It is unknown if individual fish recover and clear infection or if they become persistent carriers. ISA HPR0 has been shown to persist in populations or the environment for 3-4 months (Aamelfot et al., 2016; Christiansen et al., 2011). HPR0 detection in marine environment show seasonal fluctuations (Christiansen et al. (2011)). These epidemiological factors are different for ISA HPR-deleted. The Member believes it is likely that the prevalence of ISA HPR0 may not build to detectable levels within the period of 2 years of TS.	Agreed to rank ISAV (including HPR0 and HPR-deleted) as a 3 in the assessment of default periods and to make associated changes to default periods in the relevant articles. The change to rank 3 took into account the factors for HPR0 such as: - rate of spread and transmission period of ISAV HPR0 is unknown and assumed to be the same as HPR-deleted ISAV, - prevalence in land-based farm fish may be low, - unknown whether fish recover and become persistent carriers, - shown to persist in the environment for up to four months, - detection in marine environments has seasonal fluctuations.

Not for comment

	We recommend rankings this disease a 3. The time frame for TS in 4 d) ii) should reflect compartments. See comment for 10.4.9. 2. Aamelfot M, Christiansen DH, Dale OB, McBeath A, Benestad SL & Falk K, 2016. Localised Infection of Atlantic Salmon Epithelial Cells by HPR0 Infectious Salmon Anaemia Virus. *PLOS ONE* 11: e0151723 3. Christiansen DH, Østergaard PS, Snow M, Dale OB & Falk K, 2011. A low-pathogenic variant of infectious salmon anemia virus (ISAV-HPR0) is highly prevalent and causes a non-clinical transient infection in farmed Atlantic salmon (Salmo salar L.) in the Faroe Islands. 92: 909-918. 4. Christiansen DH, Petersen PE, Dahl MM, Vest N, Aamelfot M, Kristoffersen AB,[…] Falk K, 2021. No Evidence of the Vertical Transmission of Non-Virulent Infectious Salmon Anaemia Virus (ISAV-HPR0) in Farmed Atlantic Salmon [Internet]. *Viruses*. 5. Jónsson G, 2023. Surveillance program with focus on certain fish diseases involved in disease-free status of Iceland. Selfoss, Iceland: MAST - Iceland Food and Veterinary Authority. Aamelfot 2016 - Localised infection of Christense 2011 - a low path variant of IS. Christensen 2021 - No Evidence of the V aquaculture-surveillance-program-disease	

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;

Not for comment

	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. 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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.6_1	**Category:** Change **Proposed amended text:** 4) … d) targeted surveillance, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of HPR~~0~~ deleted ISAV. i) at least the last two [two] years in wild and farmed susceptible species without detection of HPR-deleted 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. **Rationale:** Section refers to HPR-deleted ISAV so some references to HPR0 or ISAV are incorrect	Agreed, editorial change.

Not for comment

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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.7._1	**Category:** Change **Proposed amended text:** 3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last ~~two~~ three ~~[two]~~ years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least ~~one~~ 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: i) at least the last ~~two~~ three ~~[two]~~ years in wild and farmed *susceptible species* without detection of ISAV; or	Agreed, see response to comment 10.4.5._1.

Not for comment

	ii) at least the last ~~one~~ two [~~one~~] year without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*. **Rationale:** The Member proposes ranking ISAV (including HPR0 and HPR-deleted) as a 3 and therefore would move to 2 years BBC and 3 year TS in the table above. The "rate of spread" and "transmission period" of ISAV HPR0 is unknown. They are assumed to be the same as ISA HPR-deleted, yet tissue trophism, clinical signs (Christiansen et al., 2011), and epidemiological behaviours differ (Christiansen et al. (2011)). Prevalence of IAS HPR0 in land-based farmed fish may be low to very low (Christiansen et al., 2021; Jónsson, 2023) with possible house strains. It is unknown if individual fish recover and clear infection or if they become persistent carriers. ISA HPR0 has been shown to persist in populations or the environment for 3-4 months (Aamelfot et al., 2016; Christiansen et al., 2011). HPR0 detection in marine environment show seasonal fluctuations (Christiansen et al. (2011)). These epidemiological factors are different for ISA HPR-deleted. The Member believes it is likely that the prevalence of ISA HPR0 may not build to detectable levels within the period of 2 years of TS. We recommend rankings this disease a 3. The time frame for TS in 4 d) ii) should reflect compartments. See comment for 10.4.9. 1. Aamelfot M, Christiansen DH, Dale OB, McBeath A, Benestad SL & Falk K, 2016. Localised Infection of Atlantic Salmon Epithelial Cells by HPR0 Infectious Salmon Anaemia Virus. *PLOS ONE* 11: e0151723 2. Christiansen DH, Østergaard PS, Snow M, Dale OB & Falk K, 2011. A low-pathogenic variant of infectious salmon anemia virus (ISAV-HPR0) is highly prevalent and causes a non-clinical transient infection in farmed Atlantic salmon (Salmo salar L.) in the Faroe Islands. 92: 909-918. 3. Christiansen DH, Petersen PE, Dahl MM, Vest N, Aamelfot M, Kristoffersen AB,[…] Falk K, 2021. No Evidence of the Vertical Transmission of Non-Virulent Infectious Salmon Anaemia Virus (ISAV-HPR0) in Farmed Atlantic Salmon [Internet]. *Viruses*. 4. Jónsson G, 2023. Surveillance program with focus on certain fish diseases involved in disease-free status of Iceland. Selfoss, Iceland: MAST - Iceland Food and Veterinary Authority.	

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:

Not to comment

	[…] 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~~. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.4.9._1	**Category:** Change **Proposed amended text:** 1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last ~~one~~ two~~[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	Did not agree. As described in response to comment X.X.5._5 the shorter periods for compartments take into account the unique characteristics of compartments and all articles for compartments have remained as the default period. The targeted survey needs to be sufficiently sensitive to detect the pathogenic agent if it were to be

Not for comment

	2) […] c) ~~one~~ two survey for infection with ISAV has been completed at least ~~six months~~ one year ~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~. **Rationale:** ISA HPR0 is a sub-clinical diseases and therefore cannot be detected by passive surveillance. A Competent Authorities authorising a compartment would not improve passive surveillance for these diseases. This applies to any disease where the strength of the passive surveillance will not be improved by increased oversight. Two years of TS should be considered if the pathogen require longer than 1 year to establish itself due to pathogen or host characteristics or if the pathogen has been show to persist in a closed populations at very low levels (e.g. ISA HPR0 prevalence of 0.2% or 0.3% in Christiansen et al. (2021)) 1. Christiansen DH, Petersen PE, Dahl MM, Vest N, Aamelfot M, Kristoffersen AB,[…] Falk K, 2021. No Evidence of the Vertical Transmission of Non-Virulent Infectious Salmon Anaemia Virus (ISAV-HPR0) in Farmed Atlantic Salmon [Internet]. *Viruses*. In relation to surveillance for returning to freedom for compartments specifically for ISAV HPR0, recent work by Pietrak et al. (2024) indicates that targeting surveillance to periods of physiological stress may improve the probability of detection for ISAV HPR0 (i.e., spawning and smolting). As such, one testing event within six months of stocking may not result in the highest probability for detection of ISAV HPR0 depending on the life stage/age of animals at restocking. One sampling event may be suitable for establishments that restock with eggs. However, for compartments that restocked with older fish, perhaps one testing event within six months of stocking followed by another testing event timed to a period of physiological stress, such as spawning or smolting, may be a consideration. Hence the Member has proposed 2 surveys within one year to support this situation.	present. This must include defensible assumptions about assumed prevalence in the study population.

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) […] 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;

Not for comment

	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: […] 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) […]

Not for comment

	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 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:

Not for comment

	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 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) […]

Not for comment

	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 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

Not for comment

	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 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*;

Not for comment

	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 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*;

Not for comment

	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 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*. […]

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.10.5._1	**Category:** change **Proposed amended text:** ii) at least the last one-year without detection of VHSV~~SVCV~~ if affected aquaculture establishments were not epidemiologically connected to wild populations of susceptible species.	Agreed, editorial change.

Not for comment

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 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;

Not for comment

	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. 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) […]

Not for comment

	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; 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

Not for comment

	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 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.	[…]

Not for comment

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: 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

Not for comment

	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) […] 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:

Not for comment

	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: […] 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) […]

Not for comment

	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 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;

Not for comment

	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 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

Not for comment

	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 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.	[…] 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*

Not for comment

Compartment free from infection with *P. marinus*	*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 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~~;

Not for comment

	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; 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:

Not for comment

	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 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

Not for comment

	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 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~~. […]

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_1	**Category:** General The Members in general supports the recommendations provided the comments below are considered.	Noted

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.

Not for comment

- 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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_2	**Category:** Deletion **Proposed amended text:** ~~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~~ **Rationale:** While compartments share a common biosecurity plan, that does not automatically include greater surveillance by those within the compartment or the Competent Authority. Furthermore, for those conditions where the disease is only seen in adults and can therefore take years to manifest, no amount of surveillance will speed up that biological process. Because of this, we cannot assume that, even if there is enhanced surveillance being undertaken within a compartment, that these diseases will be detected in a shorter period of time. We recommend that compartments not be treated any differently than other aquaculture establishments when making these assessments.	Did not agree to remove compartments from the assessment. As described in Chapter 1.4. 'Aquatic animal disease surveillance' a self-declaration of freedom from disease can be made at a country, zone or compartment level. It is required to have periods of BBC and TS for compartments so that Members have the information to make a declaration of freedom of disease for a compartment. As described in Article 1.4.10. 'Required periods for targeted surveillance', the shorter period of TS for compartments reflects the more clearly defined populations, the biosecurity required to maintain its population's health status and a likely narrower variation in environmental variables present in compartments.' Taking this into account, the periods are the minimum period required for either BBC and TS. However, any surveillance programme must take into account the guidance of Chapter 1.4. including Article 1.4.16. This article describes that surveillance must have 95% confidence to detect design prevalence (default 2%) and the surveillance must be planned in accordance with the conditions of the population. Thus, the periods of BBC and TS may be

Not for comment

		longer if determined necessary by the Competent Authority. As well, the *Aquatic Code* chapter on compartmentalisation is currently under revision by the Commission. When the revised chapter is adopted and becomes applicable any necessary changes to Chapter 1.4 and the disease-specific chapters will be considered.

- 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.

Reference	**Comment (in language submitted)**	**Aquatic Animals Commission Response**
Assessment_3	En el texto se presenta que para declarar ausencia de enfermedad se debe cumplir los requisitos mencionados en el capítulo 1.4. • “En el caso del procedimiento 3, el periodo mínimo por defecto de las CEB que precede a la VE para un país o zona es de un año (definido en el Capítulo 1.4.). La duración de las CEB que preceden a la VE deberá ser lo suficientemente prolongada como para alcanzar la prevalencia de diseño utilizada en el diseño de la VE, suponiendo que el patógeno se haya establecido inmediatamente antes del comienzo de las CEB. Por lo tanto, se considera “crítica” la tasa de propagación entre poblaciones. **“Períodos de VE** • El periodo mínimo por defecto de la VE para países y zonas es de dos años. En el caso de los patógenos cuya tasa de transmisión está determinada de forma significativa por las condiciones medioambientales, la prevalencia puede caer por debajo de la prevalencia de diseño en los periodos en los que las condiciones medioambientales o biológicas no son propicias para la transmisión. • En el caso de los patógenos cuya transmisión está influenciada de forma significativa por factores medioambientales y en los que la infección no provoca de forma sistemática signos clínicos observables o mortalidad, se recomienda ampliar el periodo de VE a tres años (ver Cuadro 3). • En cuanto a los compartimentos que buscan la ausencia de enfermedad de acuerdo con el procedimiento 3, se considera	Requirements for maintenance of disease free status are in Article 1.4.15. of the *Aquatic Code*.

Not to comment

	suficiente un periodo de un año para las CEB y la VE para todos los patógenos, ya que las condiciones requeridas para mantener un compartimento generarán un alto nivel de confianza en que el patógeno será detectado independientemente de sus características." **Consulta:** Se indica que, para el procedimiento 3, el período mínimo por defecto de las CEB que precede a la VE en un país o zona es de un año, mientras que el período mínimo por defecto de la VE es de dos años previos al reconocimiento del estatus sanitario adquirido. No obstante, es importante aclarar cuál es el requisito temporal para llevar a cabo la vigilancia específica posterior al reconocimiento del estatus. ¿Debe transcurrir uno o dos años entre el desarrollo de las actividades de vigilancia?	

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* VHSV	crayfish plague DIV1 WSSV	*P. olseni*	*B. dendrobatidis* *Ranavirus*

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_4	**Category:** clarification For ISAV, (including HPR0 and HPR-deleted) the Members agree with the proposed approach. However, the use of HPR-deleted ISAV and ISAV (including HPR0 and HPR-deleted) may lead to confusion as it seems that HPR-deleted ISAV is repeated twice in the same table. The Members would request the AAHC to double check the references to HPR-deleted ISAV in this table	The differentiation of the two categories for ISAV in the table is consistent with the approach taken in Chapter 10.4. 'Infection with infectious salmon anaemia' of the *Aquatic Code* as was originally adopted in 2013. As in Chapter 10.4. the articles cover a country, zone or compartment free from either • HPR-deleted ISAV

Not for comment

		• ISAV where it refers to infection with any detectable strain of ISAV, including HPR0 ISAV [reflected in the table as ISAV (including HPR0 and HPR-deleted)] Due to the distinction in the disease-specific chapter where the default periods are applied the assessment followed the same approach. Note that the assessment is provided for Members to understand the approach taken to determine the default periods for basic biosecurity conditions and targeted surveillance. The application of the assessment will be found in the individual articles in each disease-specific chapter. When utilising the default periods Competent Authorities should be considering what is written in the disease-specific chapters.

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)			

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_5	**Category:** Editorial change **Proposed amended text:** In Table 2, "EUS" should be moved to the 2nd row of the 2nd column in which the period of BBC is 15 years. **Rationale:** We notice the inconsistency of data on the recommended period of BBC when using Pathway 2 for EUS	Agreed, EUS as a rank 3 should have a BBC of 15 years.

Not for comment

<table>
<tr><td></td><td>provided in Table 2 (Recommendations for periods of BBC using Pathway 2 Historical freedom) and data on the ranking of EUS in Table 7 (Summary rankings of pathogens to determine the minimum period of BBC for pathway 2. ‘Historic freedom). As EUS is a pathogen ranked 3, the minimum BBC period for Pathway 2 should be extended to 15 years; therefore, Table 2 should be amended accordingly.</td><td></td></tr>
<tr><td>Assessment_6</td><td>Category: change
Proposed amended text:<table><tr><td>15 years</td><td><s>G. salaris</s>
KHV</td></tr><tr><td>Pathway not suitable</td><td><s>ISAV (including HPR0 and HPR-deleted)</s>
HPR (Non-deleted highly polymorphic region) ISAV
G. salaris</td></tr></table>Rationale: For ISAV, the Members agree with an approach where both genotypes of ISAV are treated in a different way. However, the proposed table 2 indicates that Pathway 2 Historical freedom’ cannot be used for any of them whereas the intention is that it can be used for HPR-deleted ISAV.
For G.salaris, it has only caused outbreaks with clinical disease in two WOAH members, although it is prevalent without clinical signs in a number of WOAH members.
As clinical disease may not occur Pathway 2 Historical freedom’ should not be considered appropriate to claim freedom for this disease.</td><td>In regards to the presentation of ISAV see response to comment Assessment_4.
In regards to G. salaris the Commission agreed that pathway 2 is not suitable as clinical signs may not always be evident with infection.</td></tr>
</table>

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*
2 years	EUS *G. salaris* KHV		*B. exitiosa* *B. ostreae* *P. marinus* *M. refringens* *P. olseni* *X. californiensis*	*Ranavirus*

Not for comment

Period	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
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*

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_7	For ISAV, (including HPR0 and HPR-deleted) the Members agree with the proposed approach. However, the use of HPR-deleted ISAV and ISAV (including HPR0 and HPR-deleted) may lead to confusion as it seems that HPR-deleted ISAV is repeated twice in the same table. The Members would request the AAHC to double check the references to HPR-deleted ISAV in this table	See response to comment Assessment_4.

Not for comment

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Not for comment

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

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_8	**Categoría:** Editorial **Texto modificado propuesto:** El Anexo 1 detalla los periodos mínimos para cada patógeno de la lista y los procedimientos estipulados en los capítulos específicos de enfermedad antes de la adopción del Capítulo 1.4. *Vigilancia de las enfermedades de los animales acuáticos*, revisado en 2022. Desde 2022, se están estudiando los periodos mínimos por defecto. **Justificación:** En el texto se habla de procedimientos, es decir en plural.	Agreed, editorial changes made in the Spanish version of the text.

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.

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

Not for comment

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 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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_9	**Categoría:** Editorial **Texto modificado propuesto:** 2) Aplicar el método a las enfermedades de los animales acuáticos de la lista de la OMSA y recomendar períodos de implementación de las CEB para los procedimientos 1 y 2, y la vigilancia específica, con el fin de demostrar la ausencia a nivel de país y zona (a través del procedimiento 3) para los capítulos específicos de enfermedad del *Código Acuático*. **Justificación:** En el texto se habla de procedimientos, es decir en plural.	Agreed, editorial changes made in the Spanish version of the text.

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

Not for comment

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.

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.

Not for comment

• 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

Not for comment

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 (in language submitted)	Aquatic Animals Commission Response
Assessment_10	**Category:** Addition **Proposed amended text:** 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 EUS, the likelihood of rapid detection is dependent on predisposing factors. **Rationale:** The sentence re EUS should be also included in this section.	Agreed, text was modified to include EUS.

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*

Not for comment

Ranking	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
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			
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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_11	**Category:** Deletion **Proposed amended text:** 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~~	Agreed to remove sentence on historical freedom as not relevant in this section.

Not for comment

	~~HPR-deleted). Pathway 2 is suitable for HPR-deleted ISAV as it is expected to cause clinical signs and mortality.~~ **Rationale:** This sentence shouldn't be included here, not relevant.	

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*

Not for comment

Ranking	Diseases of fish	Diseases of crustaceans	Diseases of molluscs	Diseases of amphibians
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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_12	**Category:** Deletion **Proposed amended text:** ~~**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.~~ **Rationale:** While compartments share a common biosecurity plan, that does not automatically include greater surveillance by those within the compartment or the Competent Authority. Furthermore, for those conditions where the disease is only seen in adults and can therefore take years to manifest, no amount of surveillance will speed up that biological process. Because of this, we cannot assume that, even if there is enhanced surveillance being undertaken within a compartment, that these diseases will be detected in a shorter period of time. We recommend that compartments not be treated any differently than other aquaculture establishments when making these assessments.	Did not agree to delete paragraph on compartments. The paragraph is addressing the period of basic biosecurity conditions (a minimum set of conditions required to ensure biosecurity for a specific disease) and as such is not addressing targeted surveillance. Also see response to Assessment_2.

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.

Not for comment

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*
2	VHSV IHNV SVCV *M. pagrus 1* HPR-deleted ISAV ISAV (including HPR0 and HPR-deleted) TiLV EHNV			*B. salamondrivorans*

Not for comment

Ranking	Fish	Crustacean	Molluscs	Amphibian
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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Assessment_13	**Category:** Deletion **Proposed amended text:** ~~**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.~~ **Rationale:** While compartments share a common biosecurity plan, that does not automatically include greater surveillance by those within the compartment or the Competent Authority. Furthermore, for those conditions where the disease is only seen in adults and can therefore take years to manifest, no amount of surveillance will speed up that biological process. Because of this, we cannot assume that, even if there is enhanced surveillance being undertaken within a compartment, that these diseases will be detected in a shorter period of time. We recommend that compartments not be treated any differently than other aquaculture establishments when making these assessments.	Did not agree, see response to Assessment_2.

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

Not for comment

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

Not for comment

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*.

Not for comment

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

Working document

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
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

Not for comment

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

LH = likelihood

Not for comment

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 Rapid onset mortality	Little information – probably unrestricted	viable in aerated seawater for 3 d	1

LH = likelihood

Not for comment

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
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

Not for comment

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.

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
9.9.2._1	**Category:** General The Member supports the Commission's changes to Article 9.9.2. and has submitted additional comments on the workplan to ensure consistent application of Article 1.5.9. in the future.	Noted
9.9.2._2	**Category:** General The Members support this revised article.	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 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

Not for comment

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 (in language submitted)	Aquatic Animals Commission Response
9.9.2_2	**Category:** Change **Proposed amended text:** *Palaemon* spp. (all species) **Rationale:** *Palaemon* spp. should remain considered to be susceptible to WSSV at the genus level until such time as specific experimental evidence is provided by a member country that one or more species of Palaemon challenged with WSSV are shown to be refractory to infection in a study published in the scientific literature. Evidence from an area where an exotic incursion of WSSV has established, found that all three species of wild caught Palaemonids examined by qPCR (*Palaemon serrifer*, *P. serenus*, *Palaemonella* spp.) were naturally infected with WSSV at prevalences up to 100% (mean prevalence for all three species combined = 31%, n = 722), with Ct as low as 28.56 showing that viral replication was occurring in some animals (Diggles 2020). **Supporting evidence:** Diggles BK (2020). Survey for WSSV vectors in the Moreton Bay White Spot Biosecurity Area. Final Report for FRDC Project No 2019-214, 55 pgs. https://www.frdc.com.au/project/2019-214	Did not agree. Even with the addition of *Palaemon serrifer* and *Palaemon serenus* (scored as '3' by the *ad hoc* Group) to the *Aquatic Manual*, the decision from September 2024 of listing *Palaemon* at the species level is appropriate (See item 6.5.2. of the September 2024 report). The *Palaemon* genus represents nearly 200 species and only 11 of these species have been assessed for susceptibility to WSSV: 3 species meeting criteria for susceptibility, 1 species with incomplete evidence of susceptibility and 7 species with positive molecular results only.
9.9.2_3	**Categoría:** editorial. **Texto modificado propuesto:** Familia / Nombre científico / Nombre común Astacidae — *Austropotamobius pallipes* — cangrejo ~~a pinzas~~ de patas blancas *Pacifastacus leniusculus* — ~~[signal crayfish]~~ cangrejo señal *Pontastacus leptodactylus* — cangrejo de patas punteadas Calanidae — *Calanus pacificus californicus* — sin nombre común Cambaridae — *Faxonius limosus* — ~~[spinycheek crayfish]~~ spinycheek crayfish [cangrejo de mejilla espinosa] *Procambarus clarkii* ~~*spp.* (todas las especies)~~ — ~~[red swamp crawfish] N/A~~ cangrejo rojo americano *Procambarus zonangulus* — sin nombre común	Did not agree. As per WOAH's style guide common names of host species used in all language versions of the *Aquatic Code* and *Aquatic Manual* are in accordance with FAOTERM. Where a common name is not in FAOTERM, the common name is in accordance with SeaLifeBase or SeaFishBase. If no common name exists for French or Spanish in these databases then the common name in English is presented in square brackets, and if no common name exists in any of the three official languages, no common name is included in the standards.

Not for comment

Cancridae	*Cancer pagurus*	buey de mar
Nephropidae	*Homarus gammarus*	bogavante
	Nephrops norvegicus	cigala
Nereididae	*Dendronereis sp.*	N/A
Paguridae	*Pagurus benedicti*	sin nombre común
Palaemonidae	*Macrobrachium nipponense*	camarón nipón
	Palaemon carinicauda ~~*spp.* (todas las especies)~~	camarón quilla ~~N/A~~
	Palaemon orientis	sin nombre común
	Palaemon ritteri	camarón de mareas
Palinuridae	*Panulirus spp.* (todas las especies)	N/A
Parastacidae	*Cherax quadricarinatus*	~~[red claw crayfish]~~ langosta de agua dulce, langosta australiana
Penaeidae	todas las especies	N/A
Polybiidae	*Liocarcinus depurator*	falsa nécora
	Necora puber	nécora
Portunidae	todas las especies	N/A
Varunidae	*Eriocheir sinensis*	cangrejo chino

Justificación: Para una mejor comprensión del texto en la versión en español, se recomienda incluir el nombre común en el mismo idioma cuando existan referencias en español. En caso de que no existan referencias en español, se sugiere presentar el nombre común en inglés y la traducción sugerida entre corchetes.

Evidencia documentada:

1. Flórez-Brand PE, Espinosa-Beltrán JO. Presencia y dispersión del cangrejo rojo americano (*Procambarus clarkii* Girard, 1852) (Decapoda: Cambaridae) en el departamento del Valle del Cauca, Colombia. Biota Colombiana. 2011 Julio-Diciembre; 12(2): 57-62. https://www.redalyc.org/pdf/491/49122304006.pdf
2. Instituto Mexicano de Investigación en Pesca y Acuacultura Sustentable. Consultado en: https://www.gob.mx/imipas/acciones-y-programas/acuacultura-camaron-azul
3. Moñino AV, Perán JA, Urbano J, Peréz L, Martínez S, Tomás A, Jover M. Características poblacionales del cangrejo de río autóctono (*Austropotamobius pallipes*) de la cuenca del río Turia en Valencia. Revista AquaTIC. 2003; 18: 15-24. https://www.redalyc.org/pdf/494/49401804.pdf
4. Zamora-Marín JM, Zamora-López A, Torralva M, Oliva-Paterna JO. Presencia de la especie invasora *Pacifastacus leniusculus* (Dana, 1852) (Decapoda, Astacidae) en la Cuenca del Río Segura (SE, España). Anales de Biología. 2016; 38: 119-122. https://www.um.es/analesdebiologia/numeros/38/PDF/38_2016_14.pdf

9.9.2._4	**Category:** change **Proposed amended text:** African Union proposes the following changes to the text: *Procambarus clarkii* ~~*spp.* (all species)~~	See response for comment 9.9.2_3

Not for comment

	red swamp crawfish ~~N/A~~ *Procambarus zonangulus* Common name: White River Crayfish. *Macrobrachium nipponense* Oriental river prawn *Palaemon orientis* Common name: Oriental prawn **Rationale:** Scientific Name: *Procambarus clarkii* Common Name: Red swamp crayfish https://pubchem.ncbi.nlm.nih.gov/taxonomy/6728 Common name https://en.wikipedia.org/wiki/Procambarus_zonangulus Common name https://www.fao.org/4/ac477e/ac477e14.pdf	

[…]

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.2._1	**Category:** General The Member supports the proposed changes.	Noted
10.2._2	**Category:** General The Members support all modifications made on Annex 15.	Noted
10.2._3	**Category:** General The Members support this revised article.	Noted

CHAPTER 10.2.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.2._4	**Categoría:** Editorial **Texto modificado propuesto:** ~~**INFECTION**~~ **INFECCIÓN POR *APHANOMYCES INVADANS* (SÍNDROME ULCERANTE EPIZOÓTICO)** **Justificación:** La palabra "INFECTION" no corresponde al idioma utilizado en el texto.	Agreed, editorial change in the Spanish version.

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

Not for comment

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

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.2.2._1	**Category:** change **Proposed amended text :** **Family** / **Scientific name** / **Common name** Channidae / ~~*Channa spp.(all species)* Channa marulius~~ / ~~N/A~~ *great snakehead* *Channa punctatus* / *Channa punctatus* *spotted snakehead* / *spotted snakehead* **Rationale:** In the result part of Report of the WOAH ad hoc Group on susceptiblity of fish species to infection with WOAH listed diseases 2024, there are 3 species of the genus Channa met the criteria for listing as susceptible to infection with A. invadans , and there is also 3 species of the genus Channa having incomplete evidence of susceptibility (see Tables 7 and 8 in the report results	Did not agree Based on the relatively small number of species in the genus and that three species were found to be susceptible and three species were found to have incomplete evidence of susceptibility, the decision from September 2024 of listing *Channa* at the genus level remains appropriate (See item 6.6. of the September 2024 report).

<table>
<tr>
<td></td>
<td>section), and it is found from the website https://fishbase.se/search.php that there are more than 40 species of the genus Channa. It is recommended that all species of Channa be temporarily postponed from being listed for susceptible species, and only the three species of the genus Channa met the criteria for listing as susceptible to infection with A. invadans be listed.

Supporting evidence:

1. a-fish-ahg-eus-report-final.pdf

2.https://fishbase.se/search.php</td>
<td></td>
</tr>
<tr>
<td>10.2.2._2</td>
<td>Categoría: editorial.

Texto modificado propuesto:

<table>
<tr><th>Familia</th><th>Nombre científico</th><th>Nombre común</th></tr>
<tr><td rowspan="2">Alosidae</td><td>Alosa sapidissima</td><td>sábalo americano</td></tr>
<tr><td>Brevoortia tyrannus</td><td>lacha tirana</td></tr>
<tr><td>Anabantidae</td><td>Anabas testudineus</td><td>perca trepadora</td></tr>
<tr><td>Bagridae</td><td>Mystus cavasius</td><td>~~[gangetic mystus]~~ gangetic mystus [bagre del Ganges]</td></tr>
<tr><td rowspan="3">Centrarchidae</td><td>Lepomis macrochirus</td><td>mojarra oreja azul</td></tr>
<tr><td>Micropterus dolomieu</td><td>lobina de boca pequeña</td></tr>
<tr><td>Micropterus salmoides</td><td>perca atruchada</td></tr>
<tr><td>Channidae</td><td>Channa spp. (todas las especies)</td><td>N/A</td></tr>
<tr><td>Cichlidae</td><td>Etroplus suratensis</td><td>cromido verde</td></tr>
<tr><td>Clariidae</td><td>Clarias gariepinus</td><td>pez-gato</td></tr>
<tr><td rowspan="6">Cyprinidae</td><td>Cirrhinus mrigala</td><td>~~[mrigal carp]~~ mrigal</td></tr>
<tr><td>Dawkinsia filamentosa</td><td>barbo filamentoso</td></tr>
<tr><td>Enteromius paludinosus</td><td>~~[straightfin barb]~~ straightfin barb [Púa de aleta recta]</td></tr>
<tr><td>Labeo catla</td><td>~~[catla]~~ catla</td></tr>
<tr><td>Labeo rohita</td><td>labeo roho</td></tr>
<tr><td>Pethia conchonius</td><td>~~barbo rosy~~ barbo rosado</td></tr>
<tr><td>Gobiidae</td><td>Glossogobius giuris</td><td>~~[tank goby]~~ tank goby [gobio de acuario]</td></tr>
<tr><td>Ictaluridae</td><td>Ictalurus punctatus</td><td>bagre de canal</td></tr>
<tr><td>Mastacembelidae</td><td>Mastacembelus armatus</td><td>gran anguila</td></tr>
<tr><td>Mugilidae</td><td>Mugil cephalus</td><td>múgol o lisa rayada</td></tr>
<tr><td>Osphronemidae</td><td>Trichogaster fasciata</td><td>gourami bandeado o colisa gigante</td></tr>
</table>
</td>
<td>Did not agree

As per WOAH's style guide common names of host species used in all language versions of the Aquatic Code and Aquatic Manual are in accordance with FAOTERM. Where a common name is not in FAOTERM, the common name is in accordance with SeaLifeBase or SeaFishBase. If no common name exists for French or Spanish in these databases then the common name in English is presented in square brackets, and if no common name exists in any of the three official languages, no common name is included in the standards.</td>
</tr>
</table>

Not for comment

	<table><tr><td>Siluridae</td><td>Wallago attu</td><td>~~[wallago]~~ wallago</td></tr><tr><td>Sparidae</td><td>Archosargus probatocephalus</td><td>sargo chopa</td></tr><tr><td>Xenocyprididae</td><td>Hypophthalmichthys nobilis</td><td>carpa cabezona</td></tr></table> **Justificación**: Para una mejor comprensión del texto en la versión en español, se recomienda incluir el nombre común en el mismo idioma cuando existan referencias en español. En caso de que no existan referencias en español, se sugiere presentar el nombre común en inglés y la traducción sugerida entre corchetes. **Evidencia documentada:** 1. FAO. Consultado en : https://www.fao.org/fishery/docs/CDrom/aquaculture/I1129m/file/es/es_mrigalcarp.htm 2. Mendoza Alfaro RE, Luna S, Rojo Ramos I, Sánchez-Alejandro F, Álvarez González L. Especies exóticas de peces ornamentales en México : un extraño enemigo. Universidad Nacional Autónoma de México. 2003. Primera edición. Ciudad de México. ISBN 9786073076951. https://www.ecologia.unam.mx/libros/especies_exoticas_peces_Mexico.pdf	
10.2.2._3	**Category:** General **Proposed amended text:** No text proposed. 1) The assessment of susceptible species using Article 1.5.9 criteria ("Listing of susceptible species at a taxonomic ranking of Genus or higher") and the risk-based approach in Item 6.5.1 of the Aquatic Animal Health Standard Commission Report varies among *ad hoc* Groups (fish, crustaceans, and molluscs). For illustrations, in Chapter 10.2 Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome): *Channa spp*. are listed at the genus level as multiple species of this genus were found to be susceptible to *A. invadans*. However, only 3 species were assessed, namely *Channa marulius*, *Channa punctatus* and *Channa striata*. While all of disease-specific chapters for molluscs listed susceptible species at species level, and several species identified as susceptible are not considered to be sufficient representative to list at the higher taxonomic level. 2) For additional considerations, we would like to request WOAH to define how to determine the proportion of species within a taxonomic group to be representative in the assessments for susceptibility. **Rationale:** To ensure consistency in assessing susceptible species across the lists of susceptible species for all aquatic animals (fish, crustaceans, and molluscs).	See response to comment 10.2.2._1.

~~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~~

Not for Comment

~~*(Osphronemus goramy)*, dusky flathead *(Platycephalus fuscus)*, spiny turbot (*Psettodes* sp.), Tairiku-baratanago *(Rhodeus ocellatus)*, Keti-Bangladeshi (*Rohtee* sp.), rudd *(Scaridinius erythrophthalmus)*, terapon (*Terapon* sp.) and three-spot gourami *(Trichogaster trichopterus)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

[…]

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
A_10.4.12._1	**Category: General** The Member supports the proposed changes.	Noted
A_10.4.12._2	**Category:** General The Members support all modifications made on Annex 16.	Noted
A_10.4.12._3	**Category:** General The Members support this revised article.	Noted

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.

[…]

_____

Not for comment

CAPÍTULO 10.4.

INFECCIÓN POR EL VIRUS DE LA ANEMIA INFECCIOSA DEL SALMÓN

[…]

Artículo 10.4.11.

Conservación del estatus libre de infección por el virus de la anemia infecciosa del salmón

En este artículo, todas las consideraciones se entenderán hechas a un país, una *zona* o un *compartimento* libres de cualquier virus detectable de la anemia infecciosa del salmón, incluido el virus de la anemia infecciosa del salmón HPR0.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
E_10.4.11_1	**Categoría:** adición/cambio **Propuesta modificación de texto:** En este artículo, todas las consideraciones se entenderán hechas a un país, una zona o un compartimento libres de cualquier virus detectable de la anemia infecciosa del salmón, con supresión en la HPR incluido el virus de la anemia infecciosa del salmón HPR0. Un país, *zona* o *compartimento* declarados libres de infección por el virus de la anemia infecciosa del salmón, de conformidad con lo dispuesto en los Artículos 10.4.5.~~6.~~, 10.4.7.~~8.~~ y 10.4.9. (según proceda), podrán conservar su estatus libre de infección por el virus de la anemia infecciosa del salmón si reúnen ininterrumpidamente los requisitos descritos en el Artículo 1.4.15. **Justificación:** Se sugiere agregar explícitamente al primer párrafo con supresión en la HPR para dar mayor claridad al texto. Por su parte en el segundo párrafo los artículos del código que corresponden a país y zona libre de infección por el virus de la anemia infecciosa del salmón son 10.4.5 y 10.4.7 ya que los señalados en el anexo (10.4.6 y 10.4.8) corresponden solo a los con supresión en la HPR.	Did not agree to addition of text. The text for HPR0 is written throughout the chapter as in the original text and considered clear as written. Agreed to change the Articles to appropriately correspond to the Article 10.4.5, and 10.4.7.

Un país, *zona* o *compartimento* declarados libres de infección por el virus de la anemia infecciosa del salmón, de conformidad con lo dispuesto en los Artículos 10.4.6., 10.4.8. y 10.4.9. (según proceda), podrán conservar su estatus libre de infección por el virus de la anemia infecciosa del salmón si reúnen ininterrumpidamente los requisitos descritos en el Artículo 1.4.15.

Artículo 10.4.12.

Conservación del estatus libre de infección por el virus de la anemia infecciosa del salmón con supresión en la HPR

En este artículo, todas las consideraciones se entenderán hechas a un país, una *zona* o un *compartimento* libres de infección por el virus de la anemia infecciosa del salmón con supresión en la HPR, pero no necesariamente libres de infección por el virus de la anemia infecciosa del salmón HPR0.

Not for comment

Un país, *zona* o *compartimento* declarados libres de infección por el virus de la anemia infecciosa del salmón con supresión en la HPR, de conformidad con lo dispuesto en los Artículos 10.4.6., 10.4.8. y 10.4.10. (según proceda), podrán conservar su estatus libre de infección por el virus de la anemia infecciosa del salmón con supresión en la HPR si reúnen ininterrumpidamente los requisitos descritos en el Artículo 1.4.15.

[…]

_____

Not for comment

Draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus1*'

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X._1	**Category:** General The Member strongly supports the listing of infection with *Megalocytivirus pagrus 1* and agrees it is important that all three genogroups of *Megalocytivirus pagrus* 1 are listed by WOAH. The Member notes there are differences in host range and pathogenicity between the genogroups that warrant the ability for a country to retain separate status classification for each genogroup, such that if a member country is unable to demonstrate freedom for one genogroup, but can demonstrate freedom for another genogroup, that the member country can continue to implement risk mitigation measures to ensure ongoing freedom from the other genogroup(s).	Currently Members can notify *Megalocytivirus pagrus1* at the genogroup levels during immediate notification and this information can be found on WAHIS under 'animal disease events'. The Commission agreed that in other areas of WAHIS it would be beneficial to display the genogroup; for example, to easily determine the animal health situation at the genogroup level of a country or region. This feedback has been shared with WOAH Information and Analysis Department for consideration during future developments of WAHIS. In regards to self-declarations as 'infection with *Megalocytivirus pagrus1*' includes the three genogroups, in order to make a self-declaration of freedom from disease a country, zone or compartment it must be free from all three genogroups.
10.X._2	**Category:** General **Proposed amended text:** n/a **Rationale:** The Member would like to highlight that some work may need to be done to provide a clear system for reporting the different genotypes of *M. pagrus 1* within the WAHIS reporting system.	See response to comment 10.X._1.
10.X.3._3	**Category:** General The Member supports the application of the existing Aquatic Code template to the newly listed disease and has inserted some specific comments within the text.	Noted
10.X._4	**Category:** General The Member agrees and appreciates the Aquatic Animal Health Standards Committee's decision to replace the original the infection with red seabream iridovirus with the infection of Megalocytivirus pagrus 1, and to establish a new chapter in the code. This modification not only clarifies the list of susceptible hosts for the disease, but also adopts the latest ICTV nomenclature, making the definition and scope of disease prevention and control, monitoring, biosecurity, international trade, etc. more clear. The effective control of this disease on a global scale and the prevention of its spread through international trade have positive and significant implications. The relevant evaluation work of this disease has gone through more than 4 years. AAHSC and the ad hoc group have comprehensively collected and analyzed a large amount of scientific literature, carefully carried out susceptible host assessment and listing assessment, repeatedly collected member's comments, and adopted the latest name of	Noted

Not for comment

	ICTV, fully reflecting the rigor, scientificity, and transparency of the entire work.	
10.X._5	**Category:** General We support this amendment.	Noted
10.X._6	**Category:** General The Members support this new chapter.	Noted

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.1._1	**Category:** deletion **Proposed amended text :** ~~All three genogroups should be notified in accordance with Chapter 1.1.~~ **Rationale:** The scope of this disease covers three genogroups, which has been clearly defined in the first paragraph and it is unnecessary to repeatedly emphasized in the second paragraph.	Did not agree, this sentence was added for clarity and to be consistent with the approach taken in Chapter 10.4.

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

Not for comment

	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

Not for comment

	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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.2._1	**Category:** General comment **Rationale:** The Member appreciates the list of susceptible species for *Megalocytivirus pagrus 1* is currently subject to further investigation by WOAH and notes the list of potential host species in the draft chapter appears to be short with some apparent gaps based on the literature and the Member's Government's own import risk analysis for freshwater ornamental finfish (Department of Agriculture 2014) that supports the Member's import requirements for the mitigation of risks associated with megalocytiviruses in all poecilids, cichlids and gouramis. Some gaps in the listed species include: - Goldfish (Girisha 2020) - *Cleithracara maronii* (Koda 2018) - Golden Perch (Rimmer 2017) - Macquarie perch (Rimmer 2017) - Australian bass (Go and Whittington 2019a & b) The Member suggests that the host listings identify genogroups against the host species as well. **Supporting evidence:** Australian Department of Agriculture 2014, *Importation of freshwater ornamental fish: review of biosecurity risks associated with gourami iridovirus and related viruses—Final import risk analysis report*, Department of Agriculture, Canberra, available at https://www.agriculture.gov.au/biosecurity-trade/policy/risk-analysis/animal/ornamental-finfish Girisha, S.K., Puneeth, T.G., Nithin, M.S., Naveen Kumar, B.T., Ajay, S.K., Vinay, T.N., Suresh, T., Venugopal, M.N. and Ramesh, K.S. (2020) 'Red sea bream iridovirus disease (RSIVD) outbreak in Asian seabass (*Lates calcarifer*) cultured in open estuarine cages along the west coast of India: First report', *Aquaculture*, 520, 734712 Go, J. and Whittington, R. (2019a) 'Australian bass *Macquaria novemaculeata* susceptibility to experimental megalocytivirus infection and utility as a model disease vector', *Diseases of Aquatic Organisms*, 133(2), 157-174. Go, J. and Whittington, R. (2019b) 'Experimental transmission of infectious spleen and kidney necrosis virus (ISKNV) from freshwater ornamental fish to silver sweep *Scorpis lineolata*, an Australian marine fish', *Diseases of Aquatic Organisms*, 137(1), 1-21. Koda, S.A., Subramaniam, K., Francis-Floyd, R., Yanong, R.P., Frasca, S., Jr., Groff, J.M., Popov, V.L., Fraser, W.A., Yan, A., Mohan, S. and Waltzek, T.B. (2018) 'Phylogenomic	The *ad hoc* Group on susceptibility of fish species to infection with WOAH listed diseases reviewed the provided papers; for assessment chart see item 6.8. of the Aquatic Animals Commission's February 2025 report. Girisha *et al*. 2020 did not provide information on goldfish susceptibility as such the species was not assessed. *Cleithracara maronii* in Koda *et al*. 2018 was assessed in the *ad hoc* Group's 2022 report and was scored as 2. As such this species will be included in the *Aquatic Manual* in section 2.2.2. as a species with incomplete evidence for susceptibility. Work on the *Aquatic Manual* chapter is ongoing. *Macquaria ambigua* and *Macquaria australasica* as discussed in Rimmer *et al.*2017 were scored as a 1 for the paper. The ideal situation to categorize a fish species as susceptible was the presence of two papers with a score of '1', as such these species were provided an overall score of 2. These species will be included in the *Aquatic Manual* in section 2.2.2. as species with incomplete evidence for susceptibility. *Percalates novemaculeata* as discussed in Go & Whittington, 2019a and Go & Whittington, 2019b was scored as 1 in both papers. As such this species was given an overall score of 1 and included in the *Aquatic Code* chapter as a species susceptible to infection with *Megalocytivirus pagrus1*.

Member comment

<table>
<tr><td></td><td>characterization of two novel members of the genus Megalocytivirus from archived ornamental fish samples', Diseases of Aquatic Organisms, 130(1), 11-24

Rimmer, A.E., Whittington, R.J., Tweedie, A. and Becker, J.A. (2017) 'Susceptibility of a number of Australian freshwater fishes to dwarf gourami iridovirus (Infectious spleen and kidney necrosis virus)', Journal of Fish Diseases, 40(3), 293-310</td><td></td></tr>
<tr><td>10.X.2._2</td><td>Category: Addition

Proposed amended text:
<table><tr><td rowspan="2">Haemulidae</td><td>Parapristipoma trilineatum</td><td>chicken grunt</td></tr><tr><td>Plectorhinchus cinctus</td><td>crescent sweetlips</td></tr><tr><td>Lateolabracidae</td><td>Lateolabrax japonicas</td><td></td></tr><tr><td>Latidae</td><td>Lates calcarifer</td><td>barramundi</td></tr></table>Rationale: The Member requests the assessment of Lateolabrax japonicas by the ad hoc Group as it may also be susceptible to RSIV based on:

Kim, K.I., Lee E.S, Do, J.W., Hwang, S.D., Cho, M., Jung, S. H., Jee, B.Y., Kwan, W.J., Jeong, H.D. (2019) Genetic diversity of Megalocytivirus from cultured fish in Korea. Aquaculture. Volume 509, 15 July 2019, Pages 16-22.

Kim et al-2019.pdf</td><td>The ad hoc Group on susceptibility of fish species to infection with WOAH listed diseases reviewed the provided paper; for assessment chart see item 6.8. of the February 2025 report.

Lateolabrax japonicas as described in Kim et al. 2019 was scored as 1. This species had been previously assessed by the ad hoc Group in their 2022 report as a 2. The previous assessment was taken into account and the species provided an overall score of 1. This species to be included in the Aquatic Code as a susceptible species.</td></tr>
<tr><td>10.X.3._3</td><td>Category: Deletion

Proposed amended text:
<table><tr><td><s>Danionidae</s></td><td><s>Danio rerio</s></td><td><s>zebrafish</s></td></tr></table>Rationale:

BERMUDEZ et al 2018 is the first demonstration of susceptibility of Danio rerio to ISKNV, all other papers have been PCR detection only or invasive challenges. This study showed TEM particles that are smaller than expected (125 nm in this study, yet the WOAH RSIV manual section states “4.2.6. Electron microscopy/cytopathology: Confirm presence of virions (200–240 nm in diameter) in the enlarged cells.”) Additionally, the environmental conditions/stressors/concurrent illness of the 5 infected fish was not described yet other fish in the facility were exposed but not sick nor infected. The author state "There was no amplification from DNA isolations of control individuals, that is individuals sharing the same aquarium as the infected ones...". The Member is questioning if the ad hoc Group considered if there were underlying factors that could have affected susceptibility results.

The Member would propose deleting Danio rerio from the list in X.X.2. for Megalocytivirus pagrus 1 and include in Section 2.2.2. of the associated manual chapter when developed until there is additional corroborating evidence for susceptibility as the second line of corroborating evidence was only ranked as a 2.</td><td>Did not agree, the ad hoc Group was asked to reassess this host species and maintains their original assessment.

It was noted that viral particle size is not unusual and that the description in the Aquatic Manual for RSIV is derived from the first report of RSIV (Inouye et al. 1992) however other papers showing TEM images describes the sizes of viral particles to range between 125 -188 nm (Jung & Oh, 2000; Koda et al.2018; Kawato et al. 2020; Ramirez-Paredes et al. 2020, Swaminathan et al. 2022). Further, Bermudez et al. 2018 describes that the size, shape and location of virions was consistent with report of infection and that the slightly smaller size may be due to shrinkage of cells from paraffin blocks.

Further in Bermudez et al. 2018 the lack of amplification of DNA isolations result is discussed as follows “it may also indicate some kind of difficulty or resistance to horizontal transmission in this species. In actual fact, there are a</td></tr>
</table>

Not for comment

		limited number of reports about iridovirus infections in cyprinids (George et al., 2015)".
10.X.3._4	**Category:** general/question *Oreochromis niloticus* is listed as a susceptible species for M.Pagrus 1, however we note that other Tilapia species and their hybrids are not included. We would like to ask why other Tilapia species and hybrids are excluded as susceptible species. The Member has detected M. Pagrus 1 in marine tilapia, which is a hybrid species (*Oreochromis* spp).	As described in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen' 'the decision to list an individual species as susceptible in a disease-specific chapter should be based on finding that the evidence is definite in accordance with Article 1.5.3.'. As such, to list hybrids requires evidence that the hybrid meets the criteria for susceptibility, as it is not known if hybrids will maintain the same susceptibility as parent species without this evidence. To include other tilapia species it would have to be listed at a Genus level or higher. Article 1.5.9. provides criteria to list a susceptible species at a taxonomic ranking of Genus or higher. At this time only *Oreochromis niloticus* is listed as susceptible and thus Article 1.5.9. cannot be applied.
10.X.4._5	**Category:** General **Proposed amended text:** No text proposed. 1. The assessment of susceptible species using Article 1.5.9 criteria ("Listing of susceptible species at a taxonomic ranking of Genus or higher") and the risk-based approach in Item 6.5.1 of the Aquatic Animal Health Standard Commission Report varies among *ad hoc* Groups (fish, crustaceans, and molluscs). We would like to request WOAH to define how to determine the proportion of species within a taxonomic group to be representative in the assessments for susceptibility. 2. According to the assessment outcome in the report of the WOAH *ad hoc* Group on susceptibility of fish species to infection with WOAH listed diseases (November 2022), we notice that some fish species are susceptible to only some genogroups of *Megalocytivirus pagrus 1.* For example, *Pterapogon kauderni* (Banggai cardinal fish) is assessed for spleen and kidney necrosis virus (ISKNV) genogroup, and Aquatic Animal Health Standards Commission proposed to include *Pterapogon kauderni* as susceptible species to *M. pagrus 1* which includes three genogroups namely ISKNV, turbot reddish body iridovirus (TRBIV) and red sea bream iridovirus (RSIV). Therefore, we would like to seek clarification on the assessment outcome for listing susceptible species to *M. pagrus 1 even though some fish species are assessed to be susceptible to some certain genogroup of M. pagrus 1, not all genogroups.* **Rationale:** To ensure consistency in assessing susceptible species across the lists of susceptible species for all aquatic animals (fish, crustaceans, and molluscs).	In response to the first point, while the susceptible species assessments are ongoing the determinations on application of Article 1.5.9 are being made on a case by case basis. Upon completion of the work on susceptible species the Commission may consider reviewing Article 1.5.9. and defining the additional considerations utilised when applying the article. These considerations included considering species proportion within a taxonomic group. In response to the second point, all three genogroups belong to the species *M. pagrus1*. As such, susceptibility to a genogroup is considered susceptible to infection with *M. pagrus1.* As described in the 2022 report from the *ad hoc* Group it was not possible to identify to the level of genogroup for many of the susceptible species. Susceptibility at the genogroup level will be added to the *Aquatic Manual* chapter for Infection with *M. pagrus1* when it is drafted as it is in *Aquatic Manual* Chapter

Not for comment

		2.3.10. “Infection with viral haemorrhagic septicaemia virus”
10.X.4._6	**Category:** addition **Proposed amended text:** We strongly recommend including a column to the susceptible species table above (similar to the VHS Manual Chapter, for example) which will specify which species are considered susceptible to which of the genogroups **Rationale:** While it is helpful to have the species susceptibility listed by genogroup in the manual chapter, it is also important to include this information in the code chapter since it is critical members know which species need to be tested/certified free from which genogroup for trade purposes. The genotype specificity is also important for trade certification since a given diagnostic assay may not cover all genogroups.	Did not agree, genogroup susceptibility will be added to the *Aquatic Manual* chapter for Infection with *M. pagrus1* when it is drafted following the approach used for *Aquatic Manual* Chapter 2.3.10. “Infection with viral haemorrhagic septicaemia virus”
10.X.4._7	**Category:** addition **Proposed amended text** Cichlidae: red hybrid tilapia (*O. niloticus* × *Oreochromis mossambicus*) **Rationale:** Including the hybrids will guide importing countries (especially Africa) to screen for ISKNV as live fish (eggs, fry or fingerlings) may potentially introduce or spread the virus into the natural environment. **Supporting evidence:** 1) Machimbirike, V. I., Jansen, M. D., Senapin, S., Khunrae, P., Rattanarojpong, T., & Dong, H. T. (2019). Viral infections in tilapines: More than just tilapia lake virus. *Aquaculture*, *503*, 508-518. https://doi.org/10.1016/j.aquaculture.2019.01.036. 2) Clyde, C. W., Tan, J. P., Yeap, S. K., & Yong, C. Y. (2024). Current updates on viral infections affecting tilapia. *Aquaculture and Fisheries*. https://doi.org/10.1016/j.aaf.2024.05.002.	The *ad hoc* Group on susceptibility of fish species to infection with WOAH listed diseases reviewed the provided papers. The papers provided were review papers that did not provide the information required to assess susceptibility as per Chapter 1.5. From the review papers the paper Suebsing *et al.* 2016 was reviewed for susceptibility of the hybrid; for assessment chart see item 6.8. of the February 2025 report. This paper was not scored as stage 2 ‘pathogen identification’ was not met. Thus the hybrid species was not scored for susceptibility and was not included in the list of susceptible species.

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.

Not for comment

Article 10.X.4.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.4._1	**Comment for 10.X.4. to 10.X.8.** **Category:** General With the inclusion of *M. pagrus 1* in the list of diseases that includes Infectious Spleen and Kidney Necrosis Virus (ISKNV), which is prevalent in freshwater tropical ornamental fish populations worldwide, the greatest threat to *M. pagrus 1*-free countries, zones, or compartments comes from incursions via the international ornamental fish trade. Clear and practical guidance is needed in the WOAH Code to assist member countries in handling scenarios where the virus is detected in imported ornamental fish circulating within the domestic supply chain, including among unregistered hobbyists. While the risk of transmission of the virus from ornamental fish owned by hobbyists to food fish aquaculture or wild populations is generally low, recommended inclusions for wild, farmed and ornamental fish into the scope of this disease chapter are crucial for comprehensive biosecurity management. Key clarifications required include the following: 1. Is destruction of ISKNV positive ornamental fish owned by hobbyists required, particularly in cases where the fish are held in discrete unregistered closed holding systems/aquaria and there is no link to food fish aquaculture or wild aquatic animal populations? (We provided comment on the definition earlier) 2. To what extent should a country test epidemiologically linked populations if an incursion due to imported fish occurs, given that wholesalers may distribute imported fish to hundreds of shops nationwide? Should there be any guidance for prioritising testing based on proximity to food fish aquaculture, wild populations, or zones of concern? 3. Should cohabitating fish species not listed as susceptible be destroyed as part of the response to a detection of *M. pagrus 1*, particularly if they share water systems with infected susceptible species*?* Addressing these points is critical to ensuring the consistent, practical, science-based implementation of the Code across member countries.	The *Aquatic Code* provides standards for the improvement of aquatic animal health. However, the disease-specific chapters of the *Aquatic Code* are not intended to provide response policy. A Member's Competent Authority can determine their own response policy to protect their status in their country, zone or compartment. Guidance provided in new draft Chapters 4.X. and 4.Y. can be utilised to support.

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.

Not for comment

Article 10.X.5.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.5._1	**Category:** General comment for Article 10.X.5 to 10.X.7 Regarding the requirements for country, zone and compartment free from infection with *Megalocytivirus pagrus 1 (M. pagrus 1),* we are of the opinion that an appropriate duration of BBC and/or TS for all pathways should take into account data on all genogroups of *M. pagrus 1* including spleen and kidney necrosis virus (ISKNV), turbot reddish body iridovirus (TRBIV) and red sea bream iridovirus (RSIV). However, we notice that the current recommendations in the draft Chapter 10.X may be directly adopted from the assessment of only RSIV genogroup. Besides, the implementation of these articles for self-declaration of disease freedom requires more information on disease surveillance, recommended diagnostic techniques and case definitions which usually provided in the Aquatic Manual. However, only information on RSIV genogroup is currently available in Aquatic Manual (Chapter 2.3.7 red sea bream iridovirus disease). To facilitate the implementation of the requirement in this chapter on self-declaration of disease freedom, we propose that a reliable means of detection and diagnosis of all genogroups of *M. pagrus 1* should be developed in the revised Chapter 2.3.7 of the Aquatic Manual. Therefore, we strongly recommend that the draft new Chapter 10.X (Infection with *Megalocytivirus pagrus 1*) of the Aquatic Code should be adopted by the Assembly once the revision of Chapter 2.3.7 of the Aquatic Manual is completed. **Proposed amended text:** No text proposed. **Rationale:** as mentioned above	During the Commission's September 2024 meeting the assessment on default periods was updated to include *M. pagrus1* taking into account all genogroups. Due to the close taxonomic relatedness between genogroups it was considered that the default periods would be the same as though assessed for RSIV. The basic biosecurity conditions and targeted surveillance included in Chapter 10.X. reflect this assessment. Work is ongoing on the chapter for *M. pagrus1* for the *Aquatic Manual* with the formation and meeting of an *ad hoc* Group as described in the February 2025 report.

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

Not for comment

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

Not for comment

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

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.10._1(M.pagrus)	**Category:** General Articles 10.X.10 through to 10.X.14 outlines various scenarios for importation from countries not free from *M. pagrus* 1; however, the use of aquatic animals as ornamental aquatic animals is not specifically addressed. Is additional guidance required for this particular use, or would a formal acknowledgement that "the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures", suffice? At a minimum, a cross-reference to Chapter 5.X. is required.	As described in the work programme in the February 2025 report that Commission is commencing work on Section 5 of the *Aquatic Code* related to trade. A part of this work will include considerations of the articles in disease-specific chapters and any cross-references that should be included. As such, this will be considered in association with that work and future revisions that may occur as that work is competed.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *M. pagrus 1*

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.10._2(M.pagrus)	**Category:** Change **Proposed amended text:** 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	As there is no *Aquatic Manual* chapter for infection with *M. pagrus1*, the reference is placed under study until the *Aquatic*

Not for comment

	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.~~ 2.3.7 of the *Aquatic Manual*; **Rationale:** Incorrect manual chapter reference	*Manual* chapter is drafted and adopted.
10.X.10._3(M.pagrus)	**Category:** change **Proposed amended text :** 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* andChapter 2.3.~~8~~7 of the *Aquatic Manual*; **Rationale:** RSIV in latest version of Aquatic Manual is Chapter 2.3.7.	See response to comment 10.X.10_2(M.pagrus).

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

Not for comment

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
10.X.13._1	**Category:** change **Proposed amended text :** 5) samples are taken and sent to the laboratories authorised by the Competent Authority for test and the quarantine is over only when the test confirms that the consignment is free from *M. pagrus* 1. Quarantine duration is determined depending on the length of the test and risk assessment . **Rationale:** The international trade of wild ornamental fish and their retail circulation after entering importing countries is quite common, but this situation is not specifically regulated in this chapter. Without strict measures, it is easy to cause the introduction, spread, and colonization of diseases. Suggest adding a new article in this chapter to address this situation. The new article stipulates that after entering the country, individuals must continue to undergo testing and isolation in designated quarantine facilities to observe for any suspicious clinical symptoms. Only after passing the testing can they leave the quarantine facility and enter retail markets..	Did not agree to addition of text. The intention of Article 10.X.13. is for aquatic animals to enter lifelong quarantine in an approved quarantine premises such as a laboratory or zoo. As described as 10.X.10_1(M. pagrus) wording in articles will be considered in association with other work in the work programme. Future revisions of all disease-specific articles may be included. Until this time the template for disease-specific articles will be used for infection with *M.pagrus1*.

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

Not for comment

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.

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
11.6._1	**Category: General** The Member supports the proposed changes.	Noted
11.6._2	**Category:** General The Members support these revised Articles.	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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
11.6.1._1	**Categoría:** Adición **Texto modificado propuesto:** 2. Artículo 11.6.1 A efectos del *Código Acuático*, la infección por *Perkinsus olseni* designa una *infección* causada ~~exclusivamente~~ por el agente patógeno *P. olseni* de la familia Perkinsidae (Lester y Davis, 1981). **Justificación:** Se añadió la referencia, ya que en cualquier documento de índole científico, mencionar de donde se tomó esa definición es fundamental. **Evidencia documentada:** 1. Lester, R. J. G and Davis, G. H. (1981). A new Perkinsus species (Apicomplexa, Perkinsea) from the abalone, *Haliotis ruber*. Journal of invertebrate *Pathology* 37:181-187.	Did not agree, references are not included in the *Aquatic Code*.

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.~~

Not for comment

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~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
11.6.2._1	**Category:** addition **Proposed amended text:** Family / Scientific name / Common name Haliotidae — *Haliotis laevigata* — greenlip abalone *Haliotis rubra* — blacklip abalone *Haliotis iris* — New Zealand black-footed abalone **Rationale:** We note from the Report of the WOAH ad hoc Group on susceptibility of mollusc species to infection with WOAH listed diseases in December 2023, *Haliotis iris* was assessed to not meet the pathogen identification criteria to be listed as a susceptible species to *Perkinsus olseni* because the paper cited (MUZNEBIN *et* al 2023) relied only on the ISH probe published by Moss *et al.,* 2006. The report noted that if more information becomes available on the molecular identity of *P. olseni* in *H. iris*, the score of this host species will be reviewed. We would like to bring to the *ad hoc* group's attention that *P. olseni* was detected for the first time in farmed black foot pāua (*Haliotis iris*) in 2014 and reported to WOAH at the time (see WOAH-WAHIS event ID#5889, 2014.). This detection was prompted after clinical signs (mantle retraction in shell) and gross pathology (nodules) were observed at harvest. The Member's national laboratory received fixed and fresh samples from the affected farm and verified the presence of *Perkinsus* species by histopathology, which was then confirmed by an in-house validated conventional PCR and sequencing.	Agreed. Additional information provided on sequencing results for the WOAH-WAHIS event ID5889 provided sufficient evidence based on the criteria outlined in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogenic agent' of the *Aquatic Code.* As a result rainbow abalone (*Haliotis iris*) was added to the list of susceptible species. See item 6.9. of the February 2025 report for details of the re-assessment.

Not for comment

	We would also like to note that this methodology was the same used to identify *P. olseni* in: - *Perna canaliculus* (New Zealand green lipped mussel), which is listed as a susceptible species here and in the Aquatic Code Chapter 11.6 Infection with *Perkinsus* olseni, Article 11.6.2 , (draft version currently out for review) and - *Pecten novaezealandia* (New Zealand scallop), which is listed as a species with incomplete evidence of susceptibility here in the Aquatic Manual Chapter 2.4.6 Infection with *Perkinsus olseni* Section 2.2.2, Noting the same methodology was used to confirm *P. olseni* infection in these three New Zealand molluscs, but clinical signs and gross pathology has only been observed in *Haliotis iris,* we also query whether all three of these mollusc species should all be listed under the same susceptibility category, *either* susceptible *or* species with incomplete evidence of susceptibility, for consistency. Alternatively, should *Perna canaliculus* and *Pecten novaezealandia* be classified as species with incomplete evidence of susceptibility for *P. olseni*, (given clinical disease or mortality has not been observed associated with *P. olseni* in these species), whereas *H. iris* would have a stronger case to be listed as susceptible to *P. olseni*, given clinical disease has been observed associated with infection. **Supporting evidence:** WOAH-WAHIS event ID#5889, 2014, https://wahis.woah.org/#/in-event/5889/dashboard WOAH-WAHIS event ID#1600, 2014 https://wahis.woah.org/#/in-event/1600/dashboard WOAH-WAHIS event ID#1672, 2014, https://wahis.woah.org/#/in-event/1672/dashboard New Zealand Regional Aquatic Animal Disease Report January – June 2024 https://rr-asia.woah.org/app/uploads/2024/09/NEW-ZEALAND-QAAD_Jan_Jun_2024.pdf Bingham P (2013). Quarterly report of investigations of suspected exotic marine and freshwater pests and diseases. Surveillance, Volume 40, Issue 4, pp 31-34, Dec 2013. Ministry for Primary Industries Bingham, P. (2015). Quarterly report of investigations of suspected exotic marine and freshwater pests and diseases. Surveillance, Volume 42, Issue 2, pp 25-26, Jun 2015. Ministry for Primary Industries MUZNEBIN, F., ALFARO, A.C. & WEBB, S.C. (2023a). Occurrence of Perkinsus olseni and other parasites in New Zealand black-footed abalone (Haliotis iris). New Zealand Journal of Marine and Freshwater Research, 57(2), 261-281.	
11.6.2._2	**Category:** addition **Proposed amended text:** The Members propose the following additions to the text: *Anadara trapezia* Common name: Sydney Cockle **Supporting evidence:** https://bie.ala.org.au/species/https://biodiversity.org.au/afd/taxa/c31c4717-6229-499d-9ebd-ce2e723ff7c1	Did not agree. As per WOAH's style guide common names of host species used in all language versions of the *Aquatic Code* and *Aquatic Manual* are in accordance with FAOTERM. Where a common name is not in FAOTERM, the common name is in accordance with SeaLifeBase or SeaFishBase. If no common name exists for French or Spanish in these databases then the

Not for comment

		common name in English is presented in square brackets, and if no common name exists in any of the three official languages, no common name is included in the standards.

[...]

Not for comment

Articles 11.7.1. and 11.7.2. of Chapter 11.6. 'Infection with *X. californiensis*'

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
11.7._1	**Category: General** The Member supports the changes proposed and has inserted comments within the text.	Noted
11.7._2	**Category:** General The Members support all modifications made on Annex 19	Noted
11.7._3	**Category:** General The Members support these revised Articles.	Noted

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*~~.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
11.7.1._1	**Categoría:** Adición **Texto modificado propuesto**: 2. **Artículo 11.7.1.** A efectos del *Código Acuático*, la infección por *Xenohaliotis californiensis* designa una *infección* causada ~~exclusivamente~~ por el *agente* patógeno intracelular *Candidatus Xenohaliotis californiensis* de la familia Anaplasmataceae ~~*X. californiensis*~~ (Dumler et al., 2001) y está estrechamente relacionada con miembros de los géneros Ehrlichia, Anaplasma y Cowdria (Friedman et al., 2000). La enfermedad causada por esta bacteria se denomina síndrome de marchitamiento (Friedman et al., 2002; Haaker et al., 1992) y puede designarse más apropiadamente como rickettsiosis del abulón. **Justificación:** Se complementó el texto con información y se añadió la referencia, ya que, en cualquier documento de índole científico, mencionar de donde se tomó esas características es fundamental. Evidencia documentada, si corresponde: 1. DUMLER J.S., BARBET A.F., BEKKER C.P.J., DASCH G.A., PALMER G.H., RAY S.C., RIKIHISA Y. & RURANGIRWA F.R.	Did not agree to add text for consistency with information provided in other chapters in the *Aquatic Code*. This information is included in the scope of the *Aquatic Manual* for disease-specific chapters.

Not for comment

	(2001). Reorganization of general in the families Rickettsiaceae and Anaplasmataceae in the order Rickettsiales: unification of some species of Ehrlichia with Anaplasma, Cowdria with Ehrlichia and Ehrlichia with Neorickettsia, descriptions of six new species combinations and designation of Ehrlichia equi and 'HGE agent' as subjective synonyms of Ehrlichia phagocytophila. Int. J. System. Evol. Microbiol., 51, 2145–2165. 2. FRIEDMAN C.S., ANDREE K.B., BEAUCHAMP K.A., MOORE J.D., ROBBINS T.T., SHIELDS J.D. & HEDRICK R.P. (2000). "Candidatus Xenohaliotis californiensis" a newly described pathogen of abalone, Haliotis spp., along the west coast of North America. Int. J. Syst. Evol. Microbiol., 50, 847–855. 3. FRIEDMAN C.S., BIGGS W., SHIELDS J.D. & HEDRICK R.P. (2002). Transmission of withering syndrome in black abalone, Haliotis cracherodii Leach. J. Shellfish Res., 21, 817–824. 4. HAAKER P.L., PARKER D.O., TOGSTAD H., RICHARDS D.V., DAVIS G.E. & FRIEDMAN C.S. (1992). Mass mortality and withering syndrome in black abalone Haliotis cracherodii, in California. In: Abalone of the World, Shepard S.A., Tegner M.J. & Guzman del Proo S.A., eds, Blackwell Scientific, Oxford, UK, 214–224.	

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

Not for comment

<table>
<tr><th>Reference</th><th>Comment (in language submitted)</th><th>Aquatic Animals Commission Response</th></tr>
<tr><td>11.7.2._1</td><td>Category: Deletion

Proposed change:
<table>
<tr><th>Family</th><th>Scientific name</th><th>Common name</th></tr>
<tr><td rowspan="11">Haliotidae</td><td>Haliotis corrugata</td><td>pink abalone</td></tr>
<tr><td>Haliotis cracherodii</td><td>black abalone</td></tr>
<tr><td>Haliotis discus discus</td><td>Japanese abalone</td></tr>
<tr><td>Haliotis diversicolor</td><td>small abalone</td></tr>
<tr><td>Haliotis fulgens</td><td>green abalone</td></tr>
<tr><td>Haliotis kamtschatkana</td><td>pinto abalone</td></tr>
<tr><td>Haliotis rufescens</td><td>red abalone</td></tr>
<tr><td>Haliotis rufescens X Haliotis discus hannai hybrid</td><td>hybrid red and Japanese abalone</td></tr>
<tr><td>Haliotis sorenseni</td><td>white abalone</td></tr>
<tr><td>Haliotis tuberculata</td><td>tuberculate abalone</td></tr>
</table>
Rationale: The Member requests the AAC list susceptibility at the species level and not at the subspecies level as was done for Infection with Abalone Herpes virus. Sub species cannot be truly distinct species in the presence of another subspecies from the same species. Species is a well-defined as a population of organisms in which any two individuals of the appropriate sexes or mating types can produce fertile offspring. But subspecies is a population that lives in different areas and vary in size, shape, or other physical characteristics (morphology), but that can successfully interbreed. Therefore, a subspecies could interbreed with another subspecies (from the same parent species) and produce offspring that are viable but no longer uniquely to the original subspecies.

As an example of this, and supporting rationale many aquatic species are bred to select for resistance to disease. This is commonly done in endemic areas to support production. However, this development of resistance in a subspecies population should not negate the parent species from be considered a susceptible species. In addition, a population of subspecies cannot easily be confirmed to be absent of genetic material of the parent species/other subspecies affecting it’s disease resistance.</td><td>Did not agree, as per the June 2024 ad hoc Group report ‘The two subspecies Haliotis discus discus and Haliotis discus hannai are accepted names in WoRMS; therefore, the ad hoc Group assessed and scored the subspecies separately. The ad hoc Group does not recommend assessing Haliotis discus at the species level as there is preliminary evidence of resistance to infection for one of the two subspecies.’

Refer to the ad hoc Group’s June 2024 report available on the WOAH Website for details.</td></tr>
</table>

~~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.~~

[…]

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.2.8._1	**Category:** General **Rationale:** Pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated: • *Palaemon gravieri* (Chinese ditch prawn) • *Palaemon macrodactylus* (migrant prawn) • *Palaemon pandaliformis* (potitinga prawn) • *Palaemon pugio* (daggerblade grass shrimp) • *Palaemon serenus* (Rock pool shrimp) • *Palaemonella* spp. (no common name) In Moreton Bay where an exotic incursion of WSSV has established, a single pool of wild caught Palaemon serenus (n = 2) was positive for natural WSSV infection by qPCR at a prevalence of 100%, and Ct of 34.72. In the same survey, a single pool of Palaemonella spp. n = 4) which were examined by qPCR were WSSV positive (prevalence 100%) and Ct of 35.71. Data from Diggles (2020). **Supporting evidence:** Diggles BK (2020). Survey for WSSV vectors in the Moreton Bay White Spot Biosecurity Area. Final Report for FRDC Project No 2019-214, 55 pgs. https://www.frdc.com.au/project/2019-214	The *ad hoc* Group on susceptibility of crustacean species to infection with WOAH listed diseases assessed the species included in Diggles (2020) and concluded that *Palaemon serenus* and *Palaemon serrifer* met the requirements of a score of 3 (see item 6.5. of the February 2025 report). The Commission agreed to add these two species in Section 2.2.2. as having pathogen-specific positive PCR results. *Palaemon graviera*, *Palaemon macrodactylus*, *Palaemon pandaliformis* and *Palaemon pugio* were already assessed by the *ad hoc* Group report as having a score of '3' and are currently included in Section 2.2.2.
2.2.8._2	**Category: General** The Member supports the application of the Article 1.5.9. for infection with WSSV and has provided a comment on the workplan to ensure it is consistently applied in the future.	Noted
2.2.8._3	We support this amendment.	Noted
2.2.8._4	**Category:** General The Members support these revised sections.	Noted

Not for comment

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

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.2.8._5	**Category:** Change **Proposed amended text:** Palaemon spp. (all species) **Rationale:** Palaemon spp. should remain considered to be susceptible to WSSV at the genus level until such time as specific experimental evidence is provided by a member country that one or more species of Palaemon challenged with WSSV are shown to be refractory to infection in a study published in the scientific literature. Evidence from an area where an exotic incursion of WSSV has established, found that all three species of wild caught Palaemonids examined by qPCR (Palaemon serrifer, P. serenus, Palaemonella spp.) were naturally infected with WSSV at prevalences up to 100% (mean prevalence for all three species combined = 31%, n = 722), with Ct as low as 28.56 showing that viral replication was occurring in some animals (Diggles 2020). **Supporting evidence:** Diggles BK (2020). Survey for WSSV vectors in the Moreton Bay White Spot Biosecurity Area. Final Report for FRDC Project No 2019-214, 55 pgs. https://www.frdc.com.au/project/2019-214	Did not agree. Even with the addition of *Palaemon serrifer* and *Palaemon serenus* (scored as '3' by the *ad hoc* Group) to the *Aquatic Manual*, the decision from September 2024 of listing *Palaemon* at the species level is appropriate (See item 6.5.2. of the September 2024 report). The *Palaemon* genus represents nearly 200 species and 11 of these species have been assessed for susceptibility to WSSV: 3 species meeting criteria for susceptibility, 1 species with incomplete evidence of susceptibility and 7 species with positive molecular results only.
2.2.8._6	**Categoría:** Cambio, General **Texto modificado propuesto**: Family | ~~Scientific name~~ Specie | Common name **Justification:** In scientific texts the concept Species is used when we refer to the genus and species (scientific name) instead of quoting verbatim the use of the word scientific name, based on the above I add a reference. **Documented evidence, if applicable:** M O'Brien and S Pellett. Diseases of Gastropoda. Front Immunol. 2021; 12: 802920. Published online 2022 Jan 13. doi: 10.3389/fimmu.2021.802920. Link: Diseases of Gastropoda - PMC (nih.gov)	Did not agree, 'scientific name' is the title used in all such tables in the standards. For consistency, scientific name will continued to be used.
2.2.8._7	**Category:** addition **Proposed amended text:** *Procambarus zonangulus* Common name: White River Crayfish *Palaemon orientis* Common name: Oriental prawn **Supporting evidence:** https://en.wikipedia.org/wiki/Procambarus_zonangulus https://www.fao.org/4/ac477e/ac477e14.pdf	Did not agree. As per WOAH's style guide common names of host species used in all language versions of the *Aquatic Code* and *Aquatic Manual* are in accordance with FAOTERM. Where a common name is not in FAOTERM, the common name is in accordance with SeaLifeBase or SeaFishBase. If no common name exists for French or Spanish in these databases then the common name in English is presented in square brackets, and if no common name exists in any of the three official languages, no common name is included in the standards.

Not for comment

~~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

Not for comment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.2.8._8	**Category:** Addition **Proposed amended text:** Macrobrachium idella (slender river prawn) Macrobrachium lamarrei (Kuncho river prawn) Macrobrachium nipponense (Oriental river prawn) Macrobrachium rosenbergii (giant river prawn) Palaemon adspersus (Baltic prawn) Palaemon serrifer (estuarine shrimp) **Rationale:** In Moreton Bay where an exotic incursion of WSSV has established, wild caught Palaemon serrifer (n = 716) were positive for natural WSSV infections at a prevalence of 30.4% (n = 218/716 infected) with Cts ranging between 28.56-42.38, indicating viral replication was occurring in some individual shrimp. Data from Diggles (2020) **Supporting evidence:** Diggles BK (2020). Survey for WSSV vectors in the Moreton Bay White Spot Biosecurity Area. Final Report for FRDC Project No 2019-214, 55 pgs. https://www.frdc.com.au/project/2019-214	Agreed, see response to comment 2.2.8._1.

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

Not for comment

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

Not for comment

	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.~~

[…]

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.3.1._1	**Category: General** The Member supports the proposed changes.	Noted
2.3.1._2	**Category:** General **The Members seek clarification on:** Why have all the fish species that were killed by this pathogenic agent been removed from the list, despite the confirmatory diagnosis at the time (mass mortality, histopathology and PCR)? Wasn't this sufficient evidence of susceptibility? How can we explain the mortalities of the stricken down species for insufficient evidence as not susceptible?	For most species there was insufficient evidence to determine pathogenic agent identification based on the criteria outlined in Chapter 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogenic agent' of the *Aquatic Code*. For details of the assessment conducted by the *ad hoc* Group refer to the *ad hoc* Group's April 2024 report available on the WOAH Website.
2.3.1._3	**Category:** General The Members support these revised sections.	Noted

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~~

Not for comment

~~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

Not for comment

	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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.3.1._4	**Category:** General **Proposed amended text:** No text proposed. 1) The assessment of susceptible species using Article 1.5.9 criteria ("Listing of susceptible species at a taxonomic ranking of Genus or higher") and the risk-based approach in Item 6.5.1 of the Aquatic Animal Health Standard Commission Report varies among *ad hoc* Groups (fish, crustaceans, and molluscs). For illustrations, in Chapter 10.2 Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome): *Channa spp*. are listed at the genus level as multiple species of this genus were found to be susceptible to *A. invadans*. However, only 3 species were assessed, namely *Channa marulius*, *Channa punctatus* and *Channa striata*. While all of disease-specific chapters for molluscs listed susceptible species at species level, and several species identified as susceptible are not considered to be sufficient representative to list at the higher taxonomic level. 2) For additional considerations, we would like to request WOAH to define how to determine the proportion of species within a taxonomic group to be representative in the assessments for susceptibility.	See response to comment 10.2.2._1.

Not for comment

	Rationale: To ensure consistency in assessing susceptible species across the lists of susceptible species for all aquatic animals (fish, crustaceans, and molluscs).	

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

[…]

Not for comment

CHAPTER 2.4.2.

INFECTION WITH *BONAMIA EXITIOSA*

Reference	Comment	Aquatic Animals Commission response
2.4.2_1	**Category:** General The Members support all modifications made on Annex 22	Noted
2.4.2_2	**Category:** General The Member supports the revised chapter	Noted
2.4.2_3	**Category:** General We support this amendment	Noted
2.4.2_4	**Category:** General The Members support this revised chapter.	Noted
2.4.2_5	**Category:** Editorial **Proposed amended text:** General comments on this text: • *Bonamia* sp., *Bonamia* spp. and *Bonamia* species is used throughout the text. • *Bonamia exitiosa* vs *B. exitiosa* - review whether the genus will be spelled out in full at every mention and when it will be abbreviate to *B. ostreae* – appears to be inconsistent. • Change Taqman to TaqMan where needed. • Check mentions of "haplosporidia" and remove italics as it not a genus in this context. • Arzul *et al.* (2010) should be Arzul *et al.* (2011) **Rationale:** For consistency and accuracy. **Supporting evidence** ARZUL I., LANGLADE A., CHOLLET B., ROBERT M., FERRAND S., OMNES E., LEROND S., COURALEAU Y., JOLY J.-P., FRANÇOIS C. & GARCIA C. (2011). Can the protozoan parasite *Bonamia ostreae* infect larvae of flat oysters *Ostrea edulis*? *Vet. Parasitol.,* **179**, 69–76. doi:10.1016/j.vetpar.2011.01.060.	Agreed. Regarding *Bonamia exitiosa* vs *B. exitiosa,* the style of the *Aquatic Manual* is to write in full first time and at beginning of sentences/paragraphs

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).

Reference	Comment	Aquatic Animals Commission response
2.4.2_2.1.1_1	**Category:** Change **Proposed amended text:** …Since the original description of the parasite in New Zealand in the mid-1980s, *B. exitiosa* and *B. exitiosa*-like microcells have been described frequently in Europe, Australia and the Americas ~~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~~,~~ and ultrastructure ~~and molecular sequences was~~ were insufficient to discriminate unequivocally between species (Hill et al., 2010b). **Rationale:** The description "various locations globally" was absolute. According to our knowledge, there is no confirmed *Bonamia exitiosa* infection case in Asia and Africa. "molecular sequences" should not appeared here, because "ITS rDNA locus" used for species identification mentioned above was molecular sequences.	Disagreed, the text is on the epidemiology of the agent and would fit better in Section 2.3.6 'Geographical distribution'. However, the Commission found that the topic is already covered in Section 2.3.6, so just removed it from here.

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

Reference	Comment	Aquatic Animals Commission response

2.4.2_2.2.1_1	**Category:** addition/deletion **Proposed amended text:** …Scientific name: Magallana (syn. Crassostrea) ariakensis; common name: ~~Ariake cupped~~ Suminoe oyster **Rationale:** Suminoe oyster appears to be a more commonly used common name for *Magallana* (syn. *Crassostrea*) *ariakensis* **Supporting evidence** https://invasions.si.edu/nemesis/species_summary/-199 https://uk.inaturalist.org/taxa/606018-Magallana-ariakensis.	Disagreed. WOAH uses FAOTerm for common names and if not present in FAOTerm then the common names listed in SealifeBase. The common name for *Crassostrea ariakensis* in FAOTerm is Ariake cupped oyster, which is the name used in the *Aquatic Code*.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_2.2.6_1	**Category:** addition/deletion **Proposed amended text:** 2.2.6. Vectors	Agreed

	None known. **Rationale:** missing subsection 2.2.6. Vectors **Supporting evidence**	

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 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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_3.2_1	**Categoría:** Editorial. **Texto modificado propuesto:** ...includes a sample of gills, mantle, gonad~~,~~ and digestive gland, **Justificación:** La coma no aplica (,).	Agreed
2.4.2_3.2_2	**Category:** addition/deletion **Proposed amended text:** Gills or heart are preferred for some tests such as imprints. For PCR in *O. edulis* it is recommended to include gills ~~and gonad~~. **Rationale:** Only one PCR assay listed in 6.3.1 uses the gonads, and collection of gonads is not always practical, particularly after spawning. Therefore, Members should not focus on this as a primary tissue for collection for PCR.	Disagreed. Added a sentence clarifying that according to the study by Ramilo *et al.* (2014), more than 1 organ (including gills, heart and gonad) should be used for PCR-based diagnosis of *B. exitiosa*, to maximise the sensitivity.

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

Reference	Comment	Aquatic Animals Commission response
2.4.2_4_1	**Category:** general **Proposed amended text:** Consider whether the species-specific *Bonamia exitiosa* ddPCR that has been developed for targeted surveillance of *Ostrea chilensis* for *B. exitiosa* in New Zealand is eligible to be included in the *Aquatic Manual*. **Rationale:** We would like to bring attention to two separate molecular diagnostic assays that have been developed for *Bonamia exitiosa* and *Bonamia ostreae* using droplet digital PCR (ddPCR) and are being used for on-going fisheries management and biosecurity surveillance of *Ostrea chilensis* in New Zealand (see surveillance reports supplied in supporting evidence). These assays were developed after reviewing and revising preexisting assays for *B. ostreae* and *B. exitiosa* and evaluated using the WOAH Validation Pathway. A manuscript describing the development and validation of these assays has been accepted with minor revisions for publication in *Diseases for Aquatic Organisms* and the authors have given permission for the manuscript to be shared with WOAH (see attached in supporting evidence). We seek advice as to whether these assays could be considered for inclusion in the *Aquatic Manual* chapters for *B. ostreae* and *B. exitiosa*, and if we should also submit a Template for the validation report form for tests recommended in the WOAH Aquatic Manual. **Supporting evidence**  Bilewitch et al DAO Accepted-Minor Rev A survey of the Foveaux Strait oyster (Ostrea chilensis) population (OYU 5) in commercial fishery areas and the status of bonamia (Bonamia exitiosa) in February 2016 FAR 2019/02 – A survey of the Foveaux Strait oyster (Ostrea chilensis) population (OYU 5) in commercial fishery areas and the status of Bonamia (Bonamia exitiosa) in February 2018 FAR 2020/11 A survey of the Foveaux Strait oyster (Ostrea chilensis) population (OYU 5) and the status of Bonamia (Bonamia exitiosa) in February 2019 FAR 2021/06 Surveys of the Foveaux Strait oyster (Ostrea chilensis) population (OYU 5) and Bonamia exitiosa prevalence, intensity, and disease related oyster mortality in February 2020 FAR 2022/48 Surveys of the Foveaux Strait oyster (Ostrea chilensis) fishery (OYU 5) and Bonamia exitiosa prevalence, intensity, and disease mortality in February 2021 FAR 2023/25 Annual surveys of the Foveaux Strait oyster (Ostrea chilensis) fishery (OYU 5) and Bonamia exitiosa prevalence, intensity, and disease mortality in February 2022.	On hold for now. The AAC policy is that new assays can only be included in the *Aquatic Manual* if they have been validated to at least level 2 according to published paper. The Member will be asked if they are confident that the paper will be published by September 2025. If yes, the chapter will be amended then and put back in the review cycle; if no, they will be asked to fill in the validation template, and the assay will be cross-referenced in the chapter.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_4.2_1	**Categoría:** Editorial. **Texto modificado propuesto:** Sections of tissue that include gills, digestive gland, mantle~~,~~ and gonad should be fixed for... **Justificación:** La coma no aplica (,).	Agreed

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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_4.2_1	**Category:** deletion/addition **Proposed amended text:** *B. exitiosa* is generally larger than *B. ostreae* and often has a central or subcentral nucleus (Lane *et al.,* 2016). Plasmodia stages characterised by irregular shape were noted in the haemocyte cytoplasm but, unlike *B. perspora*, no	Agreed

	spore has been described in *B. exitiosa*. The technique is not species-specific. **Rationale:** Included a reference that shows through histopathology that *B. exitiosa* (2.1 µm) was larger than *B. ostreae* (1.2 µm) with nuclei fitting the description in text. **Supporting evidence**: Lane H.S., Webb S C. & Duncan J. (2016). *Bonamia ostreae* in the New Zealand oyster *Ostrea chilensis:* a new host and geographic record for this haplosporidian parasite. *Dis. Aquat. Organ.*, **118**, 55–63.	

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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_4.4.1_1	**Category:** addition **Proposed amended text:** Three TaqMan PCR assays are available for the detection of *Bonamia* spp.: one targeting the ITS1 (internal transcribed spacer) region (Corbeil *et al.*, 2006)...	Agreed

	Rationale: Need to add either “region” or “gene’	

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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_4.4.1_2	**Category:** addition **Proposed amended text:** 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 two PCR assays allow the concomitant detection of *B. ostreae* and *B. exitiosa* parasites. **Rationale:** This section should clarify that the EURL method has a separate primer probe set for *B. exitiosa* and can be duplexed. Question as to why the Robert *et al.* (2009) paper was not also referenced. The Robert PCR is a SYBR PCR and targets the actin gene. **Supporting evidence** Robert M., Garcia C., Chollet B., Lopez-Flores I., Ferrand S., François C., Joly J.P. & Arzul I. (2009). Molecular detection and quantification of the protozoan *Bonamia ostreae* in the flat oyster, *Ostrea edulis*. *Mol. Cell. Probes*, **23**, 264–271. doi: 10.1016/j.mcp.2009.06.002.	Disagreed, the Commission found that the final sentence clarifies that both PCR assays allow the concomitant detection of *B. exitiosa* and *B. ostrea*. Concerning the Robert *et al.* (2009) paper, the Reference Laboratory expert advised that this paper allows the detection of *B.ostrea* and **not** *B.exitiosa*, so it would not be useful to refer to it here.’

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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_4.4.1_1	**Category:** Editorial **Proposed amended text:** Method 1: Corbeil et al., 2006a; GenBank Accession No.: DQ312295 – ITS-For: CCC-TGC-CCT-TTG-TAC-ACA-CC **Rationale:** ITS-For primer is missing an additional C nucleotide at the 3' end.	Agreed
2.4.2_4.4.1_2	**Category:** Additional **Proposed amended text:** **Rationale:** GenBank Accession number to be provided for Method 5.	Agreed: the Reference Laboratory provided it.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.2_4.4.2_1	**Category:** Additional **Proposed amended text:** **Rationale:** GenBank Accession numbers to be provided for Methods 1 and 2.	Agreed
2.4.2_4.4.2_2	**Category:** general Query as to the conventional PCRs from Ramilo *et al.,* 2013 are not included in this paragraph? **Rationale:** Species-specific conventional PCRs for *B. exitiosa* and *B. ostreae* that have been used in the our country at the earlier stages of the incursion of *B. ostreae* to the country. We could not use the two methods included because they are not species specific and *B. exitiosa* is endemic in our country. **Supporting evidence** Ramilo A., Navas J.I., Villalba A. & Abollo E. (2013). Species-specific diagnostic assays for Bonamia ostreae and B. exitiosa in European flat oyster Ostrea edulis: conventional, real-time and multiplex PCR. *Dis. Aquat. Organ.,* **104**, 149–161.	Agreed, a row has been added to the PCR table with data from the Ramilo *et al.* (2013) reference

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

Reference	Pathogen/target	ISH probe type	ISH probe
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

Reference	Comment	Aquatic Animals Commission response
2.4.2_6.2.1_1	**Category:** addition/deletion **Proposed amended text:** 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~~ **Rationale:** Gross pathology and clinical signs are not sufficiently pathognomonic.	Disagreed: gross pathology or clinical signs associated with disease, as described in this chapter, would raise suspicion, so the current text is correct.

1 For example transboundary commodities.

6.2.2. Definition of confirmed case in clinically affected animals

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

Reference	Comment	Aquatic Animals Commission response
2.4.2_6.2.2_1	**Category:** addition/deletion **Proposed amended text:** 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 **Rationale:** Confirmation by only real-time PCR is not suitable. Visualisation of the parasite by histology or imprints should be part of the confirmation.	Agreed and added new criteria for a confirmed case here and in Section 6.1.2 to include real-time PCR and conventional PCR and sequencing; real-time PCR and *in-situ* hybridisation; and tissue imprints, histology or *in-situ* hybridisation, and conventional PCR followed by sequence analysis, where appropriate.

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	Diagnosis	Two farms in *B. exitiosa* endemic areas in Australia: a coastal lease with	Gills	*Ostrea angasi*	93.5% (232)	92.2% (232)	Histology Bayesian latent class analysis	Bradley *et al.*, 2020

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
epidemiological Ct cut-off)		*B. exitiosa* associated mortalities, a land-based hatchery with no *B. exitiosa* associated mortalities (prevalences ~30 and 60%)						
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	Heart imprints	*Ostrea angasi*	61% (400)	60% (400)	Histology (DSe: 76%, DSp: 93%) and real-time PCR (DSe: 69%,	Buss *et al.,* 2019

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
		populations 60–90%, but low intensity of infection)					DSp:93%) Bayesian latent class analysis	
	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
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	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	Canier *et al.,* 2020

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
		representative of three different levels of *B. ostreae* prevalence (very low, low, high)					latent class analysis	
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
	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.

Reference	**Comment**	**Aquatic Animals Commission response**
2.4.2_6.3.2_1	**Category:** Deletion **Proposed amended text:** **Rationale:** Is Balseiro *et al.* 2006 surveillance data relevant to this table in *Bonamia exitiosa* chapter as only *Bonamia ostreae* positive material tested.	Agreed: deleted the reference here and from the list.

7. References

ABOLLO E., RAMILO A., CASAS S.M., COMESAÑA P., CAO A., CARBALLAL M.J. & VILLALBA A. (2008). First detection of the protozoan parasite *Bonamia exitiosa* (Haplosporidia) infecting flat oyster *Ostrea edulis* grown in European waters. *Aquaculture,* **274**, 201–207.

ARZUL I. & CARNEGIE R.B. (2015) New perspective on the haplosporidian parasites of molluscs. *J. Invertebr. Pathol.,* **131**, 32–42. doi: 10.1016/j.jip.2015.07.014.

ARZUL I., LANGLADE A., CHOLLET B., ROBERT M., FERRAND S., OMNES E., LEROND S., COURALEAU Y., JOLY J.-P., FRANÇOIS C. & GARCIA C. (2010). Can the protozoan parasite *Bonamia ostreae* infect larvae of flat oysters *Ostrea edulis*? *Vet. Parasitol.*, doi:10.1016/j.vetpar.2011.01.060

BALSEIRO P., CONCHAS R.F., MONTES J., GÓMEZ-LEÓN J., NOVOA B. & FIGUERAS A. (2006). Comparison of diagnosis techniques for the protozoan parasite *Bonamia ostreae* in flat oyster *Ostrea edulis*. *Aquaculture*, **261**, 1135–1143.

BISHOP M., CARNEGIE R., STOKES N., PETERSON C. & BURRESON E., (2006). Complications of a non-native oyster introduction: facilitation of a local parasite. *Mar. Ecol., Prog. Ser.,* **325**, 145–152.

BRADLEY T.L., MERCER J.A., HUMPHREY J.D., MOODY N.J.G. & HUNNAM J.C. (2020). *Bonamia exitiosa* in farmed native oysters *Ostrea angasi* in Australia: optimal epidemiological qPCR cut-point and clinical disease risk factors. *Dis. Aquat. Organ.*, **140**, 151–165.

Buss J.J., Harris J.O., Tanner J.E., Wiltshire K.H. & Deveney M.R. (2020a). Rapid transmission of *Bonamia exitiosa* by cohabitation causes mortality in *Ostrea angasi*. J. Fish Dis., **43**, 227–237. doi: 10.1111/jfd.13116.

Buss J., Wiltshire K.H., Harris J.O. & Deveney M.R. (2020b). Decontamination of *Bonamia exitiosa*. *Aquaculture*,**523**, 735210, https://doi.org/10.1016/j.aquaculture.2020.735210.

Buss J.J., Wiltshire K.H., Harris J.O., Tanner J.E. & Deveney M.R. (2020c). Infection dynamics of Bonamia exitiosa on intertidal *Ostrea angasi* farms. *J. Fish Dis.,* **43**, 359–369. doi: 10.1111/jfd.13134.

Buss J.J., Wiltshire K.H., Prowse T.A.A., Harris J.O., Deveney M.R. (2019). *Bonamia* in *Ostrea angasi*: diagnostic performance, field prevalence and intensity. *J. Fish Dis.*, **42**, 63–74. doi: 10.1111/jfd.12906

Canier L., Dubreuil C., Noyer M., Serpin D., Chollet B., Garcia C. & Arzul I. (2020). A new multiplex real-time PCR assay to improve the diagnosis of shellfish regulated parasites of the genus *Marteilia* and *Bonamia*. *Prev. Vet. Med.,* **183**, 105126.

Carnegie R., Barber B.J., Culloty S.C., Figueras A.J. & Distel D.L. (2000). Development of a PCR assay for detection of the oyster pathogen *Bonamia ostreae* and support for its inclusion in the *Haplosporidia*. *Dis. Aquat. Organ*., **42**, 199–206.

Carnegie R.B. & Cochennec-Laureau N. (2004). Microcell parasites of oysters: Recent insights and future trends. *Aquat. Living Res.*, **17**, 519–528.

Carnegie R.B., Stokes N.A., Audemard C., Bishop M.J., Wilbur A.E., Alphin T. D. & Burreson E.M. (2008). Strong seasonality of *Bonamia* sp. infection and induced *Crassostrea ariakensis* mortality in Bogue and Masonboro Sounds, North Carolina, USA. *J. Invertebr. Pathol.*, **98**, 335–343.

Cochennec N., Le Roux F., Berthe F. & Gerard A. (2000). Detection of *Bonamia ostreae* based on small subunit ribosomal probe. *J. Invertebr. Pathol*., **76**, 26–32.

Corbeil S., Arzul I., Diggles B., Heasman M., Chollet B., Berthe F.C. & Crane M.S. (2006a). Development of a TaqMan PCR assay for the detection of *Bonamia* species. *Dis. Aquat. Organ.,* **71**, 75–80.

Corbeil S., Arzul I., Robert M., Berthe F.C.J., Besnard-Cochennec N. & Crane M.S.J. (2006b). Molecular characterization of an Australian isolate of *Bonamia exitiosa*. *Dis. Aquat. Organ.,* **71**, 81-85.

Cranfield H.J., Dunn A., Doonan I.J. & Michael K.P. (2005). *Bonamia exitiosa* epizootic in *Ostrea chilensis* from Foveaux Strait, southern New Zealand between 1986 and 1992. *ICES J. Mar. Sci.,* **62**, 3–13.

Diggles B.K., Cochennec Laureau N. & Hine P.M. (2003). Comparison of diagnostic techniques for *Bonamia exitiosus* from flat oysters *Ostrea chilensis* in New Zealand. *Aquaculture,* **220**, 145–156.

Dinamani P., Hine P.M. & Jones J.B. (1987). Occurrence and characteristics of the haemocyte parasite *Bonamia* sp. in the New Zealand dredge oyster *Tiostrea lutaria. Dis. Aquat. Org.,* **3**, 37–44.

Doonan I.J., Cranfield H.J. & Michael K.P. (1994). Catastrophic reduction of the oyster, *Tiostrea chilensis* (Bivalvia: Ostreidae), in Foveaux strait, New Zealand, due to infestation by the protistan *Bonamia* sp. *NZ J. Mar. Freshwater Res.,* **28**, 335–344.

Engelsma M. & M. Hine. (2009). Infection with *Bonamia exitiosa*: disease detection, pathogen identification and typing. *In:* Epidemiology of different agents causing disease in aquatic animals: scientific review and database development, Hill B., Reese A., Dixon P., Oidtmann B., Paley R., Peeler E., Stentiford G., Stone D., Way K., Hine M., Calistri P., Ippoliti C., Di Lorenzo A., Savini L., Haenen O., Engelsma M., eds. European Food Safety Authority (EFSA), Parma, Italy, Annex B, pp. 40–41.

Engelsma M.Y., Culloty S.C., Lynch S.A., Arzul I. & Carnegie R.B. (2014). *Bonamia* parasites: a rapidly changing perspective on a genus of important mollusc pathogens. *Dis. Aquat. Organ.,* **110**, 5–23.

EURL for mollusc diseases (2023). SOP *Bonamia ostreae* and *Bonamia exitiosa* detection by Real-time Polymerase Chain Reaction (PCR), https://www.eurl-mollusc.eu/SOPs

HELMER L., HAUTON C., BEAN T., BASS D., HENDY I., HARRIS-SCOTT E. & PRESTON J. (2020). Ephemeral detection of *Bonamia exitiosa* (*Haplosporida*) in adult and larval European flat oysters *Ostrea edulis* in the Solent, United Kingdom. *J. Invertebr. Pathol.,* **174**, 107421. doi: 10.1016/j.jip.2020.107421.

HILL K.M., CARNEGIE R.B., ALOUI-BEJAOUI N., EL GHARSALLI R., WHITE D.M., STOKES N.A. & BURRESON G.M. (2010). Observation of a *Bonamia* sp. infecting the oyster *Ostrea stentina* in Tunisia, and a consideration of its phylogenetic affinities. *J. Invertebr. Pathol.,* **103**, 179–185.

HINE P.M. (1991a). The annual pattern of infection by *Bonamia* sp. in New Zealand flat oysters, *Tiostrea chilensis. Aquaculture,* **93**, 241–251.

HINE P.M. (1991b). Ultrastructural observations on the annual infection pattern of *Bonamia* sp. in flat oysters *Tiostrea chilensis*. *Dis. Aquat. Organ.,* **11**, 163–171.

HINE P. M. (1996). The ecology of *Bonamia* and decline of bivalve molluscs. *NZ J. Ecol.,* **20**, 109–116.

HINE P.M. (2002). Severe apicomplexan infection in the oyster *Ostrea chilensis:* a predisposing factor in bonamiosis. *Dis. Aquat. Organ.,* **51**, 49–60.

HINE P.M., CARNEGIE R.B., KROECK M.A., VILLALBA A., ENGELSMA M.Y. & BURRESON E.M. (2014). Ultrastructural comparison of *Bonamia* spp. (*Haplosporidia*) infecting ostreid oysters. *Dis. Aquat. Organ.,* **110**, 55–63. https://doi.org/10.3354/dao02747

HINE P.M., COCHENNEC-LAUREAU N. & BERTHE F.C.J. (2001). *Bonamia exitiosus* n. sp. (Haplosporidia) infecting flat oysters *Ostrea chilensis* (Philippi) in New Zealand. *Dis. Aquat. Organ*., **47**, 63–72.

HINE P.M., DIGGLES B.K., PARSONS M.J.D., PRINGLE A. & BULL B. (2002). The effects of stressors on the dynamics of *Bonamia exitiosus* Hine, Cochennec-Laureau and Berthe, infections in flat oysters *Ostrea chilensis* (Philippi). *J. Fish Dis.,* **25**, 545–554.

HINE P.M. & JONES J.B. (1994). *Bonamia* and other aquatic parasites of importance to New Zealand. *NZ J. Zool.,* **21**, 49–56.

HINE P.M. & WESNEY B. (1994). Interaction of phagocytosed *Bonamia* sp. (*Haplosporidia*) with haemocytes of oysters *Tiostrea chilensis*. *Dis. Aquat. Organ.,* **20**, 219–229.

Reference	Comment	Aquatic Animals Commission response
2.4.2_REFERENCES_1	**Category:** editorial **Proposed amended text:** LANE H.S., WEBB S.C. & DUNCAN J. (2016). *Bonamia ostreae* in the New Zealand oyster *Ostrea chilensis:* a new host and geographic record for this haplosporidian parasite. *Dis. Aquat. Organ.*, **118**, 55–63. https://doi.org/10.3354/dao02960 **Rationale:** Addition of a reference	Agreed

LONGSHAW M., STONE D.M., WOOD G., GREEN M.J. & WHITE P. (2013). Detection of *Bonamia exitiosa* (Haplosporidia) in European flat oysters *Ostrea edulis* cultivated in mainland Britain. *Dis. Aquat. Organ.,* **106**, 173–179. doi: 10.3354/dao02643. PMID: 24113250.

MARTY G., BOWER S., CLARKE K., MEYER G., LOWE G., OSBORN A., CHOW E., HANNAH H., BYRNE S., SOJONKY K. & ROBINSON J. (2006). Histopathology and a real-time PCR assay for detection of *Bonamia ostreae* in *Ostrea edulis* cultured in western Canada. *Aquaculture*, **261**, 33–42.

MIALHE E., BOULO V., ELSTON R., HILL B., HINE M., MONTES J., VAN BANNING P. & GRIZEL H. (1988). Serological analysis *Bonamia* in *Ostrea edulis* and *Tiostrea lutaria* using polyclonal and monoclonal antibodies. *Aquat. Living Res.*, **1**, 67–69.

NARCISI V., ARZUL I., CARGINI D., MOSCA F., CALZETTA A., TRAVERSA D., ROBERT M., JOLY J.P., CHOLLET B., RENAULT T. & TISCAR P.G. (2010). Detection of *Bonamia ostreae* and *Bonamia exitiosa* (*Haplosporidia*) in *Ostrea edulis* from the Adriatic Sea (Italy). *Dis. Aquat. Org.*, **89**, 79–85.

RAMILO A., NAVAS J.I., VILLALBA A. & ABOLLO E. (2013). Species-specific diagnostic assays for *Bonamia ostreae* and *B. exitiosa* in European flat oyster *Ostrea edulis*: conventional, real-time and multiplex PCR. *Dis Aquat Organ*., **104**, 149–161. doi: 10.3354/dao02597.

RAMILO A., VILLALBA A. & ABOLLO E. (2014). Species-specific oligonucleotide probe for detection of *Bonamia exitiosa* (Haplosporidia) using in situ hybridisation assay. *Dis. Aquat. Organ.,* **110**, 81–91.

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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*

Reference	Comment	Aquatic Animals Commission response
2.4.3_1	**Category:** General The Members support all modifications made on Annex 23	Noted
2.4.3_2	**Category:** General The Member supports the revised chapter	Noted
2.4.3_3	**Category:** General We support this amendment	Noted
2.4.3_4	**Category:** General The Members support this revised chapter.	Noted
2.4.3_5	**Category:** Editorial **Proposed amended text:** General comments on this text: • *Bonamia* sp., *Bonamia* spp. and *Bonamia* species is used throughout the text. • *Bonamia exitiosa* vs *B. exitiosa* - review whether the genus will be spelled out in full at every mention and when it will be abbreviate to *B. ostreae* – appears to be inconsistent. • Change Taqman to TaqMan where needed. • Check mentions of "haplosporidia" and remove italics as it not a genus in this context. • Arzul *et al.* (2010) should be Arzul *et al.* (2011) **Rationale:** For consistency and accuracy. **Supporting evidence** ARZUL I., LANGLADE A., CHOLLET B., ROBERT M., FERRAND S., OMNES E., LEROND S., COURALEAU Y., JOLY J.-P., FRANÇOIS C. & GARCIA C. (2011). Can the protozoan parasite *Bonamia ostreae* infect larvae of flat oysters *Ostrea edulis*? *Vet. Parasitol.,* **179**, 69–76. doi:10.1016/j.vetpar.2011.01.060.	Agreed. Regarding *Bonamia exitiosa* vs *B. exitiosa,* the style of the *Aquatic Manual* is to write in full first time and at beginning of sentences/paragraphs

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).

Reference	Comment	Aquatic Animals Commission response
2.4.3_2.1.1_1	**Category:** Change **Proposed amended text:** *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). **Rationale:** Since there are several oyster species susceptible to *Bonamia ostreae*, it is irrational to refer only to ***Ostrea edulis*** here.	Agreed. As a number of similar comments had been received, the Commission agreed to use the proposal from comment 2.4.3_2.1.1_3 below.
2.4.3_2.1.1_2	**Category:** addition **Proposed amended text:** *Bonamia ostreae* is a haplosporidian protozoan parasite (Arzul & Carnegie, 2015; Carnegie & Cochennec-Laureau, 2004) infecting haemocytes of flat oysters, primarily *Ostrea edulis,* and causing disease and mortality (Grizel, 1985). **Rationale:** Haplosporidian is not a genus so does not require italicisation or capitalisation. Other species of flat oysters are susceptible to *Bonamia ostreae,* therefore suggest adding "primarily" before *Ostrea edulis* to indicate this is the main species affected, but not the only one. **Supporting evidence** See list of susceptible species in 2.2.1.	Agreed. As a number of similar comments had been received, the Commission agreed to use the proposal from comment 2.4.3_2.1.1_3 below.
2.4.3_2.1.1_3	**Category:** change **Proposed amended text:** *Bonamia ostreae* is a *Haplosporidian* protozoan parasite (Arzul & Carnegie, 2015; Carnegie & Cochennec-Laureau, 2004) infecting haemocytes of ~~flat oysters, *Ostrea edulis*~~, several oyster species and causing disease and mortality (Grizel, 1985). **Rationale:** *Bonamia ostreae* affects more species than *Ostrea edulis*, text chosen to be in line with that used in Chapter 2.4.2 **Support evidence:** not relevant.	Agreed

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).

Reference	Comment	Aquatic Animals Commission response
2.4.3_2.1.3_1	**Category:** General	Agreed

	"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)." The cited paper's timepoints in this sentence are 12h, 24h and 48h – it is unclear where the "1 week" time period comes from. Suggest checking this is the correct paper to reference or whether a different time period should be quoted to align with this reference. **Supporting evidence** ARZUL I., GAGNAIRE B., BOND C., CHOLLET B., MORGA B., FERRAND S., ROBERT M. & RENAULT T (2009). Effects of temperature and salinity on the survival of *Bonamia ostreae*, a parasite infecting flat oysters *Ostrea edulis. Dis. Aquat. Organ.,* **85**, 67–75.	

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

Reference	Comment	Aquatic Animals Commission response
2.4.3_2.2.1_1	**Category:** addition/deletion **Proposed amended text:** …Scientific name: Magallana (syn. Crassostrea) ariakensis; common name: ~~Ariake cupped~~ Suminoe oyster **Rationale:** Suminoe oyster appears to be a more commonly used common name for *Magallana* (syn. *Crassostrea*) *ariakensis* **Supporting evidence** https://invasions.si.edu/nemesis/species_summary/-199 https://uk.inaturalist.org/taxa/606018-Magallana-ariakensis.	Disagreed. WOAH uses FAOTerm for common names and if not present in FAOTerm then the common names listed in SealifeBase. The common name for Crassostrea ariakensis in FAOTerm is Ariake cupped oyster, which is the name used in the *Aquatic Code*.

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

Reference	Comment	Aquatic Animals Commission response

<table>
<tr>
<td>2.4.3_2.2.2_1</td>
<td>Category: addition/deletion

Proposed amended text:

<table>
<tr><th>Family</th><th>Scientific name</th><th>Common name</th></tr>
<tr><td>Ostreidae</td><td>Ostrea puelchana ~~s~~</td><td>Argentinean flat oyster</td></tr>
<tr><td>Ostreidae</td><td>Ostrea angasi</td><td>Australian flat oyster</td></tr>
</table>

Rationale: Consider whether Ostrea angasi fulfils the criteria to be added based on incomplete evidence for susceptibility (also mentioned as a potential reservoir in Section 2.2.5 in this chapter).

Supporting evidence

BOUGRIER S., TIGE G., BACHERE E. & GRIZEL H. (1986). Ostrea angasi acclimatization to French coasts. Aquaculture, 58, 151–154.</td>
<td>Disagreed: experts assessed this paper and found insufficient evidence of pathogen ID (lacking molecular information; cytology, histo only) no molecular typing.</td>
</tr>
</table>

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

<table>
<tr><th>Reference</th><th>Comment</th><th>Aquatic Animals Commission response</th></tr>
<tr>
<td>2.4.3_2.2.2_2</td>
<td>Category: addition/deletion

Proposed amended text:

<table>
<tr><th>Family</th><th>Scientific name</th><th>Common name</th></tr>
<tr><td>Actiniidae</td><td>Actinia equina</td><td>beadlet anemone</td></tr>
<tr><td>Ascidiidae</td><td>Ascidiella aspersa</td><td>European sea squirt</td></tr>
<tr><td>Stylelidae</td><td>Styela clava</td><td>clubbed tunicate</td></tr>
<tr><td>Ophiotrichidae</td><td>Ophiothrix fragilis</td><td>brittle star</td></tr>
<tr><td>Ostreidae</td><td>Magallana (syn. Crassostrea) gigas</td><td>Pacific cupped oyster</td></tr>
<tr><td>N/A</td><td>grouped zooplankton</td><td>zooplankton</td></tr>
</table>

Rationale: spelling mistake – replace Actina with Actinia.

Propose including Styela clava - PCR, Sanger sequencing, and histology confirmed the presence of B. ostreae in S. clava and also maintained B. ostreae in a tank environment with no oysters present.

Supporting evidence

Costello K.E., Lynch S.A., McAllen R., O'Riordan R.M. & Culloty S.C. (2021). The role of invasive tunicates as reservoirs of molluscan pathogens. Biological Invasions, 23, 641-655.</td>
<td>Regarding Styela clava: disagreed: experts assessed this paper and found insufficient evidence of pathogen ID. Agreed to correct the spelling of Actinia</td>
</tr>
</table>

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).

Reference	Comment	Aquatic Animals Commission response
2.4.3_2.2.5_1	**Categoría:** Adición. **Texto modificado propuesto:**…In addition, the observation of parasites presumably *B. ostreae* in ~~O.~~ *Ostrea 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). **Justificación:** En la primera mención de un nombre cientifico en una obra publicada, todos sus componentes debieran imprimirse al completo. 1- Capitulo 7 De la formación y tratamiento de nombres. Recomendación 25A. Abreviaturas. **Evidencia documentada:** Alonso-Zarazaga, Miguel A. 2000. Capitulo 7 De la formación y tratamiento de nombres. Código Internacional de Nomenclatura Zoológica. Edit: Sociedad de Amigos del Museo Nacional de Ciencias Naturales. 4a Edición.	Agreed
2.4.3_2.2.5_2	**Category:** addition **Proposed amended text:** …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). *Magallana* (syn. *Crassostrea*) *gigas* and *Styela clava* have also been identified as potential reservoirs for *B. ostreae* (Costello *et al.,* 2021; Lynch *et al.,* 2010). **Rationale:** *Magallana* (syn. *Crassostrea*) *gigas* was also identified as possible reservoir for *B. ostreae* by Lynch *et al* (2010). *Styela clava* was identified as a possible reservoir for *B. ostreae* by Costello et al (2021) **Supporting evidence** Costello K.E., Lynch S.A., McAllen R., O'Riordan R.M. & Culloty S.C. (2021). The role of invasive tunicates as reservoirs of molluscan pathogens. *Biological Invasions*, **23**, 641–655.	Disagreed. Regarding *M. gigas,* experts found information regarding this host species to be conflicting: further assessment is recommended pending additional information on the viability of detected organisms and/or a finalised definition for vector species. Regarding *Styela clava:* disagreed: experts assessed this paper and found insufficient evidence of pathogen ID.

	LYNCH S.A., ABOLLO E., RAMILO A., CAO A., CULLOTY S.C. & VILLALBA A. (2010). Observations raise the question if the Pacific oyster, Crassostrea gigas, can act as either a carrier or a reservoir for *Bonamia ostreae* or *Bonamia exitiosa. Parasitology*, **137**, 1515–1526. doi:10.1017/S0031182010000326	

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).

Reference	Comment	Aquatic Animals Commission response
2.4.3_2.2.6_1	**Category:** addition/deletion **Proposed amended text:** The possible role of benthic macroinvertebrates and zooplankton in the life cycle of *B. ostreae* was investigated. The brittle star *Ophiothrix fragilis* and Pacific cupped oyster *Magallana* (syn. *Crassostrea*) gigas have been ~~was~~ identified as a possible vector for the parasite (Lynch *et al.*, 2006; 2010). **Rationale:** *Magallana* (syn. *Crassostrea*) *gigas* was also identified as possible vector for *B. ostreae* by Lynch et al 2010. **Supporting evidence** LYNCH S.A., ABOLLO E., RAMILO A., CAO A., CULLOTY S.C. & VILLALBA A. (2010). Observations raise the question if the Pacific oyster, Crassostrea gigas, can act as either a carrier or a reservoir for *Bonamia ostreae* or *Bonamia exitiosa. Parasitology*, **137**, 1515–1526. doi:10.1017/S0031182010000326	Disagreed as above, no evidence of transmission

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).

Reference	Comment	Aquatic Animals Commission response
2.4.3_2.3.1_1	**Category:** general **Proposed amended text:** n/a Consider adding short discussion of evidence of whether co-infection of *B. ostreae* with *B. exitiosa* affects mortality, morbidity and prevalence **Supporting evidence** Ramilo A., González M., Carballal M.J., Darriba S., Abollo E. & Villalba A. (2014). Oyster parasites *Bonamia ostreae* and *B. exitiosa* co-occur in Galicia (NW Spain): spatial	Disagreed, this is a stand-alone chapter. Co-infection of other diseases e.g. VHS/IHN can also occur, but comment on such co-infections are not included in the stand-alone chapters in the *Aquatic Manual*.

	distribution and infection dynamics. Dis. Aquat. Organ., 110, 123–133. https://doi.org/10.3354/dao02673 Lane H.S., Webb S.C. & Duncan J. (2016). *Bonamia ostreae* in the New Zealand oyster *Ostrea chilensis*: a new host and geographic record for this haplosporidian parasite. Dis. Aquat. Organ., 118, 55–63. https://doi.org/10.3354/dao02960	

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.

Reference	**Comment**	**Aquatic Animals Commission response**
2.4.3_2.3.4_1	**Category:** general **Proposed amended text:** A lag time of at least 3 months is generally observed before detecting the parasite in disease free batches moved into infected areas (Montes, 1991). **Rationale:** This sentence needs a reference. Montes (1991) is suggested but unsure if it is the most appropriate. **Supporting evidence** MONTES J. (1991). Lag time for the infestation of flat oyster (*Ostrea edulis* L.) by *Bonamia ostreae* in estuaries of Galicia (N.W. Spain). *Aquaculture*, **93**, 235–239. doi.org/10.1016/0044-8486(91)90235-Y	Agreed.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_3.5.2_1	**Category:** change **Proposed amended text:** Tissue samples for PCR testing should be preserved in ~~70–100%~~ 80% (v/v) analytical-grade ethanol **Rationale:** This is the concentration recommended in the same article in Chapter 2.4.2 Infection with *Bonamia exitiosa* and is in line with our understanding of best practice. **Supporting evidence**	Agreed.

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

Reference	Comment	Aquatic Animals Commission response
2.4.3_4_1	**Category:** general **Proposed amended text:** Consider whether the species-specific *Bonamia exitiosa* ddPCR that has been developed for targeted surveillance of *Ostrea chilensis* for *B. exitiosa* in New Zealand is eligible to be included in the *Aquatic Manual*. **Rationale:** We would like to bring attention to two separate molecular diagnostic assays that have been developed for *Bonamia exitiosa* and *Bonamia ostreae* using droplet digital PCR (ddPCR) and are being used for on-going fisheries management and biosecurity surveillance of *Ostrea chilensis* in New Zealand (see surveillance reports supplied in supporting evidence). These assays were developed after reviewing and revising preexisting assays for *B. ostreae* and *B. exitiosa* and evaluated using the WOAH Validation Pathway. A manuscript describing the development and validation of these assays has been accepted with minor revisions for publication in *Diseases for Aquatic Organisms* and the authors have given permission for the manuscript to be shared with WOAH (see attached in supporting evidence). We seek advice as to whether these assays could be considered for inclusion in the *Aquatic Manual* chapters for *B. ostreae* and *B. exitiosa*, and if we should also submit a Template for the validation report form for tests recommended in the WOAH Aquatic Manual. **Supporting evidence** Bilewitch et al DAO Accepted-Minor Rev https://www.mpi.govt.nz/dmsdocument/66714-Biosecurity-NZ-report-on-the-Bonamia-ostreae-Survey-23-Autumn-2024-surveillance https://www.mpi.govt.nz/dmsdocument/64218-Report-on-the-Bonamia-ostreae-Spring-2023-Surveillance-Survey-22 https://www.mpi.govt.nz/dmsdocument/60013-Report-on-the-Bonamia-ostreae-Autumn-2023-Surveillance https://www.mpi.govt.nz/dmsdocument/57199-Report-on-the-Bonamia-ostreae-Spring-2022-Surveillance https://www.mpi.govt.nz/dmsdocument/49504-Bonamia-ostreae-surveillance-Surveys-11-15-Report.	On hold for now. The AAC policy is that new assays can only be included in the *Aquatic Manual* if they have been validated to at least level 2 according to a published paper. The Member will be asked if they are confident that the paper will be published by September 2025. If yes, the chapter will be amended then and put back in the review cycle; if no, they will be asked to fill in the validation template, and the assay will be cross-referenced in the chapter.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_4.4.1_1	**Category:** addition **Proposed amended text:** Three TaqMan PCR assays are available for the detection of *Bonamia* spp.: one targeting the ITS1 (internal transcribed spacer) region (Corbeil *et al.,* 2006)... **Rationale:** Need to add either “region” or “gene’	Agreed.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_4.4.1_2	**Category:** addition **Proposed amended text:** 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. **Rationale:** This section should clarify that the EURL method has a separate primer probe set for *B. exitiosa* and can be duplexed. Question as to why the Robert *et al.* (2009) paper was not also referenced. The Robert PCR is a SYBR PCR and targets the actin gene. **Supporting evidence** Robert M., Garcia C., Chollet B., Lopez-Flores I., Ferrand S., François C., Joly J.P. & Arzul I. (2009). Molecular detection and quantification of the protozoan *Bonamia ostreae* in the flat	Disagreed, the Commission found that the final sentence clarifies that both PCR assays allow the concomitant detection of *B. exitiosa* and *B. ostrea*. Agreed to add the Robert *et al.* (2009) paper

	oyster, *Ostrea edulis*. *Mol. Cell. Probes*, **23**, 264–271. doi: 10.1016/j.mcp.2009.06.002.	

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_4.4.1_1	**Category:** Editorial **Proposed amended text:** Method 1: Corbeil et al., 2006a; GenBank Accession No.: JN040831 ITS-For: CCC-TGC-CCT-TTG-TAC-ACA-CC **Rationale:** ITS-For primer is missing an additional C nucleotide at the 3' end.	Agreed
2.4.2_3.4.1_2	**Category:** Change **Proposed amended text:**	**EN**: Agreed

	Rationale: GenBank Accession number for Method 5 to be updated to relevant actin nucleotide sequence as AF192759 is '18S small subunit ribosomal RNA'	

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_4.4.2_1	**Category:** Editorial **Proposed amended text:** **Rationale:** GenBank Accession numbers to be provided for Methods 1, 2 and 3.	Agreed. Reference Laboratory provide it.

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).

Reference	Comment	Aquatic Animals Commission response
2.4.3_4.4.2_2	**Category:** addition / general **Proposed amended text:** 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~~ *Bgl* I enzyme which allows to distinguish two profiles: *B. ostreae* (two bands of 120 and 180 bp) and *B. exitiosa* (not digested). **Rationale:** Need to specify which *Bgl enzyme.* Also, suggest mentioning in this section *Hae* II digestion can be used to distinguish *B. ostreae* and *B. exitiosa* from *B. roughleyi* as has been detailed in previous version of this *Manual* chapter (quoted below): "Neither assay is species specific. The sequence of the SSU rDNA gene of B. ostreae shows polymorphism with that of *B. exitiosa, B. roughleyi* or *B. perspora* by restriction fragment length polymorphism (RFLP) analysis after digesting the PCR product Bo–Boas with Hae II and Bgl I. The obtained profiles vary according to the parasite species. *Bonamia ostreae, B. perspora* and *B. exitiosa* show the same profile (two products of 115 and 189 bp) when digested with Hae II, while the *B. roughleyi* product is not *dige*sted. The *B. ostreae* profile consists of two bands of 120 and 180 bp when digested with *Bgl I, while B. exitiosa, B. perspora* and *B. roughleyi* are not digested (Cochennec *et al.,* 2003; Hine *et al.,* 2001)." **Supporting evidence** CHAPTER 2.4.3. INFECTION WITH BONAMIA OSTREAE https://www.woah.org/fileadmin/Home/eng/Health_standards/aahm/current/2.4.03_Bonamia_ostreae.pdf	Agreed: the enzyme is *Bgl* I Disagree with the second comment concerning the Hae II as its inclusion would not help the diagnosis of *B. ostrea*. Furthermore, *B. roughleyi* has not been well characterised.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_4.5_1	**Category:** addition / general **Proposed amended text:** Consider including the Lane & Jones (2020) ITS PCR in this section. **Rationale:**	Disagreed as the method would not be used in the case definition.

	Whilst not screening tool, it can be used on confirmed B. ostreae positives to amplify an important region of the ITS. **Supporting evidence** Lane H.S. & Jones J.B. (2020). Low internal transcribed spacer rDNA variation in New Zealand *Bonamia ostreae:* evidence for a recent arrival. *Dis. Aquat. Organ.*, **139**, 121–130. doi: 10.3354/dao03461. PMID: 32406867.	

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

1 For example transboundary commodities.

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 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

ii)

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

Reference	Comment	Aquatic Animals Commission response
2.4.3_6.2.1_1	**Category:** addition/deletion **Proposed amended text:** 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~~ **Rationale:** Gross pathology and clinical signs are not sufficiently pathognomonic.	Disagreed: gross pathology or clinical signs associated with disease, as described in this chapter, would raise suspicion, so the current text is correct.

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

Reference	Comment	Aquatic Animals Commission response
2.4.3_6.2.2_1	**Category:** addition/deletion **Proposed amended text:** 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	Agreed and added new criteria for confirmed case here and in Section 6.1.2 to include real-time PCR and conventional PCR and sequencing; real-time PCR and *in-situ* hybridisation; and tissue imprints, histology or *in-situ* hybridisation, and conventional PCR followed by

	Rationale: Confirmation by only real-time PCR is not suitable. Visualisation of the parasite by histology or imprints should be part of the confirmation.	sequence analysis, where appropriate.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_6.3_1	**Category:** addition / general **Proposed amended text:** 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.~~ Note no data are currently available for presumptive diagnosis of clinically affected animals, so data are only provided for surveillance of apparently healthy animals. This information… **Rationale:** It seems odd to refer to a blank table when no data is available. Suggest deleting this reference to the table, and being explicit on what data are available and are provided. Note if table is deleted, table numbering will need to be revised.	Disagreed: the tables are part of the approved disease-chapter template and are included in each chapter. Agreed to add "(no data are currently available)" to the table's title

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.

Reference	Comment	Aquatic Animals Commission response
2.4.3_6.3.1_1	**Category:** general **Proposed amended text:** Delete Table **Rationale:** It seems odd to insert a blank table, - suggest deleting it and reference to it in the text prior.	Disagreed: the tables are part of the approved disease-chapter template and are included in each chapter. Agreed to add "(no data are currently available)" to the table's title.

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.*	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

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
		ostreae prevalence (very low, low, high)						
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.,* 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)

7. References

Arzul I. & Carnegie R.B. (2015). New perspective on the haplosporidian parasites of molluscs. *J. Invertebr. Pathol.,* **131**, 32–42. doi: 10.1016/j.jip.2015.07.014.

Arzul I., Gagnaire B., Bond C., Chollet B., Morga B., Ferrand S., Robert M. & Renault T (2009). Effects of temperature and salinity on the survival of *Bonamia ostreae*, a parasite infecting flat oysters *Ostrea edulis. Dis. Aquat. Organ.,* **85**, 67–75.

Arzul I., Langlade A., Chollet B., Robert M., Ferrand S., Omnes E., Lerond S., Couraleau Y., Joly J.-P., François C. & Garcia C. (2010). Can the protozoan parasite *Bonamia ostreae* infect larvae of flat oysters *Ostrea edulis*? *Vet. Parasitol.,* **179**, 69–76. doi:10.1016/j.vetpar.2011.01.060.

Arzul I., Miossec L., Blanchet E., Garcia C., François C. & Joly J-P. (2006). *Bonamia ostreae* and *Ostrea edulis:* a stable host-parasite system in France? Symposia proceedings, ISVEE conference XI, Cairns, Australia, 6–11 August 2006, 5 p.

Balouet G., Poder M. & Cahour A. (1983). Haemocytic parasitosis: morphology and pathology of lesions in the French flat oyster, *Ostrea edulis* L. *Aquaculture*, **34**, 1-14.

BALSEIRO P., CONCHAS R. F., MONTES J., GÓMEZ-LEÓN J., NOVOA B. & FIGUERAS A. (2006). Comparison of diagnosis techniques for the protozoan parasite *Bonamia ostreae* in flat oyster *Ostrea edulis. Aquaculture*, **261**, 1135–1143.

BOUGRIER S., TIGÉ G., BACHÈRE E. É GRIZEL H. (1986). *Ostrea angasi* acclimatization to French coasts. *Aquaculture*, **58**, 151–154.

BUCKE D. (1988). Pathology of bonamiasis. *Parasitol. Today*, **4**, 174–176.

BUSS J.J., WILTSHIRE K.H., PROWSE T.A.A., HARRIS J.O. & DEVENEY M.R. (2019). *Bonamia* in *Ostrea angasi:* diagnostic performance, field prevalence and intensity. *J. Fish Dis.,* **42**, 63–74. 10.1111/jfd.12906

CANIER L., DUBREUIL C., NOYER M., SERPIN D., CHOLLET B., GARCIA C. & ARZUL I. (2020). A new multiplex real-time PCR assay to improve the diagnosis of shellfish regulated parasites of the genus *Marteilia* and *Bonamia. Prev. Vet. Med.,* **183**, 105126.

CARNEGIE R., BARBER B.J., CULLOTY S.C., FIGUERAS A.J. & DISTEL D.L. (2000). Development of a PCR assay for detection of the oyster pathogen *Bonamia ostreae* and support for its inclusion in the *Haplosporidia*. *Dis. Aquat. Organ*., **42**, 199–206.

CARNEGIE R.B., BARBER B.J. & DISTEL D.L. (2003). Detection of the oyster parasite *Bonamia ostreae* by fluorescent *in situ* hybridization. *Dis. Aquat. Organ.,* **55**, 247–252.

CARNEGIE R.B. & COCHENNEC-LAUREAU N. (2004). Microcell parasites of oysters: Recent insights and future trends. *Aquat. Living Resour.*, **17**, 519–528.

CARNEGIE R.B., STOKES N.A., AUDEMARD C., BISHOP M.J., WILBUR A.E., ALPHIN T.D., POSEY M.H., PETERSON C.H. & BURRESON E.M. (2008). Strong seasonality of *Bonamia* sp. infection and induced *Crassostrea ariakensis* mortality in Bogue and Masonboro Sounds, North Carolina, USA. *J. Invertebr. Pathol.*, **98**, 335–343.

COCHENNEC N., LE ROUX F., BERTHE F. & GERARD A. (2000). Detection of *Bonamia ostreae* based on small subunit ribosomal probe. J. *Invertebr. Pathol*., **76**, 26–32.

COMPS M., TIGÉ G. & GRIZEL H. (1980). Etude ultrastructurale d'un protiste parasite de l'huître *Ostrea edulis* L. *L.C.R., Acad. Sc. Paris,* Sér. D, **290**, 383–385.

CONCHAS R.F., SANTAMARINA J., LAMA A., LONGA M.A. & MONTES J. (2003). Evolution of bonamiosis in Galicia (NW Spain). *Bull. Eur. Assoc. Fish Pathol*., **23**, 265–272.

CORBEIL S., ARZUL I., DIGGLES B., HEASMAN M., CHOLLET B., BERTHE F.C. & CRANE M.S. (2006). Development of a TaqMan PCR assay for the detection of *Bonamia* species. *Dis. Aquat. Organ*., **71**, 75–80.

CULLOTY S.C. & MULCAHY M.F. (1996). Season-, age-, and sex-related variation in the prevalence of bonamiosis in flat oysters (*Ostrea edulis* L.) on the south coast of Ireland. *Aquaculture*, **144**, 53–63.

ENGELSMA M.Y., CULLOTY S.C., LYNCH S.A., ARZUL I. & CARNEGIE R.B. (2014). *Bonamia* parasites: a rapidly changing perspective on a genus of important mollusc pathogens. *Dis. Aquat. Organ.,* **110**, 5–23.

ENGELSMA M.Y., KERKHOFF S., ROOZENBURG I., HAENEN O.L.M., VAN GOOL A., SISTERMANS W., WIJNHOVEN S. & HUMMEL H. (2010). Epidemiology of Bonamia ostreae infecting European flat oyster Ostrea edulis from Lake Grevelingen, The Netherlands. Marine Ecology Progress Series, 409, 131–142.

EURL FOR MOLLUSC DISEASES (2023). SOP *Bonamia ostreae* and *Bonamia exitiosa* detection by Real-time Polymerase Chain Reaction (PCR), https://www.eurl-mollusc.eu/SOPs

FERNÁNDEZ-BOO S., PROVOT C., LECADET C., STAVRAKAKIS C., PAPIN M., CHOLLET B., AUVRAY J.-F. & ARZUL I. (2021). Inactivation of marine bivalve parasites using UV-C irradiation: Examples of *Perkinsus olseni* and *Bonamia ostreae. Aquaculture Reports*, **21**, 100859 (10p.). https://doi.org/10.1016/j.aqrep.2021.100859

FLANNERY G., LYNCH S.A., LONGSHAW M., STONE D., MARTIN P., RAMILO, A., RAMILO A., VILLALBA A. & CULLOTY S.C. (2014). Interlaboratory variability in screening for *Bonamia ostreae,* a protistan parasite of the European flat oyster *Ostrea edulis. Dis. Aquat. Organ*., **110**, 93–99.

GRIZEL H. (1985). Etudes des récentes épizooties de l'huître plate *Ostrea edulis* L. et de leur impact sur l'ostréiculture bretonne. Thèse de doctorat, Université des Sciences et Techniques de Languedoc, Montpellier, France.

HERVIO D., BACHERE E., BOULO V., COCHENNEC N., VUILLEMIN V., LE COGUIC Y., CAILLETAUX G., MAZURIE J. & MIALHE E. (1995). Establishment of an experimental infection protocol for the flat oyster *Ostrea edulis* with the intrahaemocytic protozoan parasite *Bonamia ostreae:* application in the selection of parasite-resistant oyster. *Aquaculture*, **132**, 183–194.

HILL K.M., STOKES N.A., WEBB S.C., HINE P.M., KROECK M.A., MOORE J.D., MORLEY M.S., REECE K.S., BURRESON E.M. & CARNEGIE R.B. (2014). Phylogenetics of *Bonamia* parasites based on small subunit and internal transcribed spacer region ribosomal DNA sequence data. *Dis. Aquat. Organ.,* **110**, 33–54.

HINE P.M., CARNEGIE R.B., KROECK M.A., VILLALBA A., ENGELSMA M.Y. & BURRESON E.M. (2014). Ultrastructural comparison of *Bonamia* spp. (*Haplosporidia*) infecting ostreid oysters. *Dis. Aquat. Organ.,* **110**, 55–63. https://doi.org/10.3354/dao02747

HINE P.M., COCHENNEC-LAUREAU N. & BERTHE F.C.J. (2001). *Bonamia exitiosus* n. sp. (*Haplosporidia*) infecting flat oysters *Ostrea chilensis* (Philippi) in New Zealand. *Dis. Aquat. Organ*., **47**, 63–72.

KAMERMANS P., BLANCO A., VAN DALEN P., ENGELSMA M., BAKKER N., JACOBS P., DUBBELDAM M., SAMBADE I.M., VERA M. & MARTINEZ P. (2023). *Bonamia*-free flat oyster (*Ostrea edulis* L.) seed for restoration projects: non-destructive screening of broodstock, hatchery production and test for *Bonamia*-tolerance. *Aquat. Living Resour*., **36**, 11.

LANE H.S., JONES J.B. & MCDONALD W.L. (2017). Pooled sample testing for *Bonamia ostreae:* A tale of two SYBR Green real-time PCR assays. J. Vet. Diagn. Invest., 29, 752–756. doi: 10.1177/1040638717717558.

LANE H.S., WEBB S.C. & DUNCAN J. (2016). *Bonamia ostreae* in the eu oyster *Ostrea chilensis:* a new host and geographic record for this haplosporidian parasite. *Dis. Aquat. Organ.,* **118**, 55–63. https://doi.org/10.3354/dao02960

LYNCH S.A., ARMITAGE D.V., COUGHLAN J., MULCAHY M.F. & CULLOTY S.C. (2006). Investigating the possible role of benthic macroinvertebrates and zooplakton in the life cycle of the haplosporidian *Bonamia ostreae*. *Exp. Parasitol.,* **115**, 359–368.

LYNCH S.A., FLANNERY G., HUGH-JONES T., HUGH-JONES D. & CULLOTY S.C. (2014) Thirty-year history of Irish (Rossmore) *Ostrea edulis* selectively bred for disease resistance to *Bonamia ostreae. Dis. Aquat. Organ*., **110**, 113–121. doi: 10.3354/dao02734.

LYNCH S.A., MULCAHY M.F. & CULLOTY S.C. (2008). Efficiency of diagnostic techniques for the parasite, B*onamia ostreae*, in the flat oyster, *Ostrea edulis. Aquaculture*, **281**, 17–21.

MARTY G., BOWER S., CLARKE K., MEYER G., LOWE G., OSBORN A., CHOW E., HANNAH H., BYRNE S., SOJONKY K. & ROBINSON J. (2006). Histopathology and a real-time PCR assay for detection of *Bonamia ostreae* in *Ostrea edulis* cultured in western Canada. *Aquaculture*, **261**, 33–42.

MÉROU N., LECADET C., POUVREAU S. & ARZUL I. (2020). An eDNA/eRNA-based approach to investigate the life cycle of non-cultivable shellfish micro-parasites: the case of *Bonamia ostreae*, a parasite of the European flat oyster *Ostrea edulis. Microb. Biotechnol.,* **13**, 1807–1818. doi: 10.1111/1751-7915.13617.

MEROU N., LECADET C., UBERTINI M., POUVREAU S. & ARZUL I. (2023). Environmental distribution and seasonal dynamics of *Marteilia refringens* and *Bonamia ostreae*, two protozoan parasites of the European flat oyster, *Ostrea edulis*. *Front. Cell. Infect. Microbiol.*, **13**, 1154484. doi: 10.3389/fcimb.2023.1154484.

MIALHE E., BOULO V., ELSTON R., HILL B., HINE M., MONTES J., VAN BANNING P. & GRIZEL H. (1988). Serological analysis *Bonamia* in *Ostrea edulis* and *Tiostrea lutaria* using polyclonal and monoclonal antibodies. *Aquat. Living Resour.*, **1**, 67–69.

MONTES J., ANADON R. & AZEVEDO C. (1994). A possible life cycle for *Bonamia ostreae* on the basis of electron microscopy studies. *J. Invertebr. Pathol.,* **63**, 1–6.

NACIRI-GRAVEN Y., MARTIN A.G., BAUD J.P., RENAULT T. & GERARD A. (1998). Selecting the flat oyster *Ostrea edulis* (L.) for survival when infected with the parasite *Bonamia ostreae. J. Exp. Mar. Biol. Ecol.*, **224**, 91–107.

PICHOT Y., COMPS M., TIGE G., GRIZEL H. & RABOUIN M.A. (1979). Recherches sur *Bonamia ostreae* gen. n., sp. n., parasite nouveau de l'huitre plate *Ostrea edulis L. Rev. Trav. Inst. Pêches Marit.,* **43**, 131–140.

POUILLOT R., GERBIER G. & GARDNER I.A. (2002). "TAGS", a program for the evaluation of test accuracy in the absence of a gold standard. *Prev. Vet. Med.*, **53**, 67–81.

RAMILO A., NAVAS J.I., VILLALBA A. & ABOLLO E. (2013). Species-specific diagnostic assays for *Bonamia ostreae* and *B. exitiosa* in European flat oyster *Ostrea edulis*: conventional, real-time and multiplex PCR. *Dis. Aquat. Organ*., **104**, 149–161. doi: 10.3354/dao02597.

VAN BANNING P. (1990). The life cycle of the oyster pathogen *Bonamia ostreae* with a presumptive phase in the ovarian tissue of the European flat oyster, *Ostrea edulis*. *Aquaculture*, **84**, 189–192.

VON GERSDORFF JØRGENSEN L., NIELSEN J.W., VILLADSEN M.K., VISMANN B., DALVIN S., MATHIESSEN H., MADSEN L., KANIA P.W. & BUCHMANN K. (2020). A non-lethal method for detection of *Bonamia ostreae* in flat oyster (*Ostrea edulis*) using environmental DNA. *Sci. Rep.,* **10**, 16143. https://doi.org/10.1038/s41598-020-72715-y

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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).

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.4.6._1	**Category:** General The Member supports the proposed changes.	Noted
2.4.6._2	**Category:** General The Members support these revised Sections.	Noted

Not for comment

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

Family	Scientific name	Common name
	Ruditapes philippinarum	Japanese carpet shell ~~clam~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.4.6._3	**Category:** addition **Proposed amended text:** *Anadara trapezia* Common name: Sydney Cockle **Supporting evidence:** https://bie.ala.org.au/species/https://biodiversity.org.au/afd/taxa/c31c4717-6229-499d-9ebd-ce2e723ff7c1	See response to comment 11.6.2._2.

~~*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

Not for comment

Family	Scientific name	Common name
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~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.4.6._4	**Category:** addition **Proposed amended text:** Family / Scientific name / Common name Haliotidae / *Haliotis laevigata* / greenlip abalone *Haliotis rubra* / blacklip abalone *Haliotis iris* / New Zealand black-footed abalone **Rationale:** We note from the Report of the WOAH ad hoc Group on susceptibility of mollusc species to infection with WOAH listed diseases in December 2023, *Haliotis iris* was assessed to not meet the pathogen identification criteria to be listed as a susceptible species to *Perkinsus olseni* because the paper cited (MUZNEBIN *et* al 2023) relied only on the ISH probe published by Moss *et al.,* 2006. The report noted that if more information becomes available on the molecular identity of *P. olseni* in this *H. iris*, the score of this host species will be reviewed. We would like to bring to the *ad hoc* group's attention that *P. olseni* was detected for the first time in farmed black foot pāua (*Haliotis iris*) in 2014 and reported to WOAH at the time (see WOAH-WAHIS event ID#5889, 2014.). This detection was prompted after clinical signs (mantle retraction in shell) and gross pathology (nodules) were observed at harvest. New Zealand's national laboratory received fixed and fresh samples from the affected farm and verified the presence of	See response to comment 11.6.2._1.

Not for comment

	Perkinsus species by histopathology, which was then confirmed by an in-house validated conventional PCR and sequencing. We would also like to note that this methodology was the same used to identify *P. olseni* in: - *Perna canaliculus* (New Zealand green lipped mussel), which is listed as a susceptible species here and in the Aquatic Code Chapter 11.6 Infection with *Perkinsus* olseni, Article 11.6.2 , (draft version currently out for review) and - *Pecten novaezealandia* (New Zealand scallop), which is listed as a species with incomplete evidence of susceptibility here in the Aquatic Manual Chapter 2.4.6 Infection with *Perkinsus olseni* Section 2.2.2, Noting the same methodology was used to confirm *P. olseni* infection in these three New Zealand molluscs, but clinical signs and gross pathology has only been observed in *Haliotis iris,* we also query whether all three of these mollusc species should all be listed under the same susceptibility category, *either* susceptible *or* species with incomplete evidence of susceptibility, for consistency. Alternatively, should *Perna canaliculus* and *Pecten novaezealandia* be classified as species with incomplete evidence of susceptibility for *P. olseni*, (given clinical disease or mortality has not been observed associated with *P. olseni* in these species), whereas *H. iris* would have a stronger case to be listed as susceptible to *P. olseni*, given clinical disease has been observed associated with infection. **Supporting evidence:** WOAH-WAHIS event ID#5889, 2014, https://wahis.woah.org/#/in-event/5889/dashboard WOAH-WAHIS event ID#1600, 2014 https://wahis.woah.org/#/in-event/1600/dashboard WOAH-WAHIS event ID#1672, 2014, https://wahis.woah.org/#/in-event/1672/dashboard New Zealand Regional Aquatic Animal Disease Report January – June 2024 https://rr-asia.woah.org/app/uploads/2024/09/NEW-ZEALAND-QAAD_Jan_Jun_2024.pdf Bingham P (2013). Quarterly report of investigations of suspected exotic marine and freshwater pests and diseases. Surveillance, Volume 40, Issue 4, pp 31-34, Dec 2013. Ministry for Primary Industries Bingham, P. (2015). Quarterly report of investigations of suspected exotic marine and freshwater pests and diseases. Surveillance, Volume 42, Issue 2, pp 25-26, Jun 2015. Ministry for Primary Industries MUZNEBIN, F., ALFARO, A.C. & WEBB, S.C. (2023a). Occurrence of Perkinsus olseni and other parasites in New Zealand black-footed abalone (Haliotis iris). New Zealand Journal of Marine and Freshwater Research, 57(2), 261-281.	

[…]

Not for comment

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
2.4.7._1	**Category: General** The Members support all modifications made on Annex 25	Noted
2.4.7._2	**Category:** General The Members support these revised Sections.	Noted

Not for comment

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).~~

[…]

Not for comment

Annex 4. Item 5.1. – Work Programme for the Aquatic Animal Health Standards Commission 2025-2027

Chapter	Subject	Summary of the work	Status – February 2025		
			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 Feb 2025 AAHSC report	**2**
Ch. 4.3.	Application of compartmentalisation	Revision of the chapter to focus on compartmentalisation. Members engaged through a questionnaire and discussion paper.	Circulated for comments	Refer to Feb 2025 AAHSC report (Feb 2025/1)	**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 Feb 2025 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'.	Circulated for comments	Refer to Feb 2025 AAHSC report (Feb 2025/1)	**1**
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 2025 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 2025 AAHSC report (Sep 2023/3)	**1**

Chapter	Subject	Summary of the work	Status – February 2025		
			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 2025 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 Feb 2025 AAHSC report	**3**
Ch. 5.2.	Certification procedures	Update certification procedures to align with Codex (e-certification).	Preparatory work	Refer to Feb 2025 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 Feb 2025 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 2025 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 Feb 2025 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 Feb 2025 AAHSC report	**2**
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 Feb 2025 AAHSC report (Feb 2024/2)	**1**

Chapter	Subject	Summary of the work	Status – February 2025		
			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 Feb 2025 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 Feb 2025 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 Feb 2025 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 Feb 2025 AAHSC report	**2**

Chapter	Subject	Summary of the work	Status – February 2025		
			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 Feb 2025 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 (proposed for adoption in May 2025)	Refer to Feb 2025 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 pagrus1*'	Proposed for adoption in May 2025	Refer to Feb 2025 AAHSC report	**1**
Ch. 10.X.	Infection with *Megalocytivirus pagrus1*	Development of draft new chapter 10.X. 'Infection with *Megalocytivirus pagrus1'* following the change in listing of 'infection with red sea bream iridovirus' to 'infection with *Megalocytivirus pagrus1*'	Circulated for comments (proposed for adoption in May 2025)	Refer to Feb 2025 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 Feb 2025 AAHSC report (Feb 2024/2)	**1**

Chapter	Subject	Summary of the work	Status – February 2025		
			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 (proposed for adoption in May 2025)	Refer to Feb 2025 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.	Circulated for comment	Refer to Feb 2025 AAHSC report (Feb 2025/1)	**1**
Ch. 2.1.1.	Infection with *Batrachochytrium dendrobatidis*	Update the chapter to the new template for disease-specific chapter.	Not started	Refer to Feb 2025 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 Feb 2025 AAHSC report	**3**

Chapter	Subject	Summary of the work	Status – February 2025		
			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 Feb 2025 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 Feb 2025 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 Feb 2025 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	Refer to Feb 2025 AAHSC report	**2**
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 Feb 2025 AAHSC report	**2**

Chapter	Subject	Summary of the work	Status – February 2025		
			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 Feb 2025 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 Feb 2025 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 pagrus1*'	Proposed for adoption in May 2025	Refer to Feb 2025 AAHSC report	**1**
Ch. 2.3.7.	Infection with *Megalocytivirus pagrus1*	New chapter for infection with *Megalocytivirus pagrus1* which was listed in the *Aquatic Code* in May 2024	Preparatory work	Refer to Feb 2025 AAHSC report	**2**
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 Feb 2025 AAHSC report	**3**
Ch. 2.3.X.	Infection with tilapia lake virus	New chapter for infection with tilapia lake virus which was listed in the *Aquatic Code* in May 2022	Preparatory work	Refer to Feb 2025 AAHSC report	**2**

Chapter	Subject	Summary of the work	Status – February 2025		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 2.4.2.	Infection with *Bonamia exitiosa*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments (proposed for adoption in May 2025)	Refer to Feb 2025 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 (proposed for adoption in May 2025)	Refer to Feb 2025 AAHSC report (Sep 2024/1)	**1**
Ch. 2.4.5.	Infection with *Perkinsus marinus*	Update the chapter to the new template for disease-specific chapter.	Prepatory work	Refer to Feb 2025 AAHSC report	**1**
Ch. 2.4.6.	Infection with *Perkinsus olseni*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments (proposed for adoption in May 2025)	Refer to Sep 2024 AAHSC report (Feb 2024/2)	**1**
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	Refer to Feb 2025 AAHSC report (Feb 2025/1)	**1**
Ch. 2.4.7.	Infection with *Xenohaliotis californiensis*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments (proposed for adoption in May 2025)	Refer to Feb 2025 AAHSC report (Sep 2024/1)	**1**
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 Feb 2025 AAHSC report (Feb 2025/1)	**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 outbreaks*~~*.*~~. The specific actions which are necessary to operationalise the framework in the event of a *disease outbreak* are described in Chapter 4.Y.

Article 4.X.3.

Introduction

~~*Aquatic animal 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 disease*s which are important to a country, *zone* or *compartment*, are identified in advance of a *disease outbreak* (i.e. in peacetime) by the *Competent Authority*, and that their future control is supported by adequate legislative and funding measures. The ~~statutory~~ list of important *disease*s that is developed after conducting a *risk analysis* as described in 4.X.6.*,* may include *aquatic animal disease*s which are listed in Chapter 1.3., as well as other *disease*s which have been identified as being of importance to the country, *zone* or *compartment*. 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 relevant 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, including~~as well as the~~ operational measures and compensation 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~~,~~ and 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 or strains 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.*

Application of s*S*urveillance activities and *early detection systems*

Suspicion of an *outbreak* of an important *aquatic animal disease*, which is subject to statutory control, often results from *surveillance* activities and the *early detection system*. Therefore, emergency *disease* preparedness systems and the outcomes from those systems are heavily reliant on the quality of the *surveillance* and on the proper application of an *early detection system* ~~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.

Contingency plans could also be developed for specific *aquaculture* or fishery sectors. Sector-specific *contingency plans* could identify common pathways, practices and risks, and the potential measures that could be applied to those sector-specific activities to mitigate the *risk* of a *disease*. As with *contingency plans* for *emerging diseases,* sector-specific *contingency plans* would require rapid and effective fine-tuning once the details of the *disease* are known.

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, welfare 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 taking~~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 or vectors. ~~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. A simulation exercise should be designed based on realistic scenarios that reflect actual risks with operational feasibility.

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 relevant 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 relevant 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 *free 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) considering the availability of compensation;

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* and the *Aquatic Animal Health Services* 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~~) 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., with suitable capacity~~as being suitably equipped and staffed~~ to produce reliable results in the shortest possible timeframe.

~~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*;~~

~~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.~~

45) 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.

56) whilst confirmation of the presence of the *disease* in question is ongoing, the *Competent Authority* should communicate with *Aquatic Animal Health Services* including relevant personnel, ~~relevantindustry~~ 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.;

67) 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;

78) should the suspicion not be confirmed, the alert phase is terminated by the *Competent Authority*, relevant stakeholders~~actors~~ are informed that the situation is moving back to peacetime, and any outcomes which warrant review of the *Contingency Plan*, are made;

89) ~~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~~ stakeholders ~~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.;

43) 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 relevant industry stakeholders 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, pest and bird control specialists;

d) telecommunications providers;

e) communication specialist~~specials~~ or journalist for media liaison;

~~fc) telecommunications providers;~~

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

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

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

ij~~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;

jk~~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 (jk~~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 (e.g. compensation);

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 relevant industry stakeholders to explain ~~relevant~~ details of the recovery plan and to reinforce their~~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 safe 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 *Competent Authority* of the *importing country* should require that 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~~ must~~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*. A lower design prevalence should be used if justified by epidemiological evidence. ~~I~~ 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 cryopreservation~~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;~~

7~~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;

8~~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;

9~~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 disposed of in a biosecure manner in accordance with Chapter 4.8. ~~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) extraction of *gametes*~~stripping~~ and collection of broodstock samples for *disease* testing~~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 *gamete* extraction, ~~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 inactivate ~~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 temperature~~s~~ 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 4.7.~~ apply the requirements of Article 10.X.15~~apply the requirements of Chapter 4.7.~~ regarding *gametes* or *fertilised~~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 Article 10.X.15~~apply the requirements of Chapter 4.Z.~~ regarding *gametes* or *fertilised*~~*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~~andor~~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 4.7.~~ apply the requirements of Article 10.4.20~~apply the requirements of Chapter 4.7.~~ regarding *gametes* or *fertilised*~~*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 4.7.~~ apply the requirements of Article 10.4.20~~apply the requirements of Chapter 4.7.~~ regarding *gametes* or *fertilised~~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 *Competent Authority* of the *importing country* should require that the consignment~~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 include~~s~~ 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

2~~4~~) *fertilised eggs* have been disinfected in accordance with recommendations in Chapter 4.5.; and

3~~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

4~~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 *Competent Authority* of the *importing country* should require that the consignment~~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. Item 6.2. – 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 supplied for sale ~~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 *pathogenic agent*~~*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 of *pathogenic agents* 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, for display or for competition providing opportunities for ~~*disease*~~ transmission of *pathogenic agents*. 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 legality~~eligibility ~~for the movement of a species (or a taxonomic group of species) should be determined considering~~ existing regulatory measures in the importing country regarding ~~its conservation status (e.g. species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora), and potential biodiversity and ecosystem impacts in the *importing country* (e.g. potential to become an invasive alien species), as described in Article 5.X.4.;~~

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

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

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

5) any *risk management* measures should be the least 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 movement~~import~~ of a species of *ornamental aquatic animal*, an importer and exporter ~~the *Competent Authority* of an *importing country*~~ should first determine that the movement~~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 from being~~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 sanitary 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* which support *hazard* viability, transmission and infection in *susceptible species*.

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 unintended~~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 clinical 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 and~~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) aA requirement that *aquatic animals* are not subject to pharmacological therapies prior to export which maycould mask clinical signs of *disease*;

87) 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 *pathogenic agents*~~*diseases*~~ of concern. Conditions in *quarantine* should optimise the health of the animal and also provide opportunity of expression of *disease*. 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 infected or 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 unintended~~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 of *pathogenic agents* 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. – Periods of basic biosecurity conditions and targeted surveillance for disease-specific chapters of the *Aquatic Code*

SECTION 8

DISEASES OF AMPHIBIANS

CHAPTER 8.1.

INFECTION WITH *BATRACHOCHYTRIUM DENDROBATIDIS*

[…]

Article 8.1.5.

Country free from infection with *B. dendrobatidis*

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

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

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

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

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

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

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

i) at least the last two~~[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*.

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

Article 8.1.6.

Zone free from infection with *B. dendrobatidis*

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

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

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

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

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

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

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

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

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

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

Article 8.1.7.

Compartment free from infection with *B. dendrobatidis*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last 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) it previously made a self-declaration of freedom for a *compartment* from infection with *B. dendrobatidis* and subsequently lost its free status due to the detection of *B. dendrobatidis* in the *compartment* but the following conditions have been met:

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

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

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

[…]

CHAPTER 8.2.

INFECTION WITH *BATRACHOCHYTRIUM SALMANDRIVORANS*

[…]

Article 8.2.5.

Country free from infection with *B. salamandrivorans*

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

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

1) none of the *susceptible species* referred to in Article 8.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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

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

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

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

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

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

i) at least the last two[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*.

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

Article 8.2.6.

Zone free from infection with *B. salamandrivorans*

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

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

1) none of the *susceptible species* referred to in Article 8.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with *B. salamandrivorans* and subsequently lost its free status due to the detection of *B. salamandrivorans* in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 8.2.7.

Compartment free from infection with *B. salamandrivorans*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last 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) it previously made a self-declaration of freedom for a *compartment* from infection with *B. salamandrivorans* and subsequently lost its free status due to the detection of *B. salamandrivorans* in the *compartment* but the following conditions have been met:

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

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

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

[…]

CHAPTER 8.3.

INFECTION WITH RANAVIRUS SPECIES

[…]

Article 8.3.5.

Country free from infection with *Ranavirus* species

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

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

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

   a) on detection of *Ranavirus* species, the affected area was declared an *infected zone* and a *protection zone* was established; and

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

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

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

i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *Ranavirus* species; or

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*.

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

Article 8.3.6.

Zone free from infection with *Ranavirus* species

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

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

1) 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:

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

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[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) it previously made a self-declaration of freedom for a *zone* from infection with *Ranavirus* species and subsequently lost its free status due to the detection of *Ranavirus* species in the *zone* but the following conditions have been met:

   a) on detection of *Ranavirus* species, the affected area was declared an *infected zone* and a *protection zone* was established; and

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

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

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

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.

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

Article 8.3.7.

Compartment free from infection with *Ranavirus* species

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last 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) it previously made a self-declaration of freedom for a *compartment* from infection with *Ranavirus* species and subsequently lost its free status due to the detection of *Ranavirus* species in the *compartment* but the following conditions have been met:

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 8.3.9. and 8.3.10. as appropriate; and

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

[…]

SECTION 9

DISEASES OF CRUSTACEANS

CHAPTER 9.1.

ACUTE HEPATOPANCREATIC NECROSIS DISEASE

[…]

Article 9.1.5.

Country free from infection with AHPND

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

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

1) none of the *susceptible species* referred to in Article 9.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with AHPND and subsequently lost its free status due to the detection of AHPND but the following conditions have been met:

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

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

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

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

i) at least the last two~~[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*.

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

Article 9.1.6.

Zone free from infection with AHPND

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

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

1) none of the *susceptible species* referred to in Article 9.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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.; 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 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) it previously made a self-declaration of freedom for a *zone* from infection with AHPND and subsequently lost its free status due to the detection of AHPND in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 9.1.7.

Compartment free from infection with AHPND

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with AHPND and subsequently lost its free status due to the detection of AHPND in the *compartment* but the following conditions have been met:

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.1.9. and 9.1.10. as appropriate; and

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

[…]

CHAPTER 9.2.

INFECTION WITH *APHANOMYCES ASTACI* (CRAYFISH PLAGUE)

[…]

Article 9.2.5.

Country free from infection with *A. astaci*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *A. astaci* if all shared water bodies are within countries or *zones* declared free from infection with *A. astaci* (see Article 9.2.6.).

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

1) 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

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

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

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

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

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

i) at least the last two[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*.

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

Article 9.2.6.

Zone free from infection with *A. astaci*

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

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

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

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

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

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

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

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

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

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

Article 9.2.7.

Compartment free from infection with *A. astaci*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with *A. astaci* and subsequently lost its free status due to the detection of *A. astaci* in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.2.9. and 9.2.10. as appropriate; and

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

[…]

CHAPTER 9.3.

INFECTION WITH DECAPOD IRIDESCENT VIRUS 1

[…]

Article 9.3.5.

Country free from infection with DIV1

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with ~~with~~ DIV1 if all shared water bodies are within countries or *zones* declared free from infection with DIV1 (see Article 9.3.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for its entire *territory* if it can demonstrate that:

1) 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:

   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) it previously made a self-declaration of freedom from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 but the following conditions have been met:

   a) on detection of DIV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with DIV1; and

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

i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of DIV1; or

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*.

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

Article 9.3.6.

Zone free from infection with DIV1

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with DIV1 if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for a *zone* within its *territory* if it can demonstrate that:

1) 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:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with DIV1, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[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) it previously made a self-declaration of freedom for a *zone* from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 in the *zone* but the following conditions have been met:

   a) on detection of DIV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with DIV1; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:. ~~at least the last [two] years without detection of DIV1.~~

i) at least the last two years in wild and farmed *susceptible species* without detection of DIV1; or

ii) at least the last one year without detection of DIV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 9.3.7.

Compartment free from infection with DIV1

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.3.9. and 9.3.10. as appropriate; and

   c) one survey for infection with DIV1 has been completed at least six months~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~.

[…]

CHAPTER 9.4.

INFECTION WITH *HEPATOBACTER PENAEI* (NECROTISING HEPATOPANCREATITIS)

[…]

Article 9.4.5.

Country free from infection with *H. penaei*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *H. penaei* if all shared water bodies are within countries or *zones* declared free from infection with *H. penaei* (see Article 9.4.6.).

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

1) none of the *susceptible species* referred to in Article 9.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *H. penaei* 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 *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) it previously made a self-declaration of freedom from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* but the following conditions have been met:

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

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

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

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

i) at least the last two~~[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*.

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

Article 9.4.6.

Zone free from infection with *H. penaei*

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

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

1) none of the *susceptible species* referred to in Article 9.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *H. penaei* 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 *H. penaei*, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[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) it previously made a self-declaration of freedom for a *zone* from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 9.4.7.

Compartment free from infection with *H. penaei*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with *H. penaei* and subsequently lost its free status due to the detection of *H. penaei* in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.4.9. and 9.4.10. as appropriate; and

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

[…]

CHAPTER 9.5.

INFECTION WITH HYPODERMAL AND HAEMATOPOIETIC NECROSIS VIRUS

[…]

Article 9.5.5.

Country free from infection with IHHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IHHNV if all shared water bodies are within countries or *zones* declared free from infection with IHHNV (see Article 9.5.6.).

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

1) none of the *susceptible species* referred to in Article 9.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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

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

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

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

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

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

i) at least the last two[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*.

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

Article 9.5.6.

Zone free from infection with IHHNV

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

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

1) none of the *susceptible species* referred to in Article 9.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with IHHNV and subsequently lost its free status due to the detection of IHHNV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 9.5.7.

Compartment free from infection with IHHNV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of IHHNV~~*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) it previously made a self-declaration of freedom for a *compartment* from infection with IHHNV and subsequently lost its free status due to the detection of IHHNV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.5.9. and 9.5.10. as appropriate; and

   c) one survey for infection with IHHNV~~*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~~.

[…]

CHAPTER 9.6.

INFECTION WITH INFECTIOUS MYONECROSIS VIRUS

[…]

Article 9.6.5.

Country free from infection with IMNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IMNV if all shared water bodies are within countries or *zones* declared free from infection with IMNV (see Article 9.6.6.).

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

1) none of the *susceptible species* referred to in Article 9.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with IMNV and subsequently lost its free status due to the detection of IMNV but the following conditions have been met:

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

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

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

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

i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of IMNV; or

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*.

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

Article 9.6.6.

Zone free from infection with IMNV

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

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

1) none of the *susceptible species* referred to in Article 9.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with IMNV and subsequently lost its free status due to the detection of IMNV in the *zone* but the following conditions have been met:

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

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

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

d) *targeted surveillance*, as described in Chapter 1.4., has been in place; ~~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*.

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

Article 9.6.7.

Compartment free from infection with IMNV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with IMNV and subsequently lost its free status due to the detection of IMNV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.6.9. and 9.6.10. as appropriate; and

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

[…]

CHAPTER 9.7.

INFECTION WITH NACRIBRACHIUM ROSENBERGII NODAVIRUS (WHITE TAIL DISEASE)

[…]

Article 9.7.5.

Country free from infection with MrNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with MrNV if all shared water bodies are within countries or *zones* declared free from infection with MrNV (see Article 9.7.6.).

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

1) none of the *susceptible species* referred to in Article 9.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with MrNV and subsequently lost its free status due to the detection of MrNV but the following conditions have been met:

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

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

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

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

i) at least the last two[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*.

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

Article 9.7.6.

Zone free from infection with MrNV

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

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

1) none of the *susceptible species* referred to in Article 9.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[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.; 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 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) it previously made a self-declaration of freedom for a *zone* from infection with MrNV and subsequently lost its free status due to the detection of MrNV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 9.7.7.

Compartment free from infection with MrNV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with MrNV and subsequently lost its free status due to the detection of MrNV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.7.9. and 9.7.10. as appropriate; and

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

[…]

CHAPTER 9.8.

INFECTION WITH TAURA SYNDROME VIRUS

[…]

Article 9.8.5.

Country free from infection with TSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with TSV if all shared water bodies are within countries or *zones* declared free from infection with TSV (see Article 9.8.6.).

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

1) none of the *susceptible species* referred to in Article 9.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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 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 TSV and subsequently lost its free status due to the detection of TSV but the following conditions have been met:

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

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

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

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

i) at least the last two~~[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*.

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

Article 9.8.6.

Zone free from infection with TSV

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

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

1) none of the *susceptible species* referred to in Article 9.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with TSV and subsequently lost its free status due to the detection of TSV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 9.8.7.

Compartment free from infection with TSV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with TSV and subsequently lost its free status due to the detection of TSV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.8.9. and 9.8.10. as appropriate; and

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

[…]

CHAPTER 9.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

[…]

Article 9.9.5.

Country free from infection with WSSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with WSSV if all shared water bodies are within countries or *zones* declared free from infection with WSSV (see Article 9.9.6.).

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

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

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

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

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

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

i) at least the last two~~[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*.

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

Article 9.9.6.

Zone free from infection with WSSV

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

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

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

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

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

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

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

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

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

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

Article 9.9.7.

Compartment free from infection with WSSV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with WSSV and subsequently lost its free status due to the detection of WSSV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.9.9. and 9.9.10. as appropriate; and

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

[…]

CHAPTER 9.10.

INFECTION WITH YELLOW HEAD VIRUS GENOTYPE 1

[…]

Article 9.10.5.

Country free from infection with YHV1

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with YHV1 if all shared water bodies are within countries or *zones* declared free from infection with YHV1 (see Article 9.10.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

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) it previously made a self-declaration of freedom from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 but the following conditions have been met:

   a) on detection of YHV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with YHV1; and

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

i) at least the last two[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*.

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

Article 9.10.6.

Zone free from infection with YHV1

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with YHV1 if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[six] months;

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.; 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

4) it previously made a self-declaration of freedom for a *zone* from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 in the *zone* but the following conditions have been met:

   a) on detection of YHV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with YHV1; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: [at least the last [two] years without detection of YHV1].

i) at least the last two years in wild and farmed *susceptible species* without detection of YHV1; or

ii) at least the last one year without detection of YHV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 9.10.7.

Compartment free from infection with YHV1

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.10.9. and 9.10.10. as appropriate; and

   c) one survey for infection with YHV1 has been completed at least six months~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~.

[…]

SECTION 10

DISEASES OF FISH

CHAPTER 10.1.

INFECTION WITH EPIZOOTIC HAEMATOPOIETIC NECROSIS VIRUS

[…]

Article 10.1.5.

Country free from infection with EHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with EHNV if all shared water bodies are within countries or *zones* declared free from infection with EHNV (see Article 10.1.6.).

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

1) none of the *susceptible species* referred to in Article 10.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with EHNV and subsequently lost its free status due to the detection of EHNV but the following conditions have been met:

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

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

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

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

i) at least the last two[~~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*.

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

Article 10.1.6.

Zone free from infection with EHNV

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

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

1) none of the *susceptible species* referred to in Article 10.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with EHNV and subsequently lost its free status due to the detection of EHNV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 10.1.7.

Compartment free from infection with EHNV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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

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

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.1.9. and 10.1.10. as appropriate; and

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

[…]

CHAPTER 10.2.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

[…]

Article 10.2.5.

Country free from infection with *A. invadans*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *A. invadans* if all shared water bodies are within countries or *zones* declared free from infection with *A. invadans* (see Article 10.2.6.).

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

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

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

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

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

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

i) at least the last 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*.

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

Article 10.2.6.

Zone free from infection with *A. invadans*

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

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

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

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

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

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

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

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*.

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

Article 10.2.7.

Compartment free from infection with *A. invadans*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with *A. invadans* and subsequently lost its free status due to the detection of *A. invadans* in the *compartment* but the following conditions have been met:

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.2.9. and 10.2.10. as appropriate; and

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

[…]

CHAPTER 10.3.

INFECTION WITH *GYRODACTYLUS SALARIS*

[…]

Article 10.3.5.

Country free from infection with *G. salaris*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *G. salaris* if all shared water bodies are within countries or *zones* declared free from infection with *G. salaris* (see Article 10.3.6.).

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

1) none of the *susceptible species* referred to in Article 10.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) pathway 2 (historical freedom) is not suitable for infection with *G. salaris;* ~~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~~

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

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

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

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

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

i) at least the last 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*.

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

Article 10.3.6.

Zone free from infection with *G. salaris*

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

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

1) none of the *susceptible species* referred to in Article 10.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[six] months;

OR

2) pathway 2 (historical freedom) is not suitable for infection with *G. salaris;* 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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with *G. salaris* and subsequently lost its free status due to the detection of *G. salaris* in the *zone* but the following conditions have been met:

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

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

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

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

i) at least the last three years in wild and farmed *susceptible species* without detection of *G. salaris*; or

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

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

Article 10.3.7.

Compartment free from infection with *G. salaris*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with *G. salaris* and subsequently lost its free status due to the detection of *G. salaris* in the *compartment* but the following conditions have been met:

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.3.9. and 10.3.10. as appropriate; and

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

[…]

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

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.

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with ISAV if all shared water bodies are within countries or *zones* declared free from infection with ISAV (see Article 10.4.7.).

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

1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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 three~~two~~~~[two]~~ years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~one~~~~[one]~~ year~~s~~ prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

i) at least the last threetwo[two] years in wild and farmed *susceptible species* without detection of ISAV; or

ii) at least the last twoone[one] years without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 10.4.6.

Country free from infection with HPR-deleted ISAV

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

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with HPR-deletedHPR0 ISAV if all shared water bodies are within countries or *zones* declared free from infection with HPR-deletedHPR0 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-deletedHPR0 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-deletedHPR0 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-deletedHPR0 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-deletedHPR0 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-deletedHPR0 ISAV and subsequently lost its free status due to the detection of HPR-deletedHPR0 ISAV but the following conditions have been met:

a) on detection of HPR-deletedHPR0 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:

i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of HPR-deleted~~0~~ 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*.

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

Article 10.4.7.

Zone free from infection with ISAV

In this article, all statements referring to a *zone* free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

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

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

1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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 three~~two~~[two] years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~one~~[one] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

i) at least the last three~~two~~ years in wild and farmed *susceptible species* without detection of ISAV; or

ii) at least the last two~~one~~ year without detection of ISAV 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 10.4.8.

Zone free from infection with HPR-deleted ISAV

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

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

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

1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with HPR-deleted 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 ISAV, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[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) it previously made a self-declaration of freedom for a *zone* from infection with HPR-deleted ISAV and subsequently lost its free status due to the detection of HPR-deleted ISAV in the *zone* but the following conditions have been met:

   a) on detection of HPR-deleted ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and

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

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with HPR-deleted ISAV; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of HPR-deleted ISAV.~~

      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*.

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

Article 10.4.9.

Compartment free from infection with ISAV

In this article, all statements referring to a *compartment* free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with ISAV and subsequently lost its free status due to the detection of ISAV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of

restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.4.13. and 10.4.14. as appropriate; and

c) one survey for infection with ISAV has been completed at least six months~~[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

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

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with HPR-deleted ISAV and subsequently lost its free status due to the detection of HPR-deleted ISAV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.4.13. and 10.4.14. as appropriate; and

   c) one survey for infection with HPR-deleted ISAV has been completed at least six months~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~.

[…]

CHAPTER 10.5.

INFECTION WITH INFECTIOUS SALMONID ALPHAVIRUS

[…]

Article 10.5.5.

Country free from infection with SAV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with SAV if all shared water bodies are within countries or *zones* declared free from infection with SAV (see Article 10.5.6.).

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

1) none of the *susceptible species* referred to in Article 10.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last 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) it previously made a self-declaration of freedom from infection with SAV and subsequently lost its free status due to the detection of SAV but the following conditions have been met:

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

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

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

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

i) at least the last two[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*.

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

Article 10.5.6.

Zone free from infection with SAV

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

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

1) none of the *susceptible species* referred to in Article 10.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last 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.; 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 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) it previously made a self-declaration of freedom for a *zone* from infection with SAV and subsequently lost its free status due to the detection of SAV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 10.5.7.

Compartment free from infection with SAV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with SAV and subsequently lost its free status due to the detection of SAV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.5.9. and 10.5.10. as appropriate; and

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

[…]

CHAPTER 10.6.

INFECTION WITH INFECTIOUS HAEMATOPOIETIC NECROSIS VIRUS

[…]

Article 10.6.5.

Country free from infection with IHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IHNV if all shared water bodies are within countries or *zones* declared free from infection with IHNV (see Article 10.6.6.).

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

1) none of the *susceptible species* referred to in Article 10.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with IHNV 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 IHNV, 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 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) it previously made a self-declaration of freedom from infection with IHNV and subsequently lost its free status due to the detection of IHNV but the following conditions have been met:

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

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

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

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

i) at least the last two[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*.

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

Article 10.6.6.

Zone free from infection with IHNV

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

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

1) none of the *susceptible species* referred to in Article 10.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[six] months;

OR

2) there has been no occurrence of infection with IHNV 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 IHNV, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[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) it previously made a self-declaration of freedom for a *zone* from infection with IHNV and subsequently lost its free status due to the detection of IHNV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

Article 10.6.7.

Compartment free from infection with IHNV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with IHNV and subsequently lost its free status due to the detection of IHNV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.6.9. and 10.6.10. as appropriate; and

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

[…]

CHAPTER 10.7.

INFECTION WITH KOI HERPESVIRUS

[…]

Article 10.7.5.

Country free from infection with KHV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with KHV if all shared water bodies are within countries or *zones* declared free from infection with KHV (see Article 10.7.6.).

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

1) none of the *susceptible species* referred to in Article 10.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with KHV and subsequently lost its free status due to the detection of KHV but the following conditions have been met:

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

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

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

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

i) at least the last three[two] years in wild and farmed *susceptible species* without detection of KHV; or

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*.

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

Article 10.7.6.

Zone free from infection with KHV

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

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

1) none of the *susceptible species* referred to in Article 10.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with KHV and subsequently lost its free status due to the detection of KHV in the *zone* but the following conditions have been met:

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

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

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

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

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*.

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

Article 10.7.7.

Compartment free from infection with KHV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with KHV and subsequently lost its free status due to the detection of KHV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.7.9. and 10.7.10. as appropriate; and

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

[…]

CHAPTER 10.9.

INFECTION WITH SPRING VIRAEMIA OF CARP VIRUS

[…]

Article 10.9.5.

Country free from infection with SVCV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with SVCV if all shared water bodies are within countries or *zones* declared free from infection with SVCV (see Article 10.9.6.).

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

1) none of the *susceptible species* referred to in Article 10.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with SVCV and subsequently lost its free status due to the detection of SVCV but the following conditions have been met:

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

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

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

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

i) at least the last two[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*.

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

Article 10.9.6.

Zone free from infection with SVCV

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

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

1) none of the *susceptible species* referred to in Article 10.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[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.; 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 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) it previously made a self-declaration of freedom for a *zone* from infection with SVCV and subsequently lost its free status due to the detection of SVCV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 10.9.7.

Compartment free from infection with SVCV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.9.9. and 10.9.10. as appropriate; and

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

[…]

CHAPTER 10.10.

INFECTION WITH VIRAL HAEMORRHAGIC SEPTICAEMIA VIRUS

[…]

Article 10.10.5.

Country free from infection with VHSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with VHSV if all shared water bodies are within countries or *zones* declared free from infection with VHSV (see Article 10.10.6.).

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

1) 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

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

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

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

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

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

i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of VHSV; or

ii) at least the last one~~[one]~~ year without detection of VHSV~~SVCV~~ if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 10.10.6.

Zone free from infection with VHSV

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

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

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

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

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

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

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

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

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

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

Article 10.10.7.

Compartment free from infection with VHSV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with VHSV and subsequently lost its free status due to the detection of VHSV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.10.9. and 10.10.10. as appropriate; and

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

[…]

CHAPTER 10.11.

INFECTION WITH TILAPIA LAKE VIRUS

[…]

Article 10.11.5.

Country free from infection with TiLV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with TiLV if all shared water bodies are within countries or *zones* declared free from infection with TiLV (see Article 10.11.6.).

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

1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with TILV and subsequently lost its free status due to the detection of TiLV but the following conditions have been met:

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

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

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

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

i) at least the last two[~~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*.

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

Article 10.11.6.

Zone free from infection with TILV

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

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

1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with TILV and subsequently lost its free status due to the detection of TiLV in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 10.11.7.

Compartment free from infection with TiLV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[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) it previously made a self-declaration of freedom for a *compartment* from infection with TILV and subsequently lost its free status due to the detection of TiLV in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.11.9. and 10.11.10. as appropriate; and

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

[…]

SECTION 11

DISEASES OF MOLLUSCS

CHAPTER 11.1.

INFECTION WITH ABALONE HERPESVIRUS

[…]

Article 11.1.5.

Country free from infection with abalone herpesvirus

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with abalone herpesvirus if all shared water bodies are within countries or *zones* declared free from infection with abalone herpesvirus (see Article 11.1.6.).

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

1) none of the *susceptible species* referred to in Article 11.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

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 AbHV, 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 abalone herpesvirus and subsequently lost its free status due to the detection of AbHV but the following conditions have been met:

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

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

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

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

i) at least the last two[~~two~~] years in wild and farmed *susceptible species* without detection of AbHV; or

ii) at least the last one[~~one~~] year without detection of AbHV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 11.1.6.

Zone free from infection with abalone herpesvirus

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

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

1) none of the *susceptible species* referred to in Article 11.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~six~~] months;

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.; 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 AbHV, 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 for a *zone* from infection with abalone herpesvirus and subsequently lost its free status due to the detection of AbHV in the *zone* but the following conditions have been met:

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

b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of AbHV, and the appropriate *disinfection* procedures

(as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

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

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

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

Article 11.1.7.

Compartment free from infection with abalone herpesvirus

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ years without detection of AbHV, 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) it previously made a self-declaration of freedom for a *compartment* from infection with abalone herpesvirus and subsequently lost its free status due to the detection of AbHV in the *compartment* but the following conditions have been met:

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.1.9. and 11.1.10. as appropriate; and

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

[…]

CHAPTER 11.2.

INFECTION WITH *BONAMIA EXITOSA*

[…]

Article 11.2.5.

Country free from infection with *B. exitiosa*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. exitiosa* if all shared water bodies are within countries or *zones* declared free from infection with *B. exitiosa* (see Article 11.2.6.).

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

1) none of the *susceptible species* referred to in Article 11.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with *B. exitiosa* and subsequently lost its free status due to the detection of *B. exitiosa* but the following conditions have been met:

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

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

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

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

i) at least the last 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*.

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

Article 11.2.6.

Zone free from infection with *B. exitiosa*

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

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

1) none of the *susceptible species* referred to in Article 11.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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. exitiosa*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[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) it previously made a self-declaration of freedom for a *zone* from infection with *B. exitiosa* and subsequently lost its free status due to the detection of *B. exitiosa* in the *zone* but the following conditions have been met:

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

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

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

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

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*.

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

Article 11.2.7.

Compartment free from infection with *B. exitiosa*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one[two] years 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) it previously made a self-declaration of freedom for a *compartment* from infection with *B. exitiosa* and subsequently lost its free status due to the detection of *B. exitiosa* in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.2.9. and 11.2.10. as appropriate; and

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

[…]

CHAPTER 11.3.

INFECTION WITH *BONAMIA OSTREAE*

[…]

Article 11.3.5.

Country free from infection with *B. ostreae*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. ostreae* if all shared water bodies are within countries or *zones* declared free from infection with *B. ostreae* (see Article 11.3.6.).

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

1) none of the *susceptible species* referred to in Article 11.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with *B. ostreae* and subsequently lost its free status due to the detection of *B. ostreae* but the following conditions have been met:

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

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

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

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

i) at least the last 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*.

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

Article 11.3.6.

Zone free from infection with *B. ostreae*

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

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

1) none of the *susceptible species* referred to in Article 11.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~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.; 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. 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) it previously made a self-declaration of freedom for a *zone* from infection with *B. ostreae* and subsequently lost its free status due to the detection of *B. ostreae* in the *zone* but the following conditions have been met:

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

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

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

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

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*.

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

Article 11.3.7.

Compartment free from infection with *B. ostreae*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last 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) it previously made a self-declaration of freedom for a *compartment* from infection with *B. ostreae* and subsequently lost its free status due to the detection of *B. ostreae* in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.3.9. and 11.3.10. as appropriate; and

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

[…]

CHAPTER 11.4.

INFECTION WITH *MARTEILIA REFRINGENS*

[…]

Article 11.4.5.

Country free from infection with *M. refringens*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *M. refringens* if all shared water bodies are within countries or *zones* declared free from infection with *M. refringens* (see Article 11.4.6.).

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

1) none of the *susceptible species* referred to in Article 11.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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

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

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

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

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

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

i) at least the last 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.*

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

Article 11.4.6.

Zone free from infection with *M. refringens*

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

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

1) none of the *susceptible species* referred to in Article 11.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with *M. refringens* and subsequently lost its free status due to the detection of *M. refringens* in the *zone* but the following conditions have been met:

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

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

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

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

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

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

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

Article 11.4.7.

Compartment free from infection with *M. refringens*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last 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) it previously made a self-declaration of freedom for a *compartment* from infection with *M. refringens* and subsequently lost its free status due to the detection of *M. refringens* in the *compartment* but the following conditions have been met:

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.4.9. and 11.4.10. as appropriate; and

c) 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~~.

[…]

CHAPTER 11.5.

INFECTION WITH *PERKINSUS MARINUS*

[…]

Article 11.5.5.

Country free from infection with *P. marinus*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *P. marinus* if all shared water bodies are within countries or *zones* declared free from infection with *P. marinus* (see Article 11.5.6.).

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

1) none of the *susceptible species* referred to in Article 11.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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) it previously made a self-declaration of freedom from infection with *P. marinus* and subsequently lost its free status due to the detection of *P. marinus* but the following conditions have been met:

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

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

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

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

i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *P. marinus*; or

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*.

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

Article 11.5.6.

Zone free from infection with *P. marinus*

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

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

1) none of the *susceptible species* referred to in Article 11.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with *P. marinus* and subsequently lost its free status due to the detection of *P. marinus* in the *zone* but the following conditions have been met:

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

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

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

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

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*.

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

Article 11.5.7.

Compartment free from infection with *P. marinus*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one[two] years 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) it previously made a self-declaration of freedom for a *compartment* from infection with *P. marinus* and subsequently lost its free status due to the detection of *P. marinus* in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.5.9. and 11.5.10. as appropriate; and

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

[…]

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

[…]

Article 11.6.5.

Country free from infection with *P.olseni*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *P. olseni* if all shared water bodies are within countries or *zones* declared free from infection with *P. olseni* (see Article 11.6.6.).

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

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

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

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

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

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

i) at least the last 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*.

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

Article 11.6.6.

Zone free from infection with *P. olseni*

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

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

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

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

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

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

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

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*.

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

Article 11.6.7.

Compartment free from infection with *P. olseni*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last 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) it previously made a self-declaration of freedom for a *compartment* from infection with *P. olseni* and subsequently lost its free status due to the detection of *P. olseni* in the *compartment* but the following conditions have been met:

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.6.9. and 11.6.10. as appropriate; and

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

[…]

CHAPTER 11.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

[…]

Article 11.7.5.

Country free from infection with *X. californiensis*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *X. californiensis* if all shared water bodies are within countries or *zones* declared free from infection with *X. californiensis* (see Article 11.7.6.).

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

1) none of the *susceptible species* referred to in Article 11.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[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

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

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

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

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

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

i) at least the last 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*.

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

Article 11.7.6.

Zone free from infection with *X. californiensis*

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

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

1) none of the *susceptible species* referred to in Article 11.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[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.; 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) it previously made a self-declaration of freedom for a *zone* from infection with *X. californiensis* and subsequently lost its free status due to the detection of *X. californiensis* in the *zone* but the following conditions have been met:

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

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

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

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

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*.

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

Article 11.7.7.

Compartment free from infection with *X. californiensis*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last 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) it previously made a self-declaration of freedom for a *compartment* from infection with *X. californiensis* and subsequently lost its free status due to the detection of *X. californiensis* in the *compartment* but the following conditions have been met:

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.7.9. and 11.7.10. as appropriate; and

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

[…]

Annex 13. Item 6.5. – 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 14. 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)*, Keti Bangladeshi (*Rohtee* sp.), rudd *(Scaridinius erythrophthalmus)*, terapon (*Terapon* sp.) and three-spot gourami *(Trichogaster trichopterus)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

[…]

Annex 15. 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 16. Item 6.8. – Draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus1*'

CHAPTER 10.X.

INFECTION WITH *MEGALOCYTIVIRUS PAGRUS1*

Article 10.X.1.

For the purposes of the *Aquatic Code*, infection with *Megalocytivirus pagrus1* means *infection* with the *pathogenic agent Megalocytivirus pagrus1* (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 of *M. pagrus1* 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
Lateolabracidae	*Lateolabrax japonicus*	Japanese seabass
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
Percalatidae	*Percalates novemaculeata*	Australian bass
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. pagrus1* 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. pagrus1*, regardless of the infection with *M. pagrus1* 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. pagrus1*;

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. pagrus1*;

3) fish oil;

4) fish skin leather.

Article 10.X.4.

Requirements for self-declaration of freedom from infection with *M. pagrus1*

A Member Country may make a self-declaration of freedom from infection with *M. pagrus1* 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. pagrus1*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *M. pagrus1* if all shared water bodies are within countries or *zones* declared free from infection with *M. pagrus1* (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. pagrus1* for its entire *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for infection with *M. pagrus1*;

OR

2) there has been no occurrence of infection with *M. pagrus1* 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. pagrus1*, 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. pagrus1*, 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. pagrus1* and subsequently lost its free status due to the detection of *M. pagrus1* but the following conditions have been met:

a) on detection of *M. pagrus1*, 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. pagrus1*, 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. pagrus1*; 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. pagrus1*; or

ii) at least the last one year without detection of *M. pagrus1* 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. pagrus1*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *M. pagrus1* 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. pagrus1* 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. pagrus1* 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. pagrus1*, 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. pagrus1*, 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. pagrus1* and subsequently lost its free status due to the detection of *M. pagrus1* in the *zone* but the following conditions have been met:

a) on detection of *M. pagrus1*, 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. pagrus1*, 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. pagrus1*; 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. pagrus1*; or

ii) at least the last one year without detection of *M. pagrus1* 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. pagrus1*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus1* 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. pagrus1*, 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. pagrus1* and subsequently lost its free status due to the detection of *M. pagrus1* 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. pagrus1*, 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. pagrus1* 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. pagrus1* following the provisions of Articles 10.X.4. to 10.X.7. (as relevant) may maintain its status as free from infection with *M. pagrus1* 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. pagrus1*

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. pagrus1*, 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. pagrus1*.

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. pagrus1*

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. pagrus1*, 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. pagrus1* 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. pagrus1* .

b) In the importing country:

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

ii) test the F-0 population for *M. pagrus1* 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. pagrus1*, and sample and test for *M. pagrus1* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter [under study]~~2.3.X.~~ of the *Aquatic Manual*;

v) if *M. pagrus1* is not detected in the F-1 population, it may be defined as free from infection with *M. pagrus1* and may be released from *quarantine*;

vi) if *M. pagrus1* 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. pagrus1*

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. pagrus1*, 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. pagrus1* 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. pagrus1* 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. pagrus1*

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. pagrus1*, 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. pagrus1* 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. pagrus1* 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. pagrus1*

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. pagrus1*, 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. pagrus1* 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. pagrus1* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *M. pagrus1* regardless of the infection with *M. pagrus1* 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. pagrus1*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Annex 17. 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
	Haliotis iris	black paua
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 18. 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.~~

[…]

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Annex 19. Item 7.1. – Draft new Chapter 4.3. 'Application of Compartmentalisation'

SECTION 4.

DISEASE PREVENTION AND CONTROL

CHAPTER 4.3.

APPLICATION OF COMPARTMENTALISATION

Article 4.3.1.

Objective and introduction

This chapter provides recommendations for establishing and maintaining *compartments* that are free from specified *diseases* for the purpose of facilitating trade or for *disease* prevention and control.

Compartmentalisation provides a means of demonstrating that an *aquaculture establishment* is free from one or more specified *diseases* by establishing and maintaining functional epidemiological separation between the *aquatic animals* within the *compartment* and sources of *infection* outside the *compartment*. A *compartment* may comprise a single *aquaculture establishment* or a group of interrelated *aquaculture establishments* that operate under a common set of *risk management* measures in accordance with this chapter.

Compartmentalisation provides an opportunity for the private sector to demonstrate *disease* freedom at the enterprise level, including in circumstances where alternatives such as *country* or *zone* freedom may not be feasible or cost-effective. Investment by the private sector and oversight by the relevant *Competent Authorities* is essential.

A *self-declaration of freedom from disease* for a *compartment* from specified *listed diseases* can be made if the requirements of this chapter to establish a *compartment* are met and the requirements for making a *self-declaration of freedom from disease* described in Chapter 1.4. and in the relevant disease-specific chapters have been met.

Article 4.3.2.

Purposes of compartments

Compartments provide an opportunity for trade of disease-free *commodities* from a *zone* or *country* not declared free. They can also be used to provide epidemiological separation for populations of valuable *aquatic animals* within a *free country* or *free zone* to protect them in the event of a *disease outbreak*.

There may be a range of *commodities* produced by a *compartment* and possible end-uses. The *commodity* types (e.g. *aquatic animals*, *aquatic animal products*) and end-uses (e.g. for *aquaculture*, stocking of natural water bodies, human consumption, *ornamental aquatic animals*) have implications for *risk management* and should be defined.

Article 4.3.3.

Principles for establishing a compartment

The following principles should be applied to establish and maintain a *free compartment*.

1) A *compartment* must ensure there are effective measures to prevent the entry or spread of *pathogenic agents* between the *compartment* and external environments (i.e. provide functional epidemiological separation);

2) the purpose of a *compartment* should be clearly defined (e.g. *disease(s)* for which freedom will be claimed, species and *commodities* produced, intended end-uses of *commodities*) as this will have implications for the design of *risk management* measures, as described in Article 4.3.2.;

3) *biosecurity* and *surveillance* measures should be appropriate for the category of *compartment*, i.e. those with disease-free status that is dependent on the *disease* status of the surrounding environment or those with disease-free status that is independent from the *disease* status of the surrounding environment, in Article 4.3.4.;

4) a *biosecurity plan* must be developed and maintained in accordance with Chapter 4.1. and applied consistently across all elements of the *compartment* as described in Article 4.3.5.;

5) *surveillance* measures to demonstrate that the *compartment* is free from specified *diseases*, and to maintain its free status, must be clearly described in accordance with Chapter 1.4., including elements of internal and external *surveillance* as appropriate, as described in Article 4.3.6.;

6) *surveillance* testing must be supported by reliable laboratory testing services which have independence from the *compartment* operator and which are approved by *Competent Authority*, as described in Article 4.3.7.;

7) traceability systems must provide assurance of provenance of *commodities* from the *free compartment*, as described in Article 4.3.8.;

8) record keeping must provide evidence of the ongoing application of all measures on which the *compartment* has been granted disease-free status, as described in Article 4.3.9.;

9) official oversight responsibilities must be clearly documented, including approval by the *Competent Authority*, an auditing schedule, underpinning regulatory instruments and authorising third parties within the *Aquatic Animal Health Services* for important roles, as described in Articles 4.3.10. and 4.3.11.;

10) notification and response measures must be in place in the event of detection of the *disease* for which the *compartment* has been declared free, or for other *diseases* relevant to trade from the *compartment*, as described in Article 4.3.12.;

Article 4.3.4.

Dependent and independent compartments

There are two categories of *compartments* that are determined by the degree of epidemiological separation from the surrounding environment. Independent *compartments* have complete epidemiological separation from the surrounding environment and are characterised by appropriate levels of physical and management measures to maintain effective *biosecurity*. Dependent *compartments* do not have complete epidemiological separation from the surrounding environment and require the application of appropriate *risk* mitigation measures to achieve and maintain disease-free status despite epidemiological links to the surrounding environment. If such *risk* mitigation measures cannot be applied successfully, a dependent *compartment* cannot be approved by the *Competent Authority*.

The concept of dependent *compartments* enables compartmentalisation to be applied to more types of production systems and more establishments, increasing opportunities to trade in disease-free *commodities* where these *compartment* types provide an appropriate level of *risk management*.

Independent and dependent *compartments* have the following characteristics:

1) Independent *compartments*:

    a) are closed production system types only (as described in Chapter 4.1);

b) have control over all transmission pathways and complete epidemiological separation from surrounding environments;

c) have appropriate levels of physical and management measures to maintain effective *biosecurity* for all pathways;

d) provide levels of *risk* mitigation suitable for all purposes, *commodity* types and end-uses;

e) are often preferred for high value *aquatic animals* (e.g. genetically improved lines, brood stock).

2) Dependent compartments:

a) are semi-closed production system types only (as described in Chapter 4.1.);

b) are dependent on the health status of the surrounding waters;

c) have appropriate levels of physical and management measures to maintain effective *biosecurity* for all pathways;

d) meet the additional *biosecurity* criteria and *risk* mitigation measures for transmission via intake water which the *Competent Authority* may approve in accordance with Article 4.3.5.;

e) may not provide sufficient *risk* mitigation for all purposes, *commodity* types and end-uses (e.g. supplying live *aquatic animals* for *aquaculture* or restocking, for high value *aquatic animals* such as genetically improved lines).

The suitability of a dependent *compartment* to achieve the required level of *risk* mitigation should be determined following consideration of the purpose of the *compartment* (refer to Article 4.3.2.), the *commodities* produced (e.g. *aquatic animal products* or *aquatics animals*), and their end-uses (e.g. products for human consumption versus *aquatic animals* for stocking in semi-open systems).

Based on a *risk analysis*, approved by the *Competent Authority*, dependent *compartments* may require specific measures to mitigate the *risk* of *disease* transmission from the environment to the *compartment*. The *risk* mitigation measures should be developed in accordance with Article 4.1.8. and may include the application of specific *biosecurity* measures, post-production testing, auditing within the production cycle, a higher level of internal *targeted surveillance*, external *surveillance* to monitor for change in *disease risk*, and external *disease* control measures to mitigate the *risk* of *disease* transmission into the environment adjacent to the *compartment*.

Table 1. A summary of the characteristics of independent and dependent compartments

Independent	**Dependent**
Only closed systems are a suitable production system type	Only semi-closed systems are a suitable production system type
Biosecurity across all pathways in accordance with Chapter 4.1.	*Biosecurity* across most pathways in accordance with Chapter 4.1.
Disease-free status not dependent on the status of the surrounding waters	Disease-free status dependent on the status of the surrounding waters
External *surveillance* generally not required to maintain freedom (but may be useful to inform biosecurity measures)	Ongoing external *surveillance* may be required to maintain freedom in accordance with Chapter 1.4.
Suitable for all *commodities* and pathways	May not meet the required level of *risk* mitigation for all *commodities* and pathways

Article 4.3.5.

Biosecurity and other risk mitigation measures

The integrity of a *compartment* relies on *biosecurity* to mitigate the *risk* of introduction of specific *pathogenic agents* into the *compartment* and to maintain its disease-free status. A *biosecurity plan* for the *compartment* should be developed and maintained in accordance with Chapter 4.1.

For *compartments* comprising more than one *aquaculture establishment*, the *biosecurity plan* should provide a common set of management and physical measures to provide a consistent level of *risk* mitigation across all elements of the *compartment*.

For dependent *compartments*, the *risk analysis* described in Article 4.1.8. should include the assessment of risks within the environment surrounding the *compartment* and the development of appropriate *risk management* and *surveillance* measures to mitigate the identified *risks*. The *Competent Authority* should consider in the *risk analysis:*

1) characteristics of the *pathogenic agent*;

2) absence of *susceptible species* and pathways of *infection* in the surrounding environment due to geographical location, environmental conditions or the application of *biosecurity* measures. Specific consideration should be given to:

    a) the hydrological conditions in the water body;

    b) the geographical location of each *aquaculture establishment* comprising the dependent *compartment* and the nature of the water supply;

    c) the health status of other *aquaculture establishments* within the shared water body system;

    d) the location of the *aquaculture establishments* referred to in point (c) or processing facilities and their proximity to the dependent *compartment;*

    e) the method of production and the source of the *aquatic animals* used in the *aquaculture establishments* referred to in point (c);

    f) the presence and abundance of wild *susceptible species* in the water body and their health status;

    g) the details of whether the *susceptible species* referred to in point (f) are sedentary or migratory;

    h) the exclusion of the wild *aquatic animals* referred to in point (f) from entering the *compartment*;

    i) the general *biosecurity* measures applied in *aquaculture establishments* and processing facilities in the shared water body;

3) absence of *infection* in any nearby populations of *susceptible species* demonstrated by appropriate external *surveillance*;

4) additional internal *surveillance* (i.e. in the *aquaculture establishment(s)* that comprise the *compartment*.

For some semi-closed aquaculture establishments, it may not be possible to mitigate identified *risks* from the surrounding environment (e.g. presence of *disease* in adjacent wild populations of *susceptible species*) and the *aquaculture establishment* would not be eligible to be recognised as a dependent *compartment*.

Article 4.3.6.

Surveillance requirements to demonstrate and maintain freedom

For recognition of a *free compartment*, a *self-declaration of freedom from disease* should be made which complies with the requirements of Article 1.4.4. The *surveillance* requirements to make a *self-declaration of freedom from disease* for a *compartment*, and to maintain a *free compartment*, should comply with Chapter 1.4.

Basic biosecurity conditions for a *compartment* must be in place and continuously met prior to the commencement of *targeted surveillance* to demonstrate freedom. The relevant disease-specific chapters provide the required periods that *basic biosecurity conditions* must be in place prior to commencement of *targeted surveillance*, and the period that *targeted surveillance* should be conducted prior to making a *self-declaration of freedom from disease*.

Surveillance requirements should be developed in accordance with factors as described in Article 4.3.5.

If there is an increased *risk* of exposure to the *disease* from which the *compartment* has been defined, the sensitivity of the internal and external *surveillance* system should be reviewed, documented and, where necessary, increased. At the same time, the *biosecurity plan* should be reviewed in accordance with Article 4.1.9 and revised if necessary.

1. Internal surveillance

   Internal *surveillance* (i.e. for populations of *susceptible species* within a *compartment*) is required to make a *self-declaration of freedom from disease* for both independent and dependent *compartments*. The *surveillance* requirements to maintain freedom are described in the relevant disease specific chapters and Article 1.4.15.

2. External surveillance

   External *surveillance* (i.e. for populations of *susceptible species* in the environment outside a *compartment*) can be used to identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*. External *surveillance* is required for dependent *compartments* if populations of *susceptible species* are present in the environment surrounding the *compartment*.

Article 4.3.7.

Laboratory testing

Laboratories providing testing services for a *compartment* should be approved by the relevant *Competent Authority*. In providing approval, the *Competent Authority* should ensure that the laboratory:

1) has a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*, or can demonstrate quality through another means in accordance with Chapter 3.1.;

2) is required to conduct testing in accordance with the recommendations of the *Aquatic Manual*;

3) can confirm or exclude cases of *disease* as described in Article 1.4.18.;

4) is independent from management and ownership structures of the *compartment*;

5) has a legal obligation to report positive test results to the *Competent Authority* in accordance with the requirements of *basic biosecurity conditions* specified in Article 1.4.6.

Article 4.3.8.

Traceability

Traceability systems should apply throughout the supply chain and are required to reliably differentiate *commodities* that originate from a *free compartment* from those that originate from outside a *free compartment*. The traceability system should:

1) be appropriate for the *aquatic animal* species and for application to individual or groups of *aquatic animals* or *aquatic animal products*, as necessary;

2) ensure that all movements of disease-free *aquatic animals* into a *free compartment* originate from a *free country, free zone* or *free compartment,* and in the case of international movements are certified in accordance with Chapter 5.1.;

3) be reflected in the *biosecurity plan* that is developed in accordance with Article 4.3.5. and which provides appropriate *risk management*;

4) comprise record keeping requirements in accordance with Article 4.3.9.;

5) be approved by the *Competent Authority* in accordance with Article 4.3.10.

Article 4.3.9.

Record keeping

A system of record keeping by the operator of a *compartment* should provide clear evidence that the *biosecurity*, *surveillance*, traceability and management practices that form the basis of a *self-declaration of freedom from disease* are effectively and continuously applied.

Records should be maintained consistently by the operator of the *free compartment* and be accessible on request for the purposes of an audit or in response to queries from the *Competent Authority* of an *importing country*. The record keeping system should:

1) substantiate that the *compartment*'s *biosecurity plan* is maintained in accordance with Chapter 4.1., including the maintenance of records associated with all relevant pathways described in Article 4.1.7;

2) substantiate that the *surveillance* required to declare and maintain *free compartment* status has been conducted in accordance with Chapter 1.4. and the provisions of relevant disease-specific chapters;

3) document any changes to *biosecurity*, *surveillance*, traceability or management practices, the rationale for the changes and substantiation that they continue to meet *risk management* requirements;

4) in addition to the points above, maintain any external reports, certificates or approvals associated with the requirements of this chapter, including but not limited to audit reports, laboratory reports, health certificates, and health investigations;

5) maintain records for sufficient period of time to inform tracing, recall or emergency response at any point in the supply chain if a *disease* were detected within the *compartment* or in *commodities* originating from the *compartment*. The required period should be meet requirements for *surveillance*, the *biosecurity plan*, auditing, and traceability. It may vary depending on the *disease, aquatic animal* species and *commodity* types produced and the duration of production cycles.

Article 4.3.10.

Official oversight

A *Competent Authority* must have the authority to approve the operation of the *aquaculture establishment(s)* that compromise the *compartment*. A *Competent Authority* must also have the authority to make a *self-declaration of freedom from disease* as described in Chapter 1.4., as well as grant, suspend and revoke the status of a *compartment*. It should supervise compliance with all of the requirements critical to the maintenance

of the *compartment* status described in this chapter and ensure that all relevant information (as described in Article 4.3.9) is readily accessible to *importing countries*. The *Competent Authority* should ensure appropriate auditing of the *compartment* is completed by trained officials or accredited third party auditors.

The *Veterinary Authority* should ensure that any changes to the health status of the *compartment* should be notified to the *Veterinary Authority* of *importing countries*.

Article 4.3.11.

Quality of aquatic animal health services

The quality of *Aquatic Animal Health Services* relevant to the self-declaration of *compartment* freedom should be documented, including how they meet the requirements of Chapter 3.1.

Article 4.3.12.

Notification and response measures

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

In the event of detection of any *disease* which may indicate a breach of *biosecurity* measures, the management of the *compartment* should notify the *Competent Authority*. A review should be initiated to determine whether a breach of *biosecurity* measures has occurred.

If a significant breach in *biosecurity* is identified, even in the absence of the *disease(s)* for which the *compartment* was declared free, the *compartment's* free status should be suspended. There should be an immediate suspension of trade to disease-free areas if a *disease* for which the *compartment* has been declared disease-free, is suspected or confirmed, and trading partners should be notified in accordance with Article 5.1.4.

Disease-free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original *biosecurity* level and the *Competent Authority* re-approves the status of the *compartment*. If the health status of the *compartment* is at *risk*, the *Competent Authority* should immediately re-evaluate the status of the *compartment* and consider whether any additional *biosecurity* measures are needed to ensure that the integrity of the *compartment* is maintained.

Annex 20. Item 7.1. – Glossary - Compartment

GLOSSARY

[…]

COMPARTMENT

means one or more *aquaculture establishments* containing a population of *aquatic animals* with a distinct health status for a specific *disease* or *diseases* that is established and maintained through the application of a common *biosecurity* system, appropriate *surveillance* and *disease* control measures.

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

[…]

Annex 21. Item 7.3. – Chapter 4.7. 'Fallowing in Aquaculture'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.7.

FALLOWING IN AQUACULTURE

Article 4.7.1.

Introduction

~~Gaps in *aquaculture* production at the same location are commonly recognised to be of value in resting or restoring the local environment. As part of this strategy, *fallowing* can break re-*infection* cycles by removing loci of a *disease* from a farm. Consequently, *fallowing*~~ *Fallowing* is a routine ~~carried out as a regular~~ *disease* management measure in *aquaculture*, either as a best practice especially prior to the introduction of new populations of *aquatic animals* into a previously stocked used site, as part of a *biosecurity plan* in accordance with Chapter 4.1., or on the instructions of the *Competent Authority*, following an outbreak of a *disease* which is subject to emergency management measures as described in Chapter 4.Y.

Article 4.7.2.

Considerations for fallowing

Fallowing is used to provide a temporal break in *pathogenic agent* transmission cycles between susceptible populations of *aquatic animals*. It should be implemented with consideration given to:

1) the objective of *fallowing* such as preventing transmission between sequential production cycles, suppression of *pathogenic agent infection* pressure, or to eradicate a *pathogenic agent* from an *aquaculture establishment*;

2) the sources of *infection* at the production site such as farmed or wild populations of *susceptible aquatic animals*, *vectors*, fomites or *pathogenic agents* in the environment (e.g. water or sediment);

3) whether the *pathogenic agent* is obligate or facultative;

4) for obligate *pathogenic agents*, the period that they may remain viable in the environment;

5) the need for spatial coordination to synchronously fallow epidemiologically connected *aquaculture establishments*;

6) when the infective period is not known, the farm may be fallowed for a period, the length of which should be based on a *risk assessment*.

Article 4.7.3.

Voluntary fallowing

In order to promote improved health in *aquaculture*, the *Aquatic Animal Health Service* in a country may encourage the voluntary use of *fallowing* as a part of the *biosecurity plan* set out in Chapter 4.1. as a *biosecurity* measure for an individual *aquaculture establishment* or as a common *biosecurity* measure among all

aquaculture establishments that are considered epidemiologically linked in a given area. ~~a routine management strategy for many *diseases*. Account should be taken of~~ When encouraging aquaculture operators to fallow their establishments, the *Competent Authority* should emphasise the likely beneficial effects of *fallowing* in proportion to the economic costs involved.

The *Aquatic Animal Health Service* should also ~~consider such factors as~~ take into account the level of *risk* a particular *disease* poses to ~~the~~ local ~~and national~~ *aquaculture* operations, ~~previous knowledge of the severity of a *disease(s)*~~, the infective period of the *disease* in question, ~~and distribution of the *pathogenic agent(s)*~~, as well as the relevant socioeconomic conditions ~~,and~~ when assessing the potential benefits ~~pertaining~~ to ~~the general~~ aquatic resources in the area. ~~When the infective period is not known, the farm may be fallowed for a period, the length of which should be based on a *risk assessment*.~~

Article 4.7.4.

Compulsory fallowing

Compulsory *fallowing* may be required in accordance with the instructions of the *Competent Authority* following an outbreak of an important *disease* which has been subject to the measures described in Chapters 4.X. and 4.Y. ~~However, where an official *stamping-out policy* is being carried out for a *disease* of concern, the *Aquatic Animal Health Service* should~~ The *Competent Authority* may require that an infected *aquaculture establishment*, and ~~all~~ other relevant *aquaculture establishments* in an officially declared ~~established~~ *infected zone*, are ~~be~~ subjected to a required period of *fallowing*~~, if necessary synchronised~~. This *fallowing* will be carried out for a period of time which is prescribed by the *Competent Authority*, following *risk assessment*. A period of synchronous *fallowing* may be required in relevant establishments in the *infected zone* should this be indicated by the *risk assessment*.

Article 4.7.5~~2~~.

Legal powers

In the cases referred to in Article 4.7.1. where *fallowing* is ~~may be~~ a compulsory measure, prescribed by the *Competent Authority*, ~~for instance in the establishment or restoration of a *disease free zone*, countries should establish~~ a legal framework must be in place to: ~~for the implementation of *fallowing* procedures in *aquaculture establishments*. Legal provisions could include:~~

1) define ~~defining~~ the ~~*disease*~~ circumstances when *fallowing* or synchronised *fallowing* is required;

2) define ~~defining~~ mechanisms based on *risk assessment* where individual disease-specific measures may be determined, including when *fallowing* should commence ~~*disinfection*~~ and the length of the *fallowing* period prior to the re-introduction of *susceptible species*.~~;~~

~~3) following permission by the *Competent Authority* to restock with *susceptible species*, defining a period of *surveillance* and *diagnostic* to verify freedom from the specified *disease*.~~

Article 4.7.6~~3~~.

Technical parameters for the implementation of a compulsory ~~statutory~~ fallowing plan

Taking into account the categories of *aquaculture* production systems referred to in Article 4.1.5., *fallowing* of an a*quaculture establishment* ~~*Fallowing* of a farm~~ should take paragraph 5 of Article 4.X.7. into account and start immediately after:

1) destruction of and biosecure disposal:

   a) ~~removal~~ of all *susceptible species* of *aquatic animals* for the *disease* of concern; and

b2) ~~removal~~ of all species of *aquaculture* animals which are capable of acting as *vectors* of the *disease* of concern; and

c3) ~~if appropriate, removal~~ of other species, if indicated by *risk assessment*; ~~and~~

24) removal of water in which infected stocks have been held, where feasible; and

35) appropriate *disinfection* measures have been completed on equipment and other contaminated materials in accordance with Article 4.7.4., under supervision of the *Aquatic Animal Health Services*. ~~equipment and other materials contaminated or otherwise capable of harbouring *infection* have either been removed or subjected to *disinfection* to standards approved by the *Aquatic Animal Health Service*.~~

The length of the compulsory ~~statutory~~ *fallowing* period should be based on scientific evidence of the likelihood of free ~~a~~ *pathogenic agent* remaining infective ~~outside its aquaculture host(s)~~ in the local environment, at a level likely to cause an unacceptable risk of re-*infection* of the *aquaculture establishment*. Account should be taken of the extent of the *disease outbreak*, local distribution of *susceptible species* and possible *vectors* ~~availability of alternative hosts~~, the survival and infectivity characteristics of the *pathogenic agent* and the local climatological, geographical and hydrographical factors. In addition, the level of *risk* to the local *aquaculture* industry and wider aquatic resources should be taken into consideration ~~may be included~~. A scientifically based *risk assessment* approach should be used to determine the length of the *fallowing* period.

Article 4.7.74.

~~Instructions for disinfection~~ Disinfection prior to fallowing

Competent Authorities ~~Countries~~ establishing *fallowing* procedures should develop a detailed set of instructions for *disinfection* of *aquaculture establishments* prior to *fallowing*~~,~~ where appropriate for the type of production system and circumstances. This should be completed in accordance with Chapter 4.4. and for compulsory *fallowing* Chapters 4.X. and 4.Y. ~~For this purpose, the instructions set out in Chapter 4.4. of the *Aquatic Code* and in Chapter 1.1.3. of the *Aquatic Manual* should be used as guidelines,~~ taking into account current scientific knowledge on the efficacy of the treatments for the *pathogenic agent* of concern.

Article 4.7.85.

Restocking after fallowing

An ~~No~~ *aquaculture establishment* that has been subject to~~under~~ compulsory *fallowing* should not be restocked until the compulsory *fallowing* period has been completed and permission from the *Competent Authority* has been received.

When restocking, care should be taken not to use stocks of *aquatic animals* that could ~~would~~ compromise the objectives of the *fallowing* procedure. To increase confidence in the effectiveness of the *fallowing* procedures, all farms subjected to compulsory *fallowing* should have a period of ~~high level~~ official *surveillance* after *susceptible species* have been restocked. The duration and intensity of the *surveillance* should be appropriate for the *disease* in question ~~of concern~~ and subject to the requirements set out in Chapter 1.4., and to the relevant disease-specific chapter in cases of *listed diseases* ~~local conditions~~.

Annex 22. Item 9.1.1. – 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
	Palaemon serenus	no common name
	Palaemon serrifer	carpenter prawn

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 23. Item 9.2.1. – 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

[…]

Annex 24. Item 9.3.1. – Chapter 2.4.2. 'Infection with *Bonamia exitiosa*'

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~~ 2011; 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.

2.2.6. Vectors

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, including ~~such as~~ imprints and PCR. ~~For PCR in *O. edulis* it is recommended to include gills and gonad.~~ More than 1 organ (including gills, heart and gonad) should be used for PCR-based diagnosis of *B. exitiosa*, to maximise the sensitivity (Ramilo *et al.,* 2014).

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 *B. 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* sp~~ecies~~.

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 (Lane *et al.,* 2016). 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* sp~~ecies~~.

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. 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) region (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* spp. 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-CC 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); GenBank Accession No: KM073106			
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* spp. (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]; GenBank Accession No.: AF262995			
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-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]: GenBank Accession No.: AF192759			
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: Ramilo *et al.,* 2013; amplicon size [246 bp], GenBank Accession No: DQ312295			
Bonamia exitiosa/18S-ITS1	BEXIT-F GCG-CG-TTC-TTA-GAA-GCT-TTG BEXIT-R AAG-ATT-GAT-GTC-GGC-ATG-TCT	0.3 µM 0.3 µM	35 cycles of: 94°C/30sec, 58°C/45sec, 72°C/1 min

[(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* I 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.

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* spp. 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* spp. 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~~ of 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 stain~~ing~~, 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 *B. 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 *B. exitiosa* is considered to be confirmed if at least one of the following criteria ~~criterion~~ is met:

~~i) Positive result by tissue imprints or histology followed by real-time PCR or by conventional PCR and sequencing~~

i) Positive result by real-time PCR and conventional PCR and sequencing

ii) Positive result by real-time PCR and *in-situ* hybridisation

iii) Positive result by tissue imprints, histology or *in-situ* hybridisation, and positive result by conventional PCR followed by sequence analysis

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

1 For example transboundary commodities.

The presence of infection with *B. 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

The presence of infection with *B. exitiosa* is considered to be confirmed if at least one of the following criteria ~~criterion~~ is met:

i) Positive result by real-time PCR ~~or~~ and by conventional PCR and sequencing

ii) Positive result by real-time PCR and *in-situ hybridisation*

iii) Positive result by tissue imprints, histology or *in-situ hybridisation*, and positive result by conventional PCR followed by sequence analysis

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* spp. 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* spp. 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* spp. (Corbeil *et al.,*	Diagnosis	Two farms in *B. exitiosa* endemic areas in Australia: a	Gills	*Ostrea angasi*	93.5% (232)	92.2% (232)	Histology Bayesian latent class analysis	Bradley *et al.*, 2020

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
2006a) (with epidemiological Ct cut-off)		coastal lease with *B. exitiosa* associated mortalities, a land-based hatchery with no *B. exitiosa* associated mortalities (prevalences ~30 and 60%)						
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 *B. 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	Heart imprints	*Ostrea angasi*	61% (400)	60% (400)	Histology (DSe: 76%, DSp: 93%) and real-time PCR	Buss *et al.,* 2019

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
		populations 60–90%, but low intensity of infection)					(DSe: 69%, DSp:93%) Bayesian latent class analysis	
	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
Conventional PCR *Bonamia* spp. (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 *B. 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* spp.	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* spp. (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

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
TaqMan real-time PCR *Bonamia* spp.	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
	Surveillance	30 flat oysters from an area affected by *B. 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.

7. References

ABOLLO E., RAMILO A., CASAS S.M., COMESAÑA P., CAO A., CARBALLAL M.J. & VILLALBA A. (2008). First detection of the protozoan parasite *Bonamia exitiosa* (Haplosporidia) infecting flat oyster *Ostrea edulis* grown in European waters. *Aquaculture,* **274**, 201–207.

ARZUL I. & CARNEGIE R.B. (2015) New perspective on the haplosporidian parasites of molluscs. *J. Invertebr. Pathol.,* **131**, 32–42. doi: 10.1016/j.jip.2015.07.014.

ARZUL I., LANGLADE A., CHOLLET B., ROBERT M., FERRAND S., OMNES E., LEROND S., COURALEAU Y., JOLY J.-P., FRANÇOIS C. & GARCIA C. (~~2010~~ 2011). Can the protozoan parasite *Bonamia ostreae* infect larvae of flat oysters *Ostrea edulis*? *Vet. Parasitol*., **179**, 69–76. doi:10.1016/j.vetpar.2011.01.060

~~BALSEIRO P., CONCHAS R.F., MONTES J., GÓMEZ-LEÓN J., NOVOA B. & FIGUERAS A. (2006). Comparison of diagnosis techniques for the protozoan parasite *Bonamia ostreae* in flat oyster *Ostrea edulis. Aquaculture*, **261**, 1135–1143.~~

BISHOP M., CARNEGIE R., STOKES N., PETERSON C. & BURRESON E., (2006). Complications of a non-native oyster introduction: facilitation of a local parasite. *Mar. Ecol., Prog. Ser.,* **325**, 145–152.

BRADLEY T.L., MERCER J.A., HUMPHREY J.D., MOODY N.J.G. & HUNNAM J.C. (2020). *Bonamia exitiosa* in farmed native oysters *Ostrea angasi* in Australia: optimal epidemiological qPCR cut-point and clinical disease risk factors. *Dis. Aquat. Organ.*, **140**, 151–165.

BUSS J.J., HARRIS J.O., TANNER J.E., WILTSHIRE K.H. & DEVENEY M.R. (2020a). Rapid transmission of *Bonamia exitiosa* by cohabitation causes mortality in *Ostrea angasi*. J. Fish Dis., **43**, 227–237. doi: 10.1111/jfd.13116.

BUSS J., WILTSHIRE K.H., HARRIS J.O. & DEVENEY M.R. (2020b). Decontamination of *Bonamia exitiosa*. *Aquaculture*,**523**, 735210, https://doi.org/10.1016/j.aquaculture.2020.735210.

Buss J.J., Wiltshire K.H., Harris J.O., Tanner J.E. & Deveney M.R. (2020c). Infection dynamics of Bonamia exitiosa on intertidal *Ostrea angasi* farms. *J. Fish Dis.,* **43**, 359–369. doi: 10.1111/jfd.13134.

Buss J.J., Wiltshire K.H., Prowse T.A.A., Harris J.O., Deveney M.R. (2019). *Bonamia* in *Ostrea angasi*: diagnostic performance, field prevalence and intensity. *J. Fish Dis.*, **42**, 63–74. doi: 10.1111/jfd.12906

Canier L., Dubreuil C., Noyer M., Serpin D., Chollet B., Garcia C. & Arzul I. (2020). A new multiplex real-time PCR assay to improve the diagnosis of shellfish regulated parasites of the genus *Marteilia* and *Bonamia*. *Prev. Vet. Med.,* **183**, 105126.

Carnegie R., Barber B.J., Culloty S.C., Figueras A.J. & Distel D.L. (2000). Development of a PCR assay for detection of the oyster pathogen *Bonamia ostreae* and support for its inclusion in the Haplosporidia. *Dis. Aquat. Organ*., **42**, 199–206.

Carnegie R.B. & Cochennec-Laureau N. (2004). Microcell parasites of oysters: Recent insights and future trends. *Aquat. Living Res.*, **17**, 519–528.

Carnegie R.B., Stokes N.A., Audemard C., Bishop M.J., Wilbur A.E., Alphin T. D. & Burreson E.M. (2008). Strong seasonality of *Bonamia* sp. infection and induced *Crassostrea ariakensis* mortality in Bogue and Masonboro Sounds, North Carolina, USA. *J. Invertebr. Pathol.*, **98**, 335–343.

Cochennec N., Le Roux F., Berthe F. & Gerard A. (2000). Detection of *Bonamia ostreae* based on small subunit ribosomal probe. *J. Invertebr. Pathol*., **76**, 26–32.

Corbeil S., Arzul I., Diggles B., Heasman M., Chollet B., Berthe F.C. & Crane M.S. (2006a). Development of a TaqMan PCR assay for the detection of *Bonamia* species. *Dis. Aquat. Organ.,* **71**, 75–80.

Corbeil S., Arzul I., Robert M., Berthe F.C.J., Besnard-Cochennec N. & Crane M.S.J. (2006b). Molecular characterization of an Australian isolate of *Bonamia exitiosa*. *Dis. Aquat. Organ.,* **71**, 81-85.

Cranfield H.J., Dunn A., Doonan I.J. & Michael K.P. (2005). *Bonamia exitiosa* epizootic in *Ostrea chilensis* from Foveaux Strait, southern New Zealand between 1986 and 1992. *ICES J. Mar. Sci.,* **62**, 3–13.

Diggles B.K., Cochennec Laureau N. & Hine P.M. (2003). Comparison of diagnostic techniques for *Bonamia exitiosus* from flat oysters *Ostrea chilensis* in New Zealand. *Aquaculture,* **220**, 145–156.

Dinamani P., Hine P.M. & Jones J.B. (1987). Occurrence and characteristics of the haemocyte parasite *Bonamia* sp. in the New Zealand dredge oyster *Tiostrea lutaria. Dis. Aquat. Org.,* **3**, 37–44.

Doonan I.J., Cranfield H.J. & Michael K.P. (1994). Catastrophic reduction of the oyster, *Tiostrea chilensis* (Bivalvia: Ostreidae), in Foveaux strait, New Zealand, due to infestation by the protistan *Bonamia* sp. *NZ J. Mar. Freshwater Res.,* **28**, 335–344.

Engelsma M. & M. Hine. (2009). Infection with *Bonamia exitiosa*: disease detection, pathogen identification and typing. *In:* Epidemiology of different agents causing disease in aquatic animals: scientific review and database development, Hill B., Reese A., Dixon P., Oidtmann B., Paley R., Peeler E., Stentiford G., Stone D., Way K., Hine M., Calistri P., Ippoliti C., Di Lorenzo A., Savini L., Haenen O., Engelsma M., eds. European Food Safety Authority (EFSA), Parma, Italy, Annex B, pp. 40–41.

Engelsma M.Y., Culloty S.C., Lynch S.A., Arzul I. & Carnegie R.B. (2014). *Bonamia* parasites: a rapidly changing perspective on a genus of important mollusc pathogens. *Dis. Aquat. Organ.,* **110**, 5–23.

EURL for mollusc diseases (2023). SOP *Bonamia ostreae* and *Bonamia exitiosa* detection by Real-time Polymerase Chain Reaction (PCR), https://www.eurl-mollusc.eu/SOPs

Helmer L., Hauton C., Bean T., Bass D., Hendy I., Harris-Scott E. & Preston J. (2020). Ephemeral detection of *Bonamia exitiosa* (*Haplosporida*) in adult and larval European flat oysters *Ostrea edulis* in the Solent, United Kingdom. *J. Invertebr. Pathol.,* **174**, 107421. doi: 10.1016/j.jip.2020.107421.

Hill K.M., Carnegie R.B., Aloui-Bejaoui N., El Gharsalli R., White D.M., Stokes N.A. & Burreson G.M. (2010). Observation of a *Bonamia* sp. infecting the oyster *Ostrea stentina* in Tunisia, and a consideration of its phylogenetic affinities. *J. Invertebr. Pathol.,* **103**, 179–185.

HINE P.M. (1991a). The annual pattern of infection by *Bonamia* sp. in New Zealand flat oysters, *Tiostrea chilensis. Aquaculture,* **93**, 241–251.

HINE P.M. (1991b). Ultrastructural observations on the annual infection pattern of *Bonamia* sp. in flat oysters *Tiostrea chilensis*. *Dis. Aquat. Organ.,* **11**, 163–171.

HINE P. M. (1996). The ecology of *Bonamia* and decline of bivalve molluscs. *NZ J. Ecol.,* **20**, 109–116.

HINE P.M. (2002). Severe apicomplexan infection in the oyster *Ostrea chilensis:* a predisposing factor in bonamiosis. *Dis. Aquat. Organ.,* **51**, 49–60.

HINE P.M., CARNEGIE R.B., KROECK M.A., VILLALBA A., ENGELSMA M.Y. & BURRESON E.M. (2014). Ultrastructural comparison of *Bonamia* spp. (Haplosporidia) infecting ostreid oysters. *Dis. Aquat. Organ.,* **110**, 55–63. https://doi.org/10.3354/dao02747

HINE P.M., COCHENNEC-LAUREAU N. & BERTHE F.C.J. (2001). *Bonamia exitiosus* n. sp. (Haplosporidia) infecting flat oysters *Ostrea chilensis* (Philippi) in New Zealand. *Dis. Aquat. Organ*., **47**, 63–72.

HINE P.M., DIGGLES B.K., PARSONS M.J.D., PRINGLE A. & BULL B. (2002). The effects of stressors on the dynamics of *Bonamia exitiosus* Hine, Cochennec-Laureau and Berthe, infections in flat oysters *Ostrea chilensis* (Philippi). *J. Fish Dis.,* **25**, 545–554.

HINE P.M. & JONES J.B. (1994). *Bonamia* and other aquatic parasites of importance to New Zealand. *NZ J. Zool.,* **21**, 49–56.

HINE P.M. & WESNEY B. (1994). Interaction of phagocytosed *Bonamia* sp. (Haplosporidia) with haemocytes of oysters *Tiostrea chilensis*. *Dis. Aquat. Organ.,* **20**, 219–229.

LANE H.S., WEBB S.C. & DUNCAN J. (2016). *Bonamia ostreae* in the New Zealand oyster *Ostrea chilensis:* a new host and geographic record for this haplosporidian parasite. *Dis. Aquat. Organ.,* **118**, 55–63. https://doi.org/10.3354/dao02960

LONGSHAW M., STONE D.M., WOOD G., GREEN M.J. & WHITE P. (2013). Detection of *Bonamia exitiosa* (Haplosporidia) in European flat oysters *Ostrea edulis* cultivated in mainland Britain. *Dis. Aquat. Organ.,* **106**, 173–179. doi: 10.3354/dao02643. PMID: 24113250.

MARTY G., BOWER S., CLARKE K., MEYER G., LOWE G., OSBORN A., CHOW E., HANNAH H., BYRNE S., SOJONKY K. & ROBINSON J. (2006). Histopathology and a real-time PCR assay for detection of *Bonamia ostreae* in *Ostrea edulis* cultured in western Canada. *Aquaculture*, **261**, 33–42.

MIALHE E., BOULO V., ELSTON R., HILL B., HINE M., MONTES J., VAN BANNING P. & GRIZEL H. (1988). Serological analysis *Bonamia* in *Ostrea edulis* and *Tiostrea lutaria* using polyclonal and monoclonal antibodies. *Aquat. Living Res.*, **1**, 67–69.

NARCISI V., ARZUL I., CARGINI D., MOSCA F., CALZETTA A., TRAVERSA D., ROBERT M., JOLY J.P., CHOLLET B., RENAULT T. & TISCAR P.G. (2010). Detection of *Bonamia ostreae* and *Bonamia exitiosa* (Haplosporidia) in *Ostrea edulis* from the Adriatic Sea (Italy). *Dis. Aquat. Org.*, **89**, 79–85.

RAMILO A., NAVAS J.I., VILLALBA A. & ABOLLO E. (2013). Species-specific diagnostic assays for *Bonamia ostreae* and *B. exitiosa* in European flat oyster *Ostrea edulis*: conventional, real-time and multiplex PCR. *Dis Aquat. Organ*., **104**, 149–161. doi: 10.3354/dao02597.

RAMILO A., VILLALBA A. & ABOLLO E. (2014). Species-specific oligonucleotide probe for detection of *Bonamia exitiosa* (Haplosporidia) using *in situ* hybridisation assay. *Dis. Aquat. Organ.,* **110**, 81–91.

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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).

Annex 25. Item 9.3.2. – Chapter 2.4.2. 'Infection with *Bonamia ostreae*

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*~~ several oysters species, 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 48 hours ~~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 *B. ostreae* 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	*Actinia 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~~ 2011), 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~~ 2011).

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 *Ostrea 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~~ 2011).

A lag time of at least 3 months is generally observed before detecting the parasite in disease free batches moved into infected areas (Montes, 1991).

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~~ 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.

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 *B. 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* sp~~ecies~~.

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* sp~~ecies~~.

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* spp. (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~~ 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) region (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* spp. and *Marteilia refringens* parasites.

~~Two~~ Three other real-time PCR protocols have been developed to specifically detect *B. ostreae*: ~~one~~ two SYBR-green PCR assays targeting the actin 1 gene (Robert *et al.,* 2009) and 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-CC 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
Method 6: Robert *et al.,* 2009; GenBank Accession No: AM410919, AM410920, AM410921			
SYBR Green PCR *B. Ostreae*/actin 1	Bo A1F: GCT-TCG-ACC-GAA-AGT-TCC-G Bo A2R: GGC-GAA-GAG-GTC-TTT-TCT-GA	2400 nM 1200 nM	40 Cycles of: 95°C/30 sec and 60°C/1 min, 72°C/30 sec Melt curve from 60°C to 95°C with 0.5°C increment/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* spp. (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]; GenBank Accession No.: AF262995			
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]; GenBank Accession No.: AF192759			
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]; GenBank Accession No.: KM073106			
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* I 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 *B. 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

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *B. 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~~

i) Positive result by real-time PCR and conventional PCR and sequencing

ii) Positive result by real-time PCR and *in-situ* hybridisation

iii) Positive result by tissue imprints, histology or *in-situ* hybridisation, and positive result by conventional PCR followed by sequence analysis

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 *B. 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 *B. ostreae* is considered to be confirmed if the following criterion is met:

i) Positive result by real-time PCR or and ~~by~~ conventional PCR and sequencing ~~or by species-specific *in-situ* hybridisation~~

ii) Positive result by real-time PCR and *in-situ* hybridisation

iii) Positive result by tissue imprints, histology or *in-situ* hybridisation, and positive result by conventional PCR followed by sequence analysis

1 For example transboundary commodities.

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* spp. 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 *B. ostreae* detection but also had the lowest agreement amongst laboratories (Flannery *et al.,* 2014).

6.3.1. For presumptive diagnosis of clinically affected animals (no data are currently available)

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).	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

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
		High prevalence populations						
	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* spp. (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* spp.	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* spp. (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* spp.	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

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
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)

7. References

Arzul I. & Carnegie R.B. (2015). New perspective on the haplosporidian parasites of molluscs. *J. Invertebr. Pathol.,* **131**, 32–42. doi: 10.1016/j.jip.2015.07.014.

Arzul I., Gagnaire B., Bond C., Chollet B., Morga B., Ferrand S., Robert M. & Renault T (2009). Effects of temperature and salinity on the survival of *Bonamia ostreae*, a parasite infecting flat oysters *Ostrea edulis. Dis. Aquat. Organ.,* **85**, 67–75.

Arzul I., Langlade A., Chollet B., Robert M., Ferrand S., Omnes E., Lerond S., Couraleau Y., Joly J.-P., François C. & Garcia C. (~~2010~~ 2011). Can the protozoan parasite *Bonamia ostreae* infect larvae of flat oysters *Ostrea edulis*? *Vet. Parasitol.,* **179**, 69–76. doi:10.1016/j.vetpar.2011.01.060.

Arzul I., Miossec L., Blanchet E., Garcia C., François C. & Joly J-P. (2006). *Bonamia ostreae* and *Ostrea edulis:* a stable host-parasite system in France? Symposia proceedings, ISVEE conference XI, Cairns, Australia, 6–11 August 2006, 5 p.

Balouet G., Poder M. & Cahour A. (1983). Haemocytic parasitosis: morphology and pathology of lesions in the French flat oyster, *Ostrea edulis* L. *Aquaculture*, **34**, 1-14.

Balseiro P., Conchas R. F., Montes J., Gómez-León J., Novoa B. & Figueras A. (2006). Comparison of diagnosis techniques for the protozoan parasite *Bonamia ostreae* in flat oyster *Ostrea edulis. Aquaculture*, **261**, 1135–1143.

Bougrier S., Tige G., Bachere E. e Grizel H. (1986). *Ostrea angasi* acclimatization to French coasts. *Aquaculture*, **58**, 151–154.

Bucke D. (1988). Pathology of bonamiasis. *Parasitol. Today*, **4**, 174–176.

Buss J.J., Wiltshire K.H., Prowse T.A.A., Harris J.O. & Deveney M.R. (2019). *Bonamia* in *Ostrea angasi:* diagnostic performance, field prevalence and intensity. *J. Fish Dis.,* **42**, 63–74. 10.1111/jfd.12906

Canier L., Dubreuil C., Noyer M., Serpin D., Chollet B., Garcia C. & Arzul I. (2020). A new multiplex real-time PCR assay to improve the diagnosis of shellfish regulated parasites of the genus *Marteilia* and *Bonamia. Prev. Vet. Med.,* **183**, 105126.

Carnegie R., Barber B.J., Culloty S.C., Figueras A.J. & Distel D.L. (2000). Development of a PCR assay for detection of the oyster pathogen *Bonamia ostreae* and support for its inclusion in the Haplosporidia. *Dis. Aquat. Organ*., **42**, 199–206.

Carnegie R.B., Barber B.J. & Distel D.L. (2003). Detection of the oyster parasite *Bonamia ostreae* by fluorescent *in situ* hybridization. *Dis. Aquat. Organ.,* **55**, 247–252.

Carnegie R.B. & Cochennec-Laureau N. (2004). Microcell parasites of oysters: Recent insights and future trends. *Aquat. Living Resour.*, **17**, 519–528.

CARNEGIE R.B., STOKES N.A., AUDEMARD C., BISHOP M.J., WILBUR A.E., ALPHIN T.D., POSEY M.H., PETERSON C.H. & BURRESON E.M. (2008). Strong seasonality of *Bonamia* sp. infection and induced *Crassostrea ariakensis* mortality in Bogue and Masonboro Sounds, North Carolina, USA. *J. Invertebr. Pathol.*, **98**, 335–343.

COCHENNEC N., LE ROUX F., BERTHE F. & GERARD A. (2000). Detection of *Bonamia ostreae* based on small subunit ribosomal probe. J*. Invertebr. Pathol*., **76**, 26–32.

COMPS M., TIGÉ G. & GRIZEL H. (1980). Etude ultrastructurale d'un protiste parasite de l'huître *Ostrea edulis* L. *L.C.R., Acad. Sc. Paris,* Sér. D, **290**, 383–385.

CONCHAS R.F., SANTAMARINA J., LAMA A., LONGA M.A. & MONTES J. (2003). Evolution of bonamiosis in Galicia (NW Spain). *Bull. Eur. Assoc. Fish Pathol*., **23**, 265–272.

CORBEIL S., ARZUL I., DIGGLES B., HEASMAN M., CHOLLET B., BERTHE F.C. & CRANE M.S. (2006). Development of a TaqMan PCR assay for the detection of *Bonamia* species. *Dis. Aquat. Organ*., **71**, 75–80.

CULLOTY S.C. & MULCAHY M.F. (1996). Season-, age-, and sex-related variation in the prevalence of bonamiosis in flat oysters (*Ostrea edulis* L.) on the south coast of Ireland. *Aquaculture*, **144**, 53–63.

ENGELSMA M.Y., CULLOTY S.C., LYNCH S.A., ARZUL I. & CARNEGIE R.B. (2014). *Bonamia* parasites: a rapidly changing perspective on a genus of important mollusc pathogens. *Dis. Aquat. Organ.,* **110**, 5–23.

ENGELSMA M.Y., KERKHOFF S., ROOZENBURG I., HAENEN O.L.M., VAN GOOL A., SISTERMANS W., WIJNHOVEN S. & HUMMEL H. (2010). Epidemiology of Bonamia ostreae infecting European flat oyster Ostrea edulis from Lake Grevelingen, The Netherlands. Marine Ecology Progress Series, 409, 131–142.

EURL FOR MOLLUSC DISEASES (2023). SOP *Bonamia ostreae* and *Bonamia exitiosa* detection by Real-time Polymerase Chain Reaction (PCR), https://www.eurl-mollusc.eu/SOPs

FERNÁNDEZ-BOO S., PROVOT C., LECADET C., STAVRAKAKIS C., PAPIN M., CHOLLET B., AUVRAY J.-F. & ARZUL I. (2021). Inactivation of marine bivalve parasites using UV-C irradiation: Examples of *Perkinsus olseni* and *Bonamia ostreae. Aquaculture Reports*, **21**, 100859 (10p.). https://doi.org/10.1016/j.aqrep.2021.100859

FLANNERY G., LYNCH S.A., LONGSHAW M., STONE D., MARTIN P., RAMILO, A., RAMILO A., VILLALBA A. & CULLOTY S.C. (2014). Interlaboratory variability in screening for *Bonamia ostreae,* a protistan parasite of the European flat oyster *Ostrea edulis. Dis. Aquat. Organ*., **110**, 93–99.

GRIZEL H. (1985). Etudes des récentes épizooties de l'huître plate *Ostrea edulis* L. et de leur impact sur l'ostréiculture bretonne. Thèse de doctorat, Université des Sciences et Techniques de Languedoc, Montpellier, France.

HERVIO D., BACHERE E., BOULO V., COCHENNEC N., VUILLEMIN V., LE COGUIC Y., CAILLETAUX G., MAZURIE J. & MIALHE E. (1995). Establishment of an experimental infection protocol for the flat oyster *Ostrea edulis* with the intrahaemocytic protozoan parasite *Bonamia ostreae:* application in the selection of parasite-resistant oyster. *Aquaculture*, **132**, 183–194.

HILL K.M., STOKES N.A., WEBB S.C., HINE P.M., KROECK M.A., MOORE J.D., MORLEY M.S., REECE K.S., BURRESON E.M. & CARNEGIE R.B. (2014). Phylogenetics of *Bonamia* parasites based on small subunit and internal transcribed spacer region ribosomal DNA sequence data. *Dis. Aquat. Organ.,* **110**, 33–54.

HINE P.M., CARNEGIE R.B., KROECK M.A., VILLALBA A., ENGELSMA M.Y. & BURRESON E.M. (2014). Ultrastructural comparison of *Bonamia* spp. (Haplosporidia) infecting ostreid oysters. *Dis. Aquat. Organ.,* **110**, 55–63. https://doi.org/10.3354/dao02747

HINE P.M., COCHENNEC-LAUREAU N. & BERTHE F.C.J. (2001). *Bonamia exitiosus* n. sp. (Haplosporidia) infecting flat oysters *Ostrea chilensis* (Philippi) in New Zealand. *Dis. Aquat. Organ*., **47**, 63–72.

KAMERMANS P., BLANCO A., VAN DALEN P., ENGELSMA M., BAKKER N., JACOBS P., DUBBELDAM M., SAMBADE I.M., VERA M. & MARTINEZ P. (2023). *Bonamia*-free flat oyster (*Ostrea edulis* L.) seed for restoration projects: non-destructive screening of broodstock, hatchery production and test for *Bonamia*-tolerance. *Aquat. Living Resour*., **36**, 11.

LANE H.S., JONES J.B. & MCDONALD W.L. (2017). Pooled sample testing for *Bonamia ostreae:* A tale of two SYBR Green real-time PCR assays. J. Vet. Diagn. Invest., 29, 752–756. doi: 10.1177/1040638717717558.

LANE H.S., WEBB S.C. & DUNCAN J. (2016). *Bonamia ostreae* in the New Zealand oyster *Ostrea chilensis:* a new host and geographic record for this haplosporidian parasite. *Dis. Aquat. Organ.,* **118**, 55–63. https://doi.org/10.3354/dao02960

LYNCH S.A., ARMITAGE D.V., COUGHLAN J., MULCAHY M.F. & CULLOTY S.C. (2006). Investigating the possible role of benthic macroinvertebrates and zooplakton in the life cycle of the haplosporidian *Bonamia ostreae*. *Exp. Parasitol.,* **115**, 359–368.

LYNCH S.A., FLANNERY G., HUGH-JONES T., HUGH-JONES D. & CULLOTY S.C. (2014) Thirty-year history of Irish (Rossmore) *Ostrea edulis* selectively bred for disease resistance to *Bonamia ostreae. Dis. Aquat. Organ*., **110**, 113–121. doi: 10.3354/dao02734.

LYNCH S.A., MULCAHY M.F. & CULLOTY S.C. (2008). Efficiency of diagnostic techniques for the parasite, B*onamia ostreae*, in the flat oyster, *Ostrea edulis. Aquaculture*, **281**, 17–21.

MARTY G., BOWER S., CLARKE K., MEYER G., LOWE G., OSBORN A., CHOW E., HANNAH H., BYRNE S., SOJONKY K. & ROBINSON J. (2006). Histopathology and a real-time PCR assay for detection of *Bonamia ostreae* in *Ostrea edulis* cultured in western Canada. *Aquaculture*, **261**, 33–42.

MÉROU N., LECADET C., POUVREAU S. & ARZUL I. (2020). An eDNA/eRNA-based approach to investigate the life cycle of non-cultivable shellfish micro-parasites: the case of *Bonamia ostreae*, a parasite of the European flat oyster *Ostrea edulis. Microb. Biotechnol.,* **13**, 1807–1818. doi: 10.1111/1751-7915.13617.

MEROU N., LECADET C., UBERTINI M., POUVREAU S. & ARZUL I. (2023). Environmental distribution and seasonal dynamics of *Marteilia refringens* and *Bonamia ostreae*, two protozoan parasites of the European flat oyster, *Ostrea edulis*. *Front. Cell. Infect. Microbiol.*, **13**, 1154484. doi: 10.3389/fcimb.2023.1154484.

MIALHE E., BOULO V., ELSTON R., HILL B., HINE M., MONTES J., VAN BANNING P. & GRIZEL H. (1988). Serological analysis *Bonamia* in *Ostrea edulis* and *Tiostrea lutaria* using polyclonal and monoclonal antibodies. *Aquat. Living Resour.*, **1**, 67–69.

MONTES J. (1991). Lag time for the infestation of flat oyster (*Ostrea edulis* L.) by *Bonamia ostreae* in estuaries of Galicia (N.W. Spain). *Aquaculture*, **93**, 235–239. doi.org/10.1016/0044-8486(91)90235-Y

MONTES J., ANADON R. & AZEVEDO C. (1994). A possible life cycle for *Bonamia ostreae* on the basis of electron microscopy studies. *J. Invertebr. Pathol.,* **63**, 1–6.

NACIRI-GRAVEN Y., MARTIN A.G., BAUD J.P., RENAULT T. & GERARD A. (1998). Selecting the flat oyster *Ostrea edulis* (L.) for survival when infected with the parasite *Bonamia ostreae. J. Exp. Mar. Biol. Ecol.*, **224**, 91–107.

PICHOT Y., COMPS M., TIGE G., GRIZEL H. & RABOUIN M.A. (1979). Recherches sur *Bonamia ostreae* gen. n., sp. n., parasite nouveau de l'huitre plate *Ostrea edulis L. Rev. Trav. Inst. Pêches Marit.,* **43**, 131–140.

POUILLOT R., GERBIER G. & GARDNER I.A. (2002). "TAGS", a program for the evaluation of test accuracy in the absence of a gold standard. *Prev. Vet. Med.*, **53**, 67–81.

RAMILO A., NAVAS J.I., VILLALBA A. & ABOLLO E. (2013). Species-specific diagnostic assays for *Bonamia ostreae* and *B. exitiosa* in European flat oyster *Ostrea edulis*: conventional, real-time and multiplex PCR. *Dis. Aquat. Organ*., **104**, 149–161. doi: 10.3354/dao02597.

ROBERT M., GARCIA C., CHOLLET B., LOPEZ-FLORES I., FERRAND S., FRANÇOIS C., JOLY J.P. & ARZUL I. (2009). Molecular detection and quantification of the protozoan *Bonamia ostreae* in the flat oyster, *Ostrea edulis*. *Mol. Cell. Probes*, **23**, 264–271. doi: 10.1016/j.mcp.2009.06.002.

VAN BANNING P. (1990). The life cycle of the oyster pathogen *Bonamia ostreae* with a presumptive phase in the ovarian tissue of the European flat oyster, *Ostrea edulis*. *Aquaculture*, **84**, 189–192.

VON GERSDORFF JØRGENSEN L., NIELSEN J.W., VILLADSEN M.K., VISMANN B., DALVIN S., MATHIESSEN H., MADSEN L., KANIA P.W. & BUCHMANN K. (2020). A non-lethal method for detection of *Bonamia ostreae* in flat oyster (*Ostrea edulis*) using environmental DNA. *Sci. Rep.,* **10**, 16143. https://doi.org/10.1038/s41598-020-72715-y

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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 26. Item 9.3.3. – 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
	Haliotis iris	black paua
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 27. Item 9.3.4. – 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).~~

[…]

Annex 28. Item 10.1.2. Chapter 2.4.6. 'Infection with *Perkinsus olseni*'

CHAPTER 2.4.6.

INFECTION WITH *PERKINSUS OLSENI*

1. Scope

Infection with *Perkinsus olseni* is considered to be infection with *Perkinsus. olseni* (Family: *Perkinsidae)*

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

The aetiological agent is the protozoan parasite *Perkinsus olseni*.

Current evidence using genomic sequencing data have placed *Perkinsus olseni* in the class Perkinsea of the phylum Perkinsozoa, and Kingdom Alveolata. *Perkinsus olseni* was formerly known as *Perkinsus atlanticus* in Europe (Azevedo 1989).

As trophozoites grow, cleavage furrows begin to form on the cell surface, signaling the early stages of their subdivision, or the onset of schizogony (Gajamange *et al.,* 2020). As cleavage advances, the number of daughter cells increases, progressing to the morula stage, where approximately 100 irregularly shaped merozoites are observed. Once schizonts are fully developed, they release hundreds of merozoites upon the rupture or abrasion of the schizont cellular membrane.

A study investigating genome-wide comparison of five *P. olseni* isolates from Australia (00978-12), New Zealand (PRA 205 and 207), Japan (PRA-179), and Spain (PRA-31) observed differences between different geographical locations. Indeed, *P. olseni* from Oceania (Australia and New Zealand) displayed a high heterozygosity of 5.47–7.71% compared with Eurasia (Spain and Japan) with 0.1 to 0.2% of heterozygosity (Bogema *et al.,* 2021). The gene numbers differed substantially, with the Oceanian isolates sharing a high proportion of unique orthogroups in comparison to the Eurasian isolates (Bogema *et al.,* 2021). The Oceanian isolates had a slightly higher proportion of repetitive content such as tandem gene duplication. The characterised gene contents appear to be highly conserved across *Perkinsus* species such as in *P. olseni*, *P. marinus*, and *P. chesapeaki* (Bogema *et al.,* 2021).

The ribosomal RNA transcription unit is highly duplicated with variations between the isolates from different parts of the world, which does not make it a suitable region for designing real-time PCR tests to assess the intensity of infection (Bogema *et al.,* 2021).

More studies are needed to confirm the ploidy of *P. olseni*. Indeed, some authors using genome-wide data suggested that *Perkinsus* is polyploid with a ploidy variation between individual cells and populations (Bogema *et al.,* 2021) whereas other using microsatellite loci or restriction fragment length polymorphism proposed a diploidy (Pardo *et al.,* 2011; Reece *et al.,* 1997; 2001; Robledo *et al.,* 1999; Thompson *et al.,* 2011).

2.1.2. Survival and stability in processed or stored samples

Perkinsus olseni can be propagated *in vitro* in various media formulations such as Dulbecco's Modified Eagle medium and Ham's F-12 nutrient mixture (Burreson *et al.,* 2005; Dungan & Reece, 2006) or JL-ODR-2A (La Peyre *et al.,* 2006). Both media are supplemented with various salts, FBS, lipid mixtures, and yeast ultrafiltrates. Isolates can be cryopreserved and stored indefinitely (Dungan et al., 2007).

2.1.3. Survival and stability outside the host

Long-term survival of *P. olseni* outside its bivalve host is not known. but it is at least 4 months for prezoosporangia (Casas *et al.,* 2002b).

2.2. Host factors

NB: Sections 2.2.1 and 2.2.2 are not for Member comment. Version for comment and adoption are presented in Annex 26

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
	Anadara trapezia	ark cockle
Cardiidae	*Tridacna crocea*	crocus giant clam
Haliotidae	*Haliotis laevigata*	greenlip abalone
	Haliotis rubra	blacklip abalone
Margaritidae	*Pinctada fucata*	Japanese pearl oyster
Mytilidae	*Mytilus galloprovincialis*	Mediterranean mussel
	Perna canaliculus	New Zealand mussel
Veneridae	*Austrovenus stutchburyi*	Stutchbury's venus clam
	Leukoma jedoensis	Jedo venus clam
	Paratapes undulatus [syn. Paphia undulata]	undulate venus clam
	Protapes gallus	rooster venus clam
	Protocipitar patagonicus	no common name
	Ruditapes decussatus	grooved carpet shell
	Ruditapes philippinarum	Manila clam

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 *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
Arcidae	*Tegillarca granosa*	blood cockle
	Scapharca subcrenata	
Cardiidae	*Cerastoderma glaucum*	olive green cockle
Chamidae	*Chama pacifica*	reflexed jewel box
Haliotidae	*Haliotis iris*	New Zealand black-footed abalone

Family	Scientific name	Common name
	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
	Chlamys nobilis	noble scallop
Pharidae	*Sinonovacula constricta*	constricted tagelus clam
Solenidae		
Veneridae	*Meretrix lyrata*	lyrate hard clam
	Polititapes aureus	golden carpet shell
	Venus verrucosa	warty venus clam

2.2.3. Likelihood of infection by species, host life stage, population or sub-populations

Perkinsus olseni is known to infect and cause clinical signs in many bivalve species. All stages after settlement are susceptible. *P. olseni* infection intensity increases with host age (Villalba *et al.,* 2005).

2.2.4. Distribution of the pathogen in the host

Perkinsus olseni trophozoites and schizonts can be found in various tissues and organs, including connective tissues, siphons, mantle, gills, digestive system, foot, adductor muscle, and haemolymph (Carella *et al.,* 2023; Park & Choi, 2001; Leethochavalit *et al.,* 2004). In some clams, the infection was heaviest in the digestive gland and gills (Leethochavalit *et al.,* 2004; Park & Choi, 2001). However, infection in the gills of bivalves is representative of the infection throughout the entire body and is therefore considered the organ of choice for diagnosing *P. olseni* infection (Choi *et al.,* 2002; Cui *et al.,* 2018; Dang *et al.,* 2013; Park *et al.,* 1999). *Perkinsus olseni* has also been detected in faeces of infected animals (Park *et al.,* 2010).

2.2.5. Aquatic animal reservoirs of infection

None known.

2.2.6. Vectors

None known.

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Infections in clam hosts can be lethal depending on environmental conditions, and death may occur 1 or 2 years after infection. Studies have suggested that the impact on the host depends on the intensity of infection but also on host species and locations; it can start being deleterious and lethal at densities of 10^6 parasite cells/g wet tissue (Dang *et al.,* 2013; Waki *et al.,* 2018).

Prevalence is highly variable depending on host and environmental conditions, up to 100% in susceptible host species as determined by histology or polymerase chain reaction (PCR). Prevalence and intensity of infection may be higher in individuals with more than 1 year of exposure to the pathogen because they have been exposed to *P. olseni* for longer, and larger animal have a higher filtration rate (Choi *et al.,* 2002; Villalba *et al.,* 2005). Prevalence can vary according to the season and is often higher in spring (Cui *et al.,* 2018; Villalba *et al.,* 2005).

2.3.2. Clinical signs, including behavioural changes

Perkinsus olseni infection can lead to reduced growth, reproduction issues, and mass mortalities in shellfish populations (Cho & Park, 2010). Clinical signs include mantle retraction, byssal tissue sloughing, gaping or dead molluscs but these clinical signs are not specific to infection with *P. olseni.* Individual bivalves with late-stage infections may exhibit slow responses to stimuli (Sheppard & Phillips, 2008).

2.3.3 Gross pathology

Gross signs are thin, watery tissue, pale digestive gland and nodules in several tissues such as mantle, gills, and foot of some hosts, but these signs are not specific to infection with *P. olseni*.

At high infection intensities the infected molluscs can present several milky-white cysts, abscesses or brown nodules (Azevedo, 1989; Gudkovs *et al.,* 2016; Ruano *et al.,* 2015). The cysts or nodules contain individual and grouped encapsulated trophozoites at different stages of maturation, and result from a natural defensive reaction, the infiltration of hemocytes (Abdel-Baki *et al.,* 2014).

2.3.4. Modes of transmission and life cycle

The life cycle is horizontal, direct from host to host (Villalba *et al.,* 2004). Faecal discharge and decomposition of infected tissues after the host death have been suggested as two transmission pathways for *P. olseni* (Cui *et al.,* 2018; Park *et al.,* 2010).

The life cycle consists of three main life stages: trophozoite, prezoosporangium, and zoospore (Villalba *et al.,* 2004). The trophozoite is a stage occurring in the tissues of the live host where vegetative proliferation occurs. The trophozoite undergoes successive bipartitioning to yield up to 32 daughter cells that stay together in a rosette-like arrangement inside a wall. After rupture of the wall, immature trophozoites enlarge and form a vacuole, becoming mature trophozoites. At the host death, trophozoites evolve into a prezoosporangia, which evolve into zoosporangia when they are released in the environment. Zoosporangia produces zoospores, which are the infective stage.

2.3.5. Environmental factors

Environmental factors such as temperature, salinity, oxygen levels, pH, and nutrient availability influence *Perkinsus* infection dynamics and hypnospore formation (2013; Villalba *et al.,* 2004).

Temperature and salinity appear to be the most important environmental factors controlling the transmission of *P. olseni* infection with zoosporulation occurring between 19 and 28°C and increasing with higher temperature and salinity (Kyoung & Ki, 2001; Umeda *et al.,* 2020).

Temperature and salinity also appear to be the two major environmental factors influencing the prevalence and seasonality of *P. olseni* infection, with several studies reporting higher prevalence and intensity of infection in spring (Park & Choi 2001; Soudant *et al.,* 2013; Villalba *et al.,* 2005; Waki & Yoshinaga, 2013; 2015).

2.3.6. Geographical distribution

Infections are widespread throughout the tropical Pacific Ocean, Oceania, Asia, Europe and South America (Cremonte *et al.,* 2005; Goggin & Lester, 1995; Villalba *et al.,* 2004). *Perkinsus olseni* is not known from North America.

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

Cyclohexamide, pyrimethamine, deferoxamine (DFO) and 2, 2-bipyridyl inhibit *P. olseni* development/replication *in vitro*, and DFO inhibits *P. olseni* development/infection *in vivo*. (Elandalloussi *et al.,* 2005).

2.4.3. Immunostimulation

None.

2.4.4. Breeding resistant strains

None.

2.4.5. Inactivation methods

Isolated *P. olseni* cells were killed when immersed in freshwater within 10 minutes at room temperature. Another study showed that free zoospores, free prezoosporangia and prezoosporangia in gill tissues were killed after 1 hour incubation with 50, 200, and 3000 ppm of chlorine, respectively (Casas *et al.,* 2002b). *Perkinsus olseni* cells in host tissue were much more resistant to these treatments. UV-C irradiation has been shown to be effective in inactivating *Perkinsus* parasites, with a minimum dose of 94 mJ/cm^2 required to inhibit proliferation and 450 mJ/cm^2 to completely kill all parasites (Fernandez-Boo *et al.,* 2021).

2.4.6. Disinfection of eggs and larvae

Perkinsus olseni is not known to infect eggs or larvae of its hosts, but parasite cells may occur intercellularly.

2.4.7. General husbandry

Management strategies to mitigate perkinsosis impacts include modifying culture procedures such as reducing stocking density, selective breeding for resistant strains, and using triploid or allochthonous oyster species (Villalba *et al.,* 2004).

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, clams that are at the surface instead of being buried, or freshly dead animals should be targeted to increase the chances of finding infected animals. Abalone with foot blisters should be sampled. For histology, only live animals should be taken.

3.2. Selection of organs or tissues

Connective tissue of all organs, and haemocytes.

For RFTM, the whole animal should be ideally sampled if its size allows. If not, pieces of gill followed by mantle or foot for abalone are typically used.

For culture purposes, tissue slices that can include gill, mantle, or foot (for abalone) can be cultured.

For histology, a 5 mm thick section through the visceral mass that includes digestive gland, gill and mantle is used.

For PCR, gill or mantle tissue is recommended.

3.3. Samples or tissues not suitable for pathogen detection

Rectal tissue is not reliable for PCR assays because of the presence of inhibitors.

3.4. Non-lethal sampling

For *P. marinus*, Gauthier & Vasta (1995) proposed haemolymph incubation in Ray's Fluid Thioglycollate Medium (RFTM) as an alternative to the traditional tissue RFTM, enabling non-lethal sampling of individuals. This method was further refined by Nickens *et al.* (2002). Rodriguez & Navas (1995) reviewed and compared various RFTM assays for *Perkinsus olseni*, highlighting that whole host body incubation in RFTM is the most sensitive method.

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

The results of bioassay depend strongly on the quality of samples (time since collection, time in storage, preservative used). Fresh specimens should be kept on ice and preferably sent to the laboratory within 24 hours of collection. To avoid degradation of samples, use alternative storage methods only after consultation with the receiving laboratory.

3.5.2. Preservation of samples for molecular detection

Tissue samples for PCR testing should be preserved in 80% (v/v) analytical-grade ethanol. The recommended ratio of ethanol to tissue is 10:1 based on studies in terrestrial animal and human health. The use of lower grade (laboratory or industrial grade) ethanol is not recommended. If material cannot be fixed it may be frozen.

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. If the effect of pooling on diagnostic sensitivity has not been thoroughly evaluated, 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. Pooling of very small spat (5–10 depending on size) is acceptable for PCR analyses.

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
Wet mounts												
Histopathology		++	++	2		+++	+++	NA				
Cell culture												
Transmission electron microscopy												
Real-time PCR	+++	+++	+++	3	+++	+++	+++	NA	+++	+++	+++	3
Conventional PCR	+++	+++	+++	3	+++	+++	+++	NA				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	3
In-situ hybridisation										+++	+++	3
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
RFTM		+++	+++	3		+++	+++	3				

LV = level of validation, refers to the stage of validation in the WOAH Pathway (chapter 1.1.2); PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; Ab- or Ag-ELISA = antibody or antigen enzyme-linked immunosorbent assay, respectively; IFAT = indirect fluorescent antibody test. [give definitions of abbreviations as appropriate; nPCR = nested PCR, etc. NB "RT-PCR" is reserved for reverse-transcription polymerase chain reaction methods. "real-time PCR" should always be stated in full and refers to probe-based and SYBR green assays]

[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. Smears

Not recommended as a diagnostic method.

4.2. Histopathology

Samples to be taken consist of live or moribund bivalves.

*S*ections of tissues that include gills, digestive gland and mantle should be fixed for a minimum of 24 hours 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 ×400.

Fixed sections reveal large multifocal lesions in connective tissue containing *P. olseni* cells. Haemocyte infiltration (haemocytosis) occurs in most infections. In clam hosts, *P. olseni* cells are often encapsulated by a thick layer of eosinophilic material derived from haemocyte degranulation (Villalba *et al.,* 2004).

The occurrence of spherical, uninucleate cells ranging from approximately 5 to 15 µm in diameter with a large vacuole and an eccentrically displaced nucleus with a prominent nucleolus, may indicate infection with *Perkinsus olseni*. Multinucleate schizonts (dividing forms) often accompany the uninucleate trophozoites. Cells may be phagocytosed by host haemocytes Cells may be phagocytosed by host haemocytes. *Perkinsus olseni* cells stain lightly basophilic.

4.3. Electron microscopy

Ultrastructural data show that the lysis of haemocytes and coalescence of metachromatic granules result in the nodule that encapsulates trophozoites (Sagrista *et al.,* 1995).

4.4. Nucleic acid amplification

Samples to be taken consist of live or freshly dead molluscs. 2–3 mm^2 tissue pieces are excised aseptically from gill and mantle and placed into 1.5 ml microcentrifuge tubes containing 80% ethanol. Dissecting utensils should be flamed between samples to prevent cross-contamination.

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). Each sample should be tested in duplicate.

Extraction of nucleic acids

DNA is extracted by proteinase K digestion overnight at 56°C and the spin-column methodology using commercially available kits. 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

A real-time *Perkinsus* genus PCR assay targeting the ITS region has been developed for use with host tissue (Gauthier *et al.,* 2006). It has been tested only with *P. marinus*, *P. olseni* and *P. chesapeaki*, and was shown to be more sensitive in a limited validation against the RFTM assay. This assay needs to be tested more thoroughly for specificity, but may be useful for laboratories that possess the necessary equipment.

Several real-time PCR assays all targeting the ITS region have been developed to detect and quantify *P. olseni* (Cui *et al.,* 2018; Gajamange *et al.,* 2011; Itoïz *et al.,* 2021; Ríos *et al.,* 2020; Umeda & Yoshinaga, 2012). One needs to be careful when attempting to quantify *P. olseni* as genome sequencing revealed that this region is highly duplicated, which does not make it the ideal region for quantifying parasite infection. Of all those assays, only the assay developed by Ríos *et al.* (2020) presented some level of validation such as sensitivity and reproducibility. More validation is required before a real-time PCR assay can be recommended (see chapter 1.1.2 *Principles and methods of validation of diagnostic assays for infectious diseases*). In addition, Ríos *et al.* (2020) detected non-specific hybridisation when using the Umeda & Yoshinaga (2012) and Gajamange *et al.* (2011) assays.

***Primers and probes* (*sequences*)**

Pathogen/ target gene	Primer/probe (5'–3')	Concentration	Cycling parameters[a]
Method 1: TaqMan PCR Gauthier *et al.* (2006); GenBank Accession No.: AF149876.1			
Perkinsus sp./ITS (detects at least *P. marinus, P. olseni* and *P. chesapeaki*).	PERK-F: CGT-GAA-CCA-GTA-GAA-ATC-TCA-A PERK-R: ACA-TAT-CAG-TGT-CGC-TCT-TCT-TCC Probe: GCA-TAC-TGC-ACA-AAG-GG	0.9 µM 0.9 µM 0.25 µM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 2: TaqMan PCR Itoiz *et al.* (2021); GenBank Accession No.: MW187111			
P. olseni	PolsITS2-F: CAC-CAC-AAC-ACA-GTC-GGA-C PolsITS2-R: CGT-ATT-GTA-GCC-CCT-CCG-A PolsITS2-probe: GAC-ACT-CAC-AGG-CGC-GGT-CC	0.2 µM 0.2 µM 0.5 µM	45 cycles of: 95°C/10 sec and 55°C/20 sec
Method 3: SYBR Green PCR Rios *et al.* (2020); GenBank Accession No.: ???			
P. olseni	Perk-ITS-qF1: CTG-ACC-GCC-TTA-ACG-GGC Perk-ITS-qR2: CTA-TCT-CCG-AAG-AGT-TAG-TCC-	10 µM 10 µM	40 cycles of: 95°C/30 sec and 60°C/60 sec
Method 4: Cui *et al.* (2018); GenBank Accession No.: ???; amplicon size [217 bp]			
P. olseni / ITS	PO-F: GAG-TGT-CTC-TGG-TTG-CTC-GCA PO-R: ACA-TCA-GGC-CTT-CTA-ATG-ATG	10 µM 10 µM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 6: Umeda &Yoshinaga, (2012); GenBank Accession No.: ???			
P. olseni	OF: CTT-AAC-GGG-CCG-TGT-TA OR: CAT-AAC-GAA-CTA-TCT-CCG-AAG	0.5 µM 0.5 µM	40 cycles of: 98°C/2 sec and 60°C/5 sec
Method 5: Gajamange *et al.* (2011); GenBank Accession No.: ???			
P. olseni	PK-ITS-F: CAG-AAT-TCC-GTG-AAC-CAG-TAG-A PK-ITS-R: TGT-CGC-TCT-TCT-TCC-CGA-TA Probe: TCA-ACG-CAT-ACT-GCA-CAA-AGG-GGA	10 pM 10 pM 10 pM	40 cycles of: 95°C/10 sec and 56°C/30 sec

[a]A denaturation step prior to cycling has not been included.

4.4.2. Conventional PCR

Pathogen/ target gene	Primer/probe (5'–3')	Concentration	Cycling parameters[a]
Method 1: Moss *et al.,* 2006; GenBank Accession No.: ???; amplicon size: [bp] ???			
P. olseni	PolsITS-140F: GAC-CGC-CTT-AAC-GGG-CCG-TGT-T PolsITS-600R: GGR-CTT-GCG-AGC-ATC-CAA-AG 450 bp	0.1 µM 0.1 µM	40 cycles of: 94°C/60 sec and 62°C/60 sec and 65°C/180 sec
Method 2: Casas *et al.,* 2002a; GenBank Accession No.: ???; amplicon size: [bp] ???			
Perkinsus spp. (except *P. qugwadi*)	PerkITS-85: CCG-CTT-TGT-TTG-GAT-CCC PerkITS-750: ACA-TCA-GGC-CTT-CTA-ATG-ATG 675bp product	0.1 µM 0.1 µM	40 cycles of: 95°C/1 min and 55°C/1 min and 72°C/1 min

[a]A denaturation step prior to cycling has not been included.

4.4.3. Other nucleic acid amplification methods

A PCR-restriction fragment length polymorphism (RFLP) assay has been developed that may be useful for specific diagnoses of *P. olseni* (Abollo *et al.,* 2006), although it has not been tested for specificity against all known *Perkinsus* species.

A LAMP assay was developed by (Feng *et al.,* 2013) targeting ITS-2 and appeared to be rapid, sensitive (detection limit of 10 copies of plasmid DNA), and specific for *Perkinsus* spp. detection.

4.5. Amplicon sequencing

The size of the PCR amplicon should be verified, for example by agarose gel electrophoresis. Both DNA strands of the PCR product must be sequenced and analysed in comparison with reference sequences.

4.6. *In-situ* hybridisation

***Perkinsus* genus assays (PCR and *in-situ* hybridisation)**

For *in-situ* hybridisation (ISH), probes have been developed that target the small subunit (SSU) of the rRNA gene complex (Elston *et al.,* 2004).

***Perkinsus* genus-specific *in-situ* hybridisation**

Samples to be taken: follow the procedure for 'fixed sections' above, except that tissue sections must be placed on positively charged glass slides or slides coated with 3-aminopropyl-triethoxylane, without staining. Deparaffinise sections in xylene for 10 minutes and then rehydrate in an alcohol series. Wash sections twice for 5 minutes in phosphate-buffered saline (PBS).

A specific DNA probe that targets the small subunit rRNA gene has been developed for the genus *Perkinsus* (Elston *et al.,* 2004): Perksp700DIG (5'-CGC-ACA-GTT-AAG-TRC-GTG-RGC-ACG-3'). The probe should be 5' end-labelled with digoxigenin.

The tissue sections are treated with 125 µg ml–1 pronase in PBS, at 37°C for 30 minutes. The reaction is then stopped by washing the sections in PBS with 0.2% glycine for 5 minutes. The sections are then placed in 2× SSC (standard saline citrate; 20× SSC = 3 M NaCl; 0.3 M Na-citrate; pH 7.0) for 10 minutes.

The sections are prehybridised for 1 hour at 42°C in prehybridisation solution (4× SSC, 50% formamide, 5× Denhardt's solution, 0.5 mg ml–1 yeast tRNA, and 0.5 mg ml–1 heat-denatured salmon sperm DNA) in a humid chamber.

The prehybridisation solution is then replaced with prehybridisation buffer containing 7 ng µl–1 of the digoxigenin-labelled *Perkinsus* genus probe. The sections are covered with in-situ hybridisation plastic cover-slips and placed on a heating block at 90°C for 12 minutes. The slides are then cooled on ice for 1 minute before hybridisation overnight at 42°C in a humid chamber.

The sections are washed twice for 5 minutes each in 2× SSC at room temperature, twice for 5 minutes each in 1× SSC at room temperature, and twice for 10 minutes each in 0.5× SSC at 42°C. The sections are then placed in Buffer 1 (100 mM Tris, pH 7.5, 150 mM NaCl) for 1–2 minutes.

The sections are placed in Buffer 1 (see above) supplemented with 0.3% Triton X-100 and 2% sheep serum for 30 minutes. Anti-digoxigenin alkaline phosphatase antibody conjugate is diluted 1/500 (or according to the manufacturer's recommendations) in Buffer 1 supplemented with 0.3% Triton X-100 and 1% sheep serum and applied to the tissue sections. The sections are covered with in-situ hybridisation cover-slips and incubated for 3 hours at room temperature in a humid chamber.

The slides are washed twice in Buffer 1 for 5 minutes each and twice in Buffer 2 (100 mM Tris, pH 9.5, 100 mM NaCl, 50 mM $MgCl_2$) for 5 minutes each. The slides are then placed in colour development solution (337.5 µg ml–1 nitroblue tetrazolium, 175 µg ml–1 5-bromo-4-chloro-3-indolylphosphate p-toluidine salt, 240 µg ml^{-1} levamisole in Buffer 2) for 2 hours in the dark. The colour reaction is stopped by washing in TE buffer (10 mM Tris, pH 8.0, 1 mM EDTA [ethylene diamine tetra-acetic acid]).

The slides are then rinsed in sterile distilled water (dH_2O). The sections are counterstained with Bismarck Brown Y, rinsed in dH_2O, and cover-slips are applied using an aqueous mounting medium.

Positive/negative controls: these are compulsory. Positive controls are tissue sections from any Perkinsus sp.-infected mollusc. Negative controls are either no-probe assays or assays with uninfected oysters.

***Perkinsus olseni*-specific *in-situ* hybridisation**

The probe should be end-labelled with digoxygenin. The ISH procedures are the same as for the *Perkinsus* genus probe presented above.

Positive/negative controls: these are compulsory. Positive controls are tissue sections from any susceptible host infected with *P. olseni*. Negative controls are either no-probe assays or assays with uninfected oysters.

*A*DNA probe that targets the LSU of the rRNA gene of *P. olseni* has been developed (Moss *et al.,* 2006) (PolsLSU-464DIG 5'-CTC-ACA-AGT-GCC-AAA-CAA-CTG-3').

Muznebin *et al.,* (2023) also used ISH using the DIG PCR probe synthesis kit (Roche). A DIG-labelled probe was generated using the PCR primers Pols140F (5'-GAC-CGC-CTT-AAC-GGG-CCG-TGT-T-3') and PolsITS-600R (5'-GGR-CTT-GCG-AGC-ATC-CAA-AG-3') (Moss *et al.,* 2006). The DIG-labelled probe was used at a concentration of 5 ng/µl.

4.7. Immunohistochemistry

Not available.

4.8. Bioassay

Not available.

4.9. Antibody- or antigen-based detection methods (ELISA, etc.)

Not currently available for diagnostic purposes but monoclonal antibodies have been developed (Hanrio et al., 2021; 2022; Park et al., 2010;).

4.10. Other methods

4.10.1. Ray's fluid thioglycollate culture method (RFTM)

Incubation in thioglycollate is routinely used for surveillance of *P. olseni.* The technique is simple, inexpensive and very sensitive, but not species-specific. Trophozoites of *P. olseni* in host tissue will enlarge when cultured for at least 5 days in fluid thioglycollate medium containing dextrose that is supplemented with antibiotics (penicillin, streptomycin) and an antifungal compound (nystatin) to reduce bacterial and fungal growth. When the tissue is macerated after culture to allow penetration of aqueous iodine solution (Lugol's), the enlarged trophozoites (hypnospores or prezoosporangia in the old terminology) readily take up Lugol's and they easily become visible at low power because of their generally bluish–black coloration and their spherical shape.

Samples to be taken consist of live or freshly dead molluscs.

Tissue assay (Ray, 1966): tissue samples measuring approximately 5–10 mm are excised giving preference to rectal, gill and mantle tissue from oysters and clams, and adductor or foot muscles or mantle for abalone, and placed in test tubes containing thioglycollate medium (thioglycollate medium containing dextrose 14.6 g; NaCl, 10.0 g; sterile distilled water (dH_2O), 485 ml). A total of 9.5 ml is dispensed into disposable test tubes, which are autoclaved for 15 minutes at 1.2 kg cm^{-2} pressure. The autoclaved solution can be stored in tubes for up to 3 weeks. Dissecting utensils should be rinsed in 95% ethanol and flamed between hosts to prevent carry-over. The recommended antifungal/antibiotics are: 500 units ml^{-1} penicillin G and 500 units ml^{-1} dihydro-streptomycin in media (penicillin, 3.13 g; streptomycin, 6.55 g; 500 ml dH_2O; freeze in 50 ml aliquots; add 0.5 ml to each tube), and 50 µl of mycostatin (nystatin) per tube. Chloromycetin can be used in place of penicillin/streptomycin. The tube is plugged with a foam rubber or cotton stopper. Incubation is at 22–25°C for between 5 and 7 days, in the dark. After incubation, the fragments of tissue are collected and chopped with a scalpel blade on a glass slide, a drop of Lugol's iodine solution is added (stock Lugol's iodine solution:

potassium iodide, 6.0 g; iodine, 4.0 g; dH_2O, 100 ml. Lugol's iodine working solution: dH_2O, 30.0 ml; Lugol's stock solution, 15.0 ml) and the preparation is covered with a cover-slip and allowed to sit for 10 minutes. The preparations are examined in the fresh state.

Whole body burden assay (Fisher & Oliver, 1996): the entire host, cut into 2–5 mm pieces, is placed in fluid thioglycollate culture medium and incubated as in the tissue assay above. If host organisms are too large to use the entire host, then selected target tissue can be used. The solution is centrifuged at 1500 ***g*** for 10 minutes and the supernatant is discarded. 2 M NaOH (20 ml g^{-1} tissue) is added and the solution is incubated at 60°C for 2–6 hours until tissue is digested. The solution is centrifuged at 1500 ***g*** for 10 minutes and the supernatant is discarded. The solution is washed three times in deionised water, the pellet is resuspended in 1 ml Lugol's iodine working solution, and the cells are counted. Serial dilutions may have to be made to reduce the total cell number to a manageable number.

5. Test(s) recommended for surveillance to demonstrate freedom in apparently healthy populations

Real-time PCR and RFTM tissue or whole-body burden assays are recommended for targeted surveillance to declare freedom from infection with *P. olseni*.

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. There are currently no WOAH Reference Laboratory for *Perkinsus olseni*.

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 *P. olseni* shall be suspected if at least one of the following criteria is met:

i) Histopathological changes consistent with the presence of the pathogen or the disease

ii) Positive result by conventional PCR

iii) Positive result by real-time PCR

iv) Positive result by RFTM

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *P. olseni* is considered to be confirmed if the following criterion is met:

i) Positive result by real-time PCR and positive result by conventional PCR followed by amplicon sequencing

ii) Positive result by *In-situ* hybridisation and positive result by conventional PCR followed by amplicon sequencing

iii) Positive result by *In-situ* hybridisation and positive result by species specific real-time PCR.

1 For example transboundary commodities.

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 *P. olseni* 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, with or without elevated mortality

ii) Histopathological changes consistent with the presence of the pathogen or the disease

iii) Positive result by conventional PCR

iv) Positive result by real-time PCR

v) Positive result by RFTM

6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection with *P. olseni* is considered to be confirmed if at least one of the following criteria is met:

i) Positive result by real-time PCR and conventional PCR followed by sequence analysis

ii) Positive result ISH and conventional PCR followed by sequence analysis

ii) Positive result of real-time PCR and ISH

6.3. Diagnostic sensitivity and specificity for diagnostic tests

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with *P. olseni* are provided in Tables 6.3.1. and 6.3.2 (no data are currently available for either). 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.

6.3.1. For presumptive diagnosis of clinically affected animals (no data are currently available)

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 (no data are currently available)

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.

7. References

ABDEL-BAKI A.A.S., AL-QURAISHY S., DKHIL M.A., OLIVEIRA E., CASAL G. & AZEVEDO C. (2014). *Perkinsus* sp. (Alveolata, Perkinsidae) a parasite of the clam *Meretrix meretrix* (Veneridae) from Arabian gulf: Ultrastructural observations of the trophozoites and the cellular response of the host. *Acta Protozoologica*, **53**, 215–221.

ABOLLO E., CASAS S.M., CESCHIA G. & VILLALBA A. (2006). Differential diagnosis of *Perkinsus* species by polymerase chain reaction-restriction fragment length polymorphism assay. *Mol. Cell. Probes,* **20**, 323–329.

AZEVEDO C. (1989). Fine structure of *Perkinsus atlanticus* n. sp. (Apicomplexa, Perkinsea) parasite of the clam *Ruditapes decussatus* from Portugal. *J. Parasitol.,* **75**, 627–635.

BOGEMA D.R., YAM J., MICALLEF M.L., GHOLIPOURKANANI H., GO J., JENKINS C. & DANG C. (2021). Draft genomes of *Perkinsus olseni* and *Perkinsus chesapeaki* reveal polyploidy and regional differences in heterozygosity. *Genomics*, **113**, 677–688.

BURRESON E.M., REECE K.S. & DUNGAN C.F. (2005). Molecular, morphological, and experimental evidence support the synonymy of *Perkinsus chesapeaki* and *Perkinsus andrewsi*. *J. Eukaryot. Microbiol*., **52**, 258–270.

CASAS S.M., LA PEYRE J.F., REECE K.S., AZEVEDO C. & VILLALBA A. (2002a). Continuous in vitro culture of the carpet shell clam *Tapes decussatus* protozoan parasite *Perkinsus atlanticus*. *Dis. Aquat. Organ*., **52**, 217–231.

CASAS S.M., VILLALBA A. & REECE K.S. (2002b). Study of the perkinsosis of the carpet shell clam *Tapes decussatus* in Galicia (NW Spain). I. Identification of the etiological agent and *in vitro* modulation of zoosporulation by temperature and salinity. *Dis. Aquat. Organ.*, **50**, 51–65.

CARELLA F., FERNANDEZ TEJEDOR M., VILLARI G., ANDREE K.B. & DE VICO G. (2023). The endoparasite *Perkinsus olseni* affecting the Mediterranean mussels (*Mytilus galloprovincialis*) in the Italian and Spanish waters: A new possible threat for mussel aquaculture and wild animal population. *Front. Mar. Sci.*, **10**.

CHO K.-S. & PARK K. (2010). Review on the Protozoan Parasite *Perkinsus olseni* (Lester and Davis 1981) Infection in Asian Waters. Coastal Environmental and Ecosystem Issues of the East China Sea. https://api.semanticscholar.org/CorpusID:40174231

CREMONTE F., BALSEIRO P. & FIGUERAS A. (2005). Occurrence of *Perkinsus olseni* (Protozoa: Apicomplexa) and other parasites in the venerid commercial clam *Pitar rostrata* from Uruguay, southwestern Atlantic coast. *Dis. Aquat. Organ.,* **64**, 85–90.

CUI Y.Y., YE L.T., WU L. & WANG J.Y. (2018). Seasonal occurrence of *Perkinsus* spp. and tissue distribution of *P. olseni* in clam (*Soletellina acuta*) from coastal waters of Wuchuan County, southern China. *Aquaculture*, **492**, 300–305.

DANG C., DE MONTAUDOUIN X., BINIAS C., SALVO F., CAILL-MILLY N., BALD J. & SOUDANT P. (2013). Correlation between perkinsosis and growth in clams ruditapes spp. *Dis. Aquat. Organ*., **106**, 255–265.

DUNGAN C.F. & REECE K.S. (2006). *In vitro* propagation of two *Perkinsus* spp. parasites from Japanese Manila clams *Venerupis philippinarum* and description of *Perkinsus honshuensis* n. sp. *J. Eukaryot. Microbiol.*, **53**, 316–326.

DUNGAN C.F., REECE K.S., MOSS J.A., HAMILTON R.M. & DIGGLES B.K. (2007). *Perkinsus olseni in vitro* isolates from the New Zealand clam *Austrovenus stutchburyi. J. Eukaryot. Microbiol.*, **54**, 263–270.

ELANDALLOUSSI L.M., LEITE R.B., RODRIGUES P.M., AFONSO R., NUNES P.A. & CANCELA M.L. (2005). Effect of antiprotozoal drugs on the proliferation of the bivalve parasite *Perkinsus olseni*. *Aquaculture,* **243**, 9–17.

FENG C., WANG C., LIN X., ZHANG Y., LV J., DENG J., YUAN X., MEI L. & WU S. (2013). Development of a loop-mediated isothermal amplification method for detection of *Perkinsus* spp. in mollusks. *Dis. Aquat. Organ.*, **104**, 141–148.

FERNANDEZ-BOO S., PROVOT C., LECADET C., STAVRAKAKIS C., PAPIN M., CHOLLET B., AUVRAY J. & ARZUL I. (2021). Inactivation of marine bivalve parasites using UV-C irradiation: Examples of *Perkinus olseni* and *Bonamia ostreae*. *Aquaculture Rep.*, **21**, 100859.

FISHER W.S. & OLIVER L.M. (1996). A whole-oyster procedure for diagnosis of *Perkinsus marinus* disease using Ray's fluid thioglycollate culture medium. *J. Shellfish Res.,* **15**, 109–117.

GAJAMANGE D., JONG-MAN Y. & PARK J.K. (2011). Development of a real-time PCR method for detection and quantification of the parasitic protozoan *Perkinsus olseni. Korean J. Malacol.*, **27**, 1225–3480.

GAJAMANGE D., KIM S.H., CHOI K.S., AZEVEDO C. & PARK K.I. (2020). Scanning electron microscopic observation of the in vitro cultured protozoan, *Perkinsus olseni,* isolated from the Manila clam, R*uditapes philippinarum. BMC Microbiol.*, **20**.

GAUTHIER J.D., MILLER C.R. & WILBUR A.E. (2006). TaqMan® MGB real-time PCR approach to quantification of *Perkinsus marinus* and *Perkinsus* spp. in oysters. *J. Shellfish Res.,* **25**, 619–624.

GAUTHIER J.D. & VASTA G.R. (1995). *In Vitro* Culture of the Eastern Oyster Parasite *Perkinsus marinus:* Optimization of the Methodology. *J. Invertebr. Pathol.*, **66**, 156–168.

GOGGIN C.L. & LESTER R.J.G. (1995). *Perkinsus*, a protistan parasite of abalone in Australia: a review. *Aust. J. Mar. Freshwater Res*., **46**, 639–646.

GUDKOVS N., CUMMINS D., JONES B., COLLING A., SINGANALLUR B.S. & CRANE M. (2016). Aquatic Animal Health Subprogram: Development of improved molecular diagnostic tests for *Perkinsus olseni* in Australian molluscs. *In:* Fisheries Research and Development Corporation (FRDC) Project No. 2011/004, CSIRO Publishing, p. 128.

HANRIO E., BATLEY J., DAVERN K. & DANG C. (2022). Development of monoclonal antibodies against *Perkinsus olseni* using whole cells. *Aquaculture Rep.*, **24**.

HANRIO E., BATLEY J., DUNGAN C.F. & DANG C. (2021). Immunoassays and diagnostic antibodies for *Perkinsus* spp. pathogens of marine molluscs. *Dis. Aquat. Organ*., **147**, 13–23.

ITOÏZ S., PERENNOU M., MOURONVALLE C., DERELLE E., LE GOÏC N., BIDAULT A., DE MONTAUDOUIN X., ARZUL I., SOUDANT P. & CHAMBOUVET A. (2021). Development of duplex TaqMan-based real-time PCR assay for the simultaneous detection of *Perkinsus olseni* and *P. chesapeaki* in host Manila clam tissue samples. *J. Invertebr. Pathol.,* **184**.

KYOUNG J.A. & KI H.K. (2001). Effect of temperature and salinity on in vitro zoosporulation of *Perkinsus* sp. in Manila clams *Ruditapes philippinarum. Dis. Aquat. Organ*., **48**, 43–46.

LA PEYRE M., CASAS S. LA PEYRE J. (2006). Salinity effects on viability, metabolic activity and proliferation of three *Perkinsus* species. *Dis. Aquat. Organ.,* **71,** 59–74.

LEETHOCHAVALIT S., CHALERMWAT K., UPATHAM E.S., CHOI K.S., SAWANGWONG P. & KRUATRACHUE M. (2004). Occurrence of Perkinsus sp. in undulated surf clams *Paphia undulata* from the Gulf of Thailand. *Dis. Aquat. Organ*., **60**, 165–171.

MOSS J.A., BURRESON E.M. & REECE K.S. (2006). Advanced *Perkinus marinus* infections in *Crassostrea ariakensis* maintained under laboratory conditions. *J. Shellfish Res.,* **25**, 65–72.

MUZNEBIN F., ALFARO A.C.& WEBB S.C. (2023). Occurrence of *Perkinsus olseni* and other parasites in New Zealand black-footed abalone (*Haliotis iris*). *NZ J. Marine Freshw. Res.*, **57**, 261–281.

NICKENS A.D., LA PEYRE J.F., WAGNER E.S. & TIERSCH T.R. (2002). An improved procedure to count *Perkinsus marinus* in eastern oyster hemolymph. *J. Shellfish Res*., **21**, 725–732.

PARDO B.G., CAO A., VILAS R., ABOLLO E., VILLALBA A. & MARTÍNEZ P. (2011). Microsatellite marker development in the protozoan parasite *Perkinsus olseni. Dis. Aquat. Organ*., **94**, 161–165.

PARK K.I. & CHOI K.S. (2001). Spatial distribution of the protozoan parasite *Perkinsus* sp. found in the Manila clams, *Ruditapes philippinarum*, in Korea. *Aquaculture*, **203**, 9–22.

PARK K.I., CHOI K.S. & CHOI J.W. (1999). Epizootiology of *Perkinsus* sp. found in the manila clam *Ruditapes philippinarum* in Komsoe Bay, Korea. *J. Korean Fish. Soc*., **32**, 303–309.

PARK K.I., YANG H.S., KANG H.S., CHO M, PARK KJ. & CHOI K.S. (2010). Isolation and identification of *Perkinsus olseni* from feces and marine sediment using immunological and molecular techniques. *J. Invertebr. Pathol.*, **105**, 261–269.

RAY S.M. (1966). A review of the culture method of detecting *Dermocystidium marinum* with suggested modifications and precautions. *Proc. Natl. Shellfish Assoc.,* **54**, 55–69.

REECE K., BUSHEK D., HUDSON K. & GRAVES J. (2001). Geographic distribution of *Perkinsus marinus* genetic strains along the Atlantic and Gulf coasts of the USA. *Marine Biol.*, **139**, 1047–1055.

REECE K.S., SIDDAL M.E., BURRESON E.M. & GRAVES J.E. (1997). Phylogenetic analysis of *Perkinsus* based on actin gene sequences. *J. Parasitol.*, **83**, 417–423.

RÍOS R., ARANGUREN R., GASTALDELLI M., ARCANGELI G., NOVOA B. & FIGUERAS A. (2020). Development and validation of a specific real-time PCR assay for the detection of the parasite *Perkinsus olseni. J. Invertebr. Pathology*, **169**, 107301.

ROBLEDO J.A.F., WRIGHT A.C., MARSH A.G. & VASTA G.R. (1999). Nucleotide sequence variability in the nontranscribed spacer of the rRNA locus in the oyster parasite *Perkinsus marinus. J. Parasitol.*, **85**, 650–656.

RODRIGUEZ F. & NAVAS J.I. (1995). A comparison of gill and hemolymph assays for the thioglycollate diagnosis of *Perkinsus atlanticus* (Apicomplexa, Perkinsea) in clams, *Ruditapes decussatus* (L.) and *Ruditapes philippinarum* (Adams et Reeve). *Aquaculture*, **132**, 145–152.

RUANO F., BATISTA F.M. & ARCANGELI G. (2015). Perkinsosis in the clams *Ruditapes decussatus* and *R. philippinarum* in the Northeastern Atlantic and Mediterranean Sea: A review. *J. Invertebr. Pathol.,* **131**, 58-67.

SAGRISTA E., DURFORT M. & AZEVEDO C. (1995). *Perkinsus* sp. (Phylum Apicomplexea) in Mediterranean clam *Ruditapes semidecussatus*: ultrastructural observations of the cellular response of the host. *Aquaculture,* **132**, 153–160.

SHEPPARD B.J. & PHILLIPS A.C. (2008). *Perkinsus olseni* detected in Vietnamese aquacultured reef clams Tridacna crocea imported to the USA, following a mortality event. *Dis. Aquat. Organ*., **79**, 229–235.

SOUDANT P.E., CHU F.L. & VOLETY A. (2013). Host-parasite interactions: Thompson PC, Rosenthal BM, Hare MP. 2011. An evolutionary legacy of sex and clonal reproduction in the protistan oyster parasite Perkinsus marinus. Infection, Genetics and Evolution 11:598-609.

UMEDA K., YANG X., WAKI T., YOSHINAGA T. & ITOH N. (2020). The effects of environmental and nutritional conditions on the development of *Perkinsus olseni* prezoosporangia. *Exp. Parasitol.*, **209**.

UMEDA K. & YOSHINAGA T. (2012). Development of real-time PCR assays for discrimination and quantification of two *Perkinsus* spp. in the Manila clam *Ruditapes philippinarum*. *Dis. Aquat. Organ.*, **99**, 215–225.

VILLALBA A., CASAS S.M., LÓPEZ C., & CARBALLAL M.J. (2005). Study of perkinsosis in the carpet shell clam *Tapes decussatus* in Galicia (NW Spain). II. Temporal pattern of disease dynamics and association with clam mortality. *Dis. Aquat. Organ.,* **65**, 257–267.

VILLALBA A., REECE K.S., ORDAS M.C., CASA S.M. & FIGUERAS A. (2004). Perkinsosis in molluscs: a review. *Aquat. Living Resour.,* **17**, 411–432.

WAKI T., TAKAHASHI M., EKI T., HIASA M., UMEDA K., KARAKAWA N. & YOSHINAGA T. (2018). Impact of *Perkinsus olseni* infection on a wild population of Manila clam *Ruditapes philippinarum* in Ariake Bay, Japan. *J. Inverteb. Pathol.*, **153**, 134–144.

WAKI T. & YOSHINAGA T. (2013). Experimental challenges of juvenile and adult Manila clams with the protozoan *Perkinsus olseni* at different temperatures. *Fisheries Sci*., **79**, 779–786.

WAKI T. & YOSHINAGA T. (2015). Suppressive effects of low salinity and low temperature on *in-vivo* propagation of the protozoan *Perkinsus olseni* in Manila clam. *Fish Pathol.*, **50**, 16–22.

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* *

NB: Currently (2025) there is no WOAH Reference Laboratory for infection with *Perkinsus olseni*
(please consult the WOAH web site:
https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3).

NB: FIRST ADOPTED IN 1995 AS PERKINSOSIS. MOST RECENT UPDATES ADOPTED IN 2015.

Annex 29. Item 10.1.3. Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis*'

CHAPTER 2.4.7

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

1. Scope

Infection with *Xenohaliotis californiensis* means infection with the pathogenic agent *Candidatus* Xenohaliotis californiensis of the Family Anaplasmataceae. For the purposes of this chapter, the pathogenic agent will be referred to as *Xenohaliotis californiensis.*

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

Xenohaliotis californiensis is an intracellular bacterium in the family Anaplasmataceae (Dumler *et al.,* 2001) and is closely related to members of the genera *Ehrlichia, Anaplasma* and *Cowdria* (Friedman *et al.,* 2000). The disease caused by this bacterium is known as withering syndrome (Friedman *et al.,* 2002; Haaker *et al.,* 1992) and may be more appropriately termed abalone rickettsiosis. Some *X. californiensis* may be infected with a phage (Friedman & Crosson, 2012). The dimorphic rod-to-spherical-shaped bacterium measures an average of 332 × 1550 nm in the bacillus form and an average of 1405 nm in the spherical morphotype. The bacterium reproduces within intracytoplasmic vacuoles 14–56 µm in diameter within gastrointestinal epithelia (Friedman *et al.,* 2000).

2.1.2. Survival and stability in processed or stored samples

As the pathogen has not been cultured the survival and stability in stored samples is unknown.

2.1.3. Survival and stability outside the host

Although *X. californiensis* is thought to be an obligate intracellular organism, the bacterium may survive outside the host for an undetermined period of time as evidenced by water-borne transmission studies (Balseiro *et al*., 2006; Braid *et al*., 2005; Friedman *et al*., 2002; 2007; Rosenblum *et al*., 2008).

For inactivation methods, see Section 2.4.5.

2.2. Host factors

NB: Sections 2.2.1 and 2.2.2 are not for Member comment. Version for comment and adoption are presented in Annex 27

~~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~~

~~Family~~	~~Scientific name~~	~~Common name~~
	~~*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~~

~~2.2.2. Species with incomplete evidence for susceptibility~~

~~*Haliotis gigantea* has incomplete evidence to fulfil the criteria for listing as susceptible to infection with X. californiensis according to Chapter 1.5.~~

~~In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in *Haliotis discus hannai*, but no active infection has been demonstrated.~~

2.2.3. Likelihood of infection by species, host life stage, population or sub-populations

The bacterium divides by binary fission (Friedman *et al.,* 2000) and has direct, horizontal transmission (Braid *et al*., 2005; Friedman *et al*., 2002; Moore *et al*., 2001). Although not typically observed in farmed abalones until they are in grow-out conditions (>2.5 cm maximum size), polymerase chain reaction (PCR) examination of exposed 6-week-old abalones suggested that 1–2 mm abalones may become infected (Moore *et al*., unpublished observations). Probability of detection increases with increasing abalone size. Animals less than 10 mm in size have a reduced probability of detection using histology but equal probability of detection using PCR (Friedman *et al*., 2007; Moore *et al*., 2011).

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).

2.2.4. Distribution of the pathogen in the host

Xenohaliotis californiensis infects the gastrointestinal epithelial cells of the posterior oesophagus, digestive gland and, to a lesser extent, intestine (Friedman *et al*., 2000).

2.2.5. Aquatic animal reservoirs of infection

None.

2.2.6. Vectors

None.

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Susceptibility varies with species as the bacterium is known to cause disease in *H. cracherodii* (up to 99% mortality; Moore *et al*., 2009), *H. sorenseni* (up to 100% mortality; Friedman & McCormick, unpublished observations), *H. rufescens* (up to 35% mortality; Moore *et al*., 2000; 2001), *H. corrugata* and *H. fulgens* (Tinajero *et al*., 2002). Unlike the other abalone species studied to date, the magnitude of abalone mortality is not well documented in *H. corrugata* and *H. fulgens*. However, in Baja California, Mexico, up to 100% of *H. fulgens* and 63% of *H. corrugata* may be infected, with up to 43% of *H. fulgens* and 71% of *H. corrugata* having microscopic signs of disease (degenerated or metaplastic digestive gland; Tinajero *et al*., 2002).

The incubation period varies with temperature but typically involves a prolonged 3- to 7-month prepatent period. Mortality typically occurs 1–2.5 months after the onset of visible clinical signs (Friedman *et al*., 1997). Prevalence has not been well documented but up to 61% of *H. diversicolor supertexta* were infected at a farm in Thailand, however, like the European abalone, *H. tuberculata*, no abalones exhibited clinical signs of withering syndrome (Balseiro *et al*., 2001).

Infections may persist for long periods without the development of clinical disease when the host is maintained at cool water temperatures (e.g. 15°C for *H. rufescens*), and exposure to elevated seawater temperatures (e.g. >17°C for *H. rufescens*, *H. cracherodii* and *H. sorenseni*) typically results in clinical disease (Friedman & Finley, 2003; Moore *et al*., 2000; Steinbeck *et al*., 1992). Varying seawater temperatures with a lower mean temperature (e.g. 16.5°C for *H. rufescens*) may exacerbate losses (Moore *et al*., 2011). There is some suggestion that species, especially those inhabiting warmer waters may harbour the bacterium without the development of clinical disease (Wetchateng, 2008; Wetchateng *et al*., 2010).

2.3.2. Clinical signs, including behavioural changes

This intracellular pathogen infects the gastrointestinal epithelial cells, leading to clinical signs of starvation, including pedal and digestive gland atrophy. Abalones with *X. californiensis* infections may be sub-clinically infected during the prepatent period or at water temperatures ≤15°C. Infected individuals may be slightly to severely emaciated (atrophied) under permissive water temperatures.

During an epidemic, affected abalones will often cling to horizontal (as opposed to vertical or inverted) substrates and appear weak (easily removed from the substrate by hand) and emaciated (withered) (Haaker *et al*., 1992). Farmed abalones will also be anorexic. In addition, the presence of an abnormally high number of fresh shells may also indicate disease.

2.3.3 Gross pathology

Clinical disease is characterised by morphological changes in the digestive gland, which vary between species and may include degeneration (atrophy of tubules, increase in connective tissues and inflammation) and/or metaplasia of the digestive tubules. Metaplasia involves the replacement of terminal secretory/absorptive acini with absorptive/transport ducts similar in appearance to the post-oesophagus. These morphological changes are accompanied by anorexia, depletion of glycogen reserves, followed by use of the foot muscle as an energy source and subsequent death (Balseiro *et al*., 2006; Braid *et al*., 2005; Friedman *et al*., 1997; 2007; Kismohandaka *et al*., 1995; Moore *et al*., 2000; 2001). The foot of affected abalones contains fewer and less organised muscle bundles, abundant connective tissue and may contain more cerous cells than unaffected individuals (Friedman *et al*., 2007; Moore *et al*., 2000; Van Blaricom *et al*., 1993). Surviving abalones appear to remain infected, even in low water temperature environments, such as in northern California (Friedman & Finley, 2003).

2.3.4. Modes of transmission and life cycle

Transmission of *X. californiensis* is horizontal and is postulated to be via a faecal–oral route. Exposure of abalones to seawater containing infectious material is sufficient for transmission of the bacterium, and no direct animal contact is required (Balseiro *et al*., 2006; Braid *et al*., 2005; Friedman *et al*., 2002; Moore *et al*., 2000; 2001). Temperatures below 13°C have been demonstrated to limit transmission of the bacterium (i.e. less than 1% transmission) relative to those held at ~18°C (72–94% transmission) (Braid *et al*., 2005).

2.3.5. Environmental factors

Disease (withering syndrome) occurs at elevated water temperatures (~18–25°C in abalones with moderate to severe infections (Braid *et al*., 2005; Friedman *et al*., 2000; 2002; Moore *et al*., 2000; 2011; Rosenblum *et al*., 2008). Parasite transmission is enhanced in fed (94%) as opposed to starved. (72%) abalones (Balseiro *et al*., 2006; Braid *et al*., 2005). Subclinical infections have been observed in *H. diversicolor supertexta* raised at 27–29°C. As abalones are obligate marine species, salinity tolerances of the Rickettsia-like organism (RLO) have not been investigated.

2.3.6. Geographical distribution

Xenohaliotis californiensis occurs along the south-west coast of North America. However, as infected abalones have been transported to South America, Asia-Pacific, and Europe and possibly other regions, the geographical range of the aetiological agent is suspected to be broad where California red abalones, *Haliotis rufescens*, are cultured or areas where native species have been exposed to red abalones (e.g. Wetchateng, 2008)

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

No vaccines are available.

2.4.2. Chemotherapy including blocking agents

Reducing densities and application of an oxytetracycline-medicated diet may reduce losses (Friedman *et al*., 2003; 2007; Rosenblum *et al*., 2008). Oral administration of 12–19% TM-100 (90–100 mg kg^{-1}) in a medicated diet for 10 or 20 days provides protection against bacterial re-infection for several months. A single day oral administration of 12% TM-100 may reduce bacterial infections from 80% to 10% prevalence and mean infection intensity from 1.4 to 0.1 on a scale of 0–3 (Friedman *et al*., 2000; 2007).

2.4.3. Immunostimulation

No immunostimulants are currently known

2.4.4. Breeding resistant strains

Interest in selecting for resistant abalones, particularly for restoration purposes, is increasing. Wild black abalones have continued to recruit along the California Channel Islands since 2002 and some recruits survive, suggesting that these individuals may be more resistant to this rickettsial disease (Tinajero *et al*., 2002).

2.4.5. Inactivation methods

Based on successful decontamination in the laboratory, this bacterium is readily inactivated by immersion in <10% bleach. In addition, exposure of seawater containing the bacterium to >10 mg litre–1 [ppm] calcium hypochlorite and disinfection of equipment in a bath of 1% tamed iodine in freshwater for 1 hour are effective disinfectants based on the use of these disinfection methods at a marine laboratory with flow-through seawater and a lack of detection of this pathogen in adjacent abalone populations (Friedman & Finley, 2003).

2.4.6. Disinfection of eggs and larvae

No attempts to disinfect eggs and larvae have been undertaken.

2.4.7. General husbandry

Husbandry practices to control *X. californiensis* are typical of those for any bacterial disease and include the purchase of inspected seed (devoid of evidence of infection), maintaining separate families or groups (i.e. avoid high grading and mixing of disparate groups), rinsing hands and equipment in freshwater or iodinated water and drying them in between uses. Isolation of infected groups is recommended if possible.

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

To optimise detection (targeted sampling), selection of abalones exhibiting the clinical sign of reduced weight (atrophied pedal muscle) is recommended. If possible, animals should be sampled after exposure to a period (e.g. 30 days) of warm water (e.g. >18°C).

3.2. Selection of organs or tissues

The best target tissue is the posterior oesophagus, and the second-best tissue is the digestive gland/intestine complex.

3.3. Samples or tissues not suitable for pathogen detection

Non-digestive tissues do not contain rickettsial DNA and should be avoided.

3.4. Non-lethal sampling

None

3.5. Preservation of samples for submission

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. The recommended ratio of ethanol to tissue is 10:1 based on studies in terrestrial animal and human health. The use of lower grade (laboratory or industrial grade) ethanol is not recommended. If material cannot be fixed it may be frozen.

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. If the effect of pooling on diagnostic sensitivity has not been thoroughly evaluated, specimens should be processed and tested individually. Small life stages such as spat can be pooled to obtain the minimum amount of material for virus isolation or 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
Wet mounts												
Histopathology	+	++	++	1	+	+++	+++	1				
Cell cultures												
Real-time PCR	+++	+++	+++	3	+++	+++	+++	3	+++	+++	+++	3
Conventional PCR	+++	+++	+++	1	+++	+++	+++	1				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	1
In-situ hybridisation					+	+	+	1	+	+	+	1
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
Other antigen detection methods[3]												
Other methods[3]												

LV = level of validation, refers to the stage of validation in the WOAH Pathway (chapter 1.1.2); PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; Ab- or Ag-ELISA = antibody or antigen enzyme-linked immunosorbent assay, respectively; IFAT = indirect fluorescent antibody test. [give definitions of abbreviations as appropriate; nPCR = nested PCR, etc. NB "RT-PCR" is reserved for reverse-transcription polymerase chain reaction methods. "real-time PCR" should always be stated in full and refers to probe-based and SYBR green assays]

[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. Wet mounts

Not applicable.

4.2. Histopathology and cytopathology

The presence of basophilic, ovoid intracytoplasmic bacterial inclusions in digestive epithelia (posterior oesophagus, transport ducts and metaplastic epithelia of the digestive gland, and/or intestine). Metaplastic changes in the digestive gland that include the transformation of the terminal digestive tubules into absorptive/transport epithelia occurs in abalones infected with *X. californiensis* (Balseiro *et al*., 2006; Braid *et al*., 2005; Friedman *et al*., 2002; Moore *et al*., 2000; 2001). Although metaplasia has been observed in all affected species examined to date, the response to infection may vary between hosts. Red abalones and white abalones, for example, typically respond with a metaplastic change (Balseiro *et al*., 2006; Braid *et al*., 2005; Moore *et al*., 2000), while black abalones generally respond with a combination of metaplasia, digestive tubule degeneration and inflammation (Friedman *et al*., 1997; 2002). Affected individuals contain less pedal glycogen and fewer muscle bundles than do unaffected individuals (Balseiro *et al*., 2006; Braid *et al*., 2005; Gardner *et al*., 1995). In some abalones, an increase in serous cells may be observed in the foot muscle (Van Blaricom *et al*., 1993), but these signs are not pathognomonic for this disease. Juvenile white abalone may contain an apparently metaplastic digestive without presence of *X. californiensis* (Friedman *et al*., 2007). Thus, the presence of *X. californiensis* in digestive epithelia in conjunction with the morphological changes noted above indicate the presence of clinical withering syndrome.

4.3. Cell culture for isolation

Not applicable.

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). 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

Pathogen/ target gene	Primer/probe (5'–3')	Concentration	Cycling parameters
Method 1: Friedman *et al.,* 2014; GenBank Accession No.: AF133090, amplicon size: 147 bp			
16S rDNA	Fwd WSN1 F: AGT-TTA-CTG-AAG-GCA-AGT-AGC-AGA Rev WSN1 R: TCT-AAC-TTG-GAC-TCA-TTC-AAA-AGC Probe WS-RLO_P: TGC-TTG-GAA-ATC-TAC-TCA-GAA-GAC-ATG-A	320 nM 320 nM 200 nM	45 cycles of: 95°C/15 sec and 60°C/30 sec

4.4.2. Conventional PCR

Pathogen/ target gene	Primer (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Andree *et al.,* 2000; GenBank Accession No.: AF133090, amplicon size: 160 bp			
16S rDNA	Fwd RA 5-1: GTT-GAA-CGT-GCC-TTC-AGT-TTA-C Rev RA 3-6: ACT-TGG-ACT-CAT-TCA-AAA-GCG-GA	500 nM 500 nM	40 cycles of: 95°C/60 sec, 50°C/30 sec and 72°C/30 sec
Method 2: Cicala *et al.,* 2017; GenBank Accession No.: KU645900, amplicon size: 426 bp			

16S rDNA	Fwd ss16S-F: GCC-TCA-GTT-TGG-CTG-GGT-TCT-TCA Rev ss16S-R: GAA-TTG-CCA-CTT-TAA-AGT-ATG-GAC-GG	300 nM 300 nM	40 cycles of: 94°C/60 sec, 66°C/30 sec and 72°C/30 sec

4.4.3. Other nucleic acid amplification methods

Not applicable.

4.5. Amplicon sequencing

The size of the PCR amplicon should be verified, for example by agarose gel electrophoresis. Both DNA strands of the PCR product must be sequenced and analysed in comparison with reference sequences.

4.6. *In-situ* hybridisation

Use of Rickettsiales-like prokaryotes specific DNA probes with histological sections is useful to demonstrate the presence of *X. californiensis* nucleic acid in infected cells (Antonio *et al*., 2000). See Chapter 2.4.0 Section 5.5.4 for general comments on *in-situ* hybridisation.

Antonio *et al.* (2000) developed an ISH method targeting the 16S rDNA gene. This method allows the detection of Rickettsiales-like prokaryotes in tissue sections. Although this method has not been formally validated, tests for specificity using several bivalve and fish rickettsial organisms suggested that the test was specific for *X. californiensis*.

Reference	Pathogen/target gene	ISH probe	Probe size
Antonio *et al.* (2000)	16S rDNA	RA 5-1: GTT-GAA-CGT-GCC-TTC-AGT-TTA-C RA 3-6: ACT-TGG-ACT-CAT-TCA-AAA-GCG-GA; RA 3-8: CCA-CTG-TGA-GTG-GTT-ATC-TCC-TG; RA 5-6: GAA-GCA-ATA-TTG-TGA-GAT-AAA-GCA.	oligo nucleotide probes

4.7. Immunohistochemistry

Not applicable.

4.8. Bioassay

Not applicable.

4.9. Antibody- or antigen-based detection methods (ELISA, etc.)

Not applicable.

4.10. Other methods

Not applicable.

5. Test(s) recommended for surveillance to demonstrate freedom in apparently healthy populations

The recommended method for surveillance is real-time PCR using the assay by Friedman *et al.* (2014).

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. There are currently no WOAH Reference Laboratories for *Xenohaliotis californiensis*.

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 *X. californiensis* shall be suspected if at least one of the following criteria is met:

i) Histopathological changes consistent with the presence of the pathogen or the disease

ii) Positive result by conventional PCR

iii) Positive result by real-time PCR

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *X. californiensis* is considered to be confirmed if at least one of the following criteria is met:

i) Positive result by real-time PCR and positive result by conventional PCR followed by amplicon sequencing

ii) Positive result by *in-situ* hybridisation and positive result by conventional PCR followed by amplicon sequencing

iii) Positive result by *in-situ* hybridisation and positive result by real-time PCR

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 *X. californiensis* shall be suspected if at least one of the following criteria is met:

i) Histopathological changes consistent with the presence of the pathogen or the disease

ii) Positive result by *in-situ* hybridisation

iii) Positive result by conventional PCR

iv) Positive result by real-time PCR

6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection with *X. californiensis* is considered to be confirmed if at least at least one of the following criteria is met:

i) Positive result by real-time PCR and positive result by conventional PCR followed by amplicon sequencing.

ii) Positive result by *in-situ* hybridisation and positive result by conventional PCR followed by amplicon sequencing.

iii) Positive result by *In-situ* hybridisation and positive result by real-time PCR.

6.3. Diagnostic sensitivity and specificity for diagnostic tests

1 For example transboundary commodities.

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with *Xenohaliotis californiensis* are provided in Tables 6.3.1. and 6.3.2). 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.

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
Real-time PCR	Diagnosis	Clinically diseased abalone from farms	Posterior esophagus and digestive gland tissue	*Haliotis rufescens*, *H. sorensoni*, *H. fulgens*, *H. discushannai*, *H. cracherodii*, *H. kamtschatkana*	100 (518)	99.7 (518)	Histopathology	Friedman *et al.* (2014)

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 (no data are currently available)

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.

7. References

ANDREE K.B., FRIEDMAN C.S., MOORE J.D. & HEDRICK R.P. (2000). A polymerase chain reaction for detection of genomic DNA of a Rickettsiales-like prokaryote associated with Withering Syndrome in Black Abalone (*Haliotis cracherodii*). *J. Shellfish Res*., **19**, 213–218.

ANTONIO D.B., ANDREE K.B., MOORE J.D., FRIEDMAN C.S. & HEDRICK R.P. (2000). Detection of Rickettsiales-like prokaryotes (RLPs) by *in situ* hybridization in black abalone *Haliotis cracherodii* with withering syndrome. *J. Invertebr. Pathol.*, **75**, 180–182.

BALSEIRO P., ARANGUREN R., GESTAL C., NOVOA B. & FIGUERAS A. (2006). *Candidatus* Xenohaliotis californiensis and *Haplosporidium montforti* associated with mortalities of abalone *Haliotis tuberculata* cultured in Europe. *Aquaculture*, **258**, 63–72.

BRAID B.A., MOORE J.D., ROBBINS T.T., HEDRICK R.P., TJEERDEMA R.S. & FRIEDMAN C.S. (2005). Health and survival of red abalone, *Haliotis rufescens*, under varying temperature, food supply and exposure to the agent of withering syndrome. *J. Invertebr. Pathol.,* **89**, 219–231.

CICALA F., MOORE J.D., CACERES-MARTINEZ J., DEL RIO-PORTILLA M.A., HERNANDEX-RODRIGUES M., VASQUEZ_YEOMANS R. & ROCHA-OLIVARES A. (2017). Multigenic characterisation of "*Çandidatus* Xenohaliotis californiensis". *Int. J. Syst. Evol. Microbiol.*, **67**, 42–49.

DUMLER J.S., BARBET A.F., BEKKER C.P.J., DASCH G.A., PALMER G.H., RAY S.C., RIKIHISA Y. & RURANGIRWA F.R. (2001). Reorganization of general in the families Rickettsiaceae and Anaplasmataceae in the order Rickettsiales: unification of some species of *Ehrlichia* with *Anaplasma*, *Cowdria* with *Ehrlichia* and *Ehrlichia* with *Neorickettsia*, descriptions of six new species combinations and designation of *Ehrlichia equi* and 'HGE agent' as subjective synonyms of E*hrlichia phagocytophila. Int. J. System. Evol. Microbiol*., **51**, 2145–2165.

FRIEDMAN C.S., ANDREE K.B., BEAUCHAMP K.A., MOORE J.D., ROBBINS T.T., SHIELDS J.D. & HEDRICK R.P. (2000). "*Candidatus* Xenohaliotis californiensis" a newly described pathogen of abalone, *Haliotis* spp., along the west coast of North America. *Int. J. Syst. Evol. Microbiol.,* **50**, 847–855.

FRIEDMAN C.S., BIGGS W., SHIELDS J.D. & HEDRICK R.P. (2002). Transmission of withering syndrome in black abalone, *Haliotis cracherodii* Leach. *J. Shellfish Res*., **21**, 817–824.

FRIEDMAN C.S. & CROSSON L.M. (2012). Putative phage hyperparasite in the Rickettsial Pathogen of Abalone, "*Candidatus* Xenohaliotis californiensis". *Invertebr. Microbiol*., **64**, 1064–1072.

FRIEDMAN C.S. & FINLEY C.A. (2003). Evidence for an anthropogenic introduction of "*Candidatus* Xenohaliotis californiensis", the etiological agent of withering syndrome, into northern California abalone populations via conservation efforts. *Can. J. Fish Aquat. Sci.,* **60**, 1424–1431.

FRIEDMAN C.S., THOMSON M., CHUN C., HAAKER P.L. & HEDRICK, R.P. (1997). Withering syndrome of the black abalone, *Haliotis cracherodii* (Leach): Water temperature, food availability, and parasites as possible causes. *J. Shellfish Res.*, **16**, 403–411.

FRIEDMAN C.S., TREVELYAN G., MULDER E.P. & FIELDS R. (2003). Development of an oral administration of oxytetracycline to control losses due to withering syndrome in cultured red abalone *Haliotis rufescens. Aquaculture*, **224**, 1–23.

FRIEDMAN C.S., SCOTT B.B., STRENGE R.E. & MCCORMICK T.B. (2007). Oxytetracycline as a tool to manage and prevent losses of the endangered white abalone, *Haliotis sorenseni,* due to withering syndrome. *J. Shellfish Res*., **26**, 877–885.

FRIEDMAN C.S., WIGHT N., CROSSON L.M., WHITE S.J. & STRENGE R.M. (2014). Validation of a qualitative PCR assay for detection and quantification of '*Candidatus* Xenohaliotis californiensis'. *Dis. Aquat. Organ*.,**108**, 251–259.

GARDNER G.R., HARSHBARGER J.C., LAKE J., SAWYER T.K., PRICE K.L., STEPHENSON M.D., HAAKER P.L. & TOGSTAD H.A. (1995). Association of prokaryotes with symptomatic appearance of withering syndrome in black abalone *Haliotis craherodii. J. Invertebr. Pathol.*, **66**, 111–120.

HAAKER P.L., PARKER D.O., TOGSTAD H., RICHARDS D.V., DAVIS G.E. & FRIEDMAN C.S. (1992). Mass mortality and withering syndrome in black abalone *Haliotis cracherodii*, in California. *In:* Abalone of the World, Shepard S.A., Tegner M.J. & Guzman del Proo S.A., eds, Blackwell Scientific, Oxford, UK, 214–224.

KISMOHANDAKA G., ROBERTS W., HEDRICK R.P. & FRIEDMAN C.S. (1995). Physiological alterations of the black abalone, *Haliotis cracherodii* Leach, with withering syndrome. *J. Shellfish Res*., **14**, 269–270.

MOORE J.D., JUHASZ C.I., ROBBINS T.T. & VILCHIS I. (2009). Green abalone, *Haliotis fulgens*, infected with the agent of withering syndrome do not express disease signs under a temperature regime permissive for red abalone, *Haliotis rufescens*. *Marine Biol.,* **156**, 2325–2330.

MOORE J.D., MARSHMAN B.C. & CHUN C.C. (2011). Health and survival of red abalone *Haliotis rufescens* from San Miguel Island, California, USA, in a laboratory simulation of La Niña and El Niño conditions. *J. Aquat. Anim. Health*, **23**, 78–84.

MOORE J.D., ROBBINS T.T. & FRIEDMAN C.S. (2000). Withering syndrome in farmed red abalone *Haliotis rufescens:* Thermal induction and association with a gastrointestinal rickettsia-like prokaryote. *J. Aquat. Anim. Health,* **12**, 26–34.

MOORE J.D., ROBBINS T.T., HEDRICK R.P. & FRIEDMAN C.S. (2001) Transmission of the Rickettsiales-like procaryote "*Candidatus* Xenohaliotis californiensis" and its role in withering syndrome of California abalone *Haliotis* spp. *J. Shellfish Res.*, **20**, 867–874.

ROSENBLUM E.S., JUHASZ C., FRIEDMAN C.S., ROBBINS T.T., CRAIGMILL A., TJEERDEMA R.S. & MOORE J.D. (2008). Oxytetracycline as a treatment for abalone withering syndrome Part II: Efficacy, pharmacokinetics, and long term resistance to re-infection at elevated sea water temperatures. *Aquaculture*, **277**, 138–148.

STEINBECK J.R., GROFF J.M., FRIEDMAN C.S., MCDOWELL T. & HEDRICK R.P. (1992). Investigations into mortality among populations of the California black abalone, *Haliotis cracherodii,* on the central coast of California, USA. *In:* Abalone of the World, Shepard S.A., Tegner M.J. & Guzman del Proo S.A., eds. Blackwell Scientific, Oxford, UK, 203–213.

TINAJERO M.D.C.A., CACERES-MARTINEZ J., & AVILES J.G.G. (2002) Histopathological evaluation of the yellow abalone *Haliotis corrugata* and the blue abalone *Haliotis fulgens* from Baja California, Mexico. *J. Shellfish Res*., **21**, 825–830.

VAN BLARICOM G.R., RUEDIGER J.L., FRIEDMAN C.S., WOODARD D.D. & HEDRICK R.P. (1993). Discovery withering syndrome among black abalone populations at San Nicolas Island, California *J. Shellfish Res.*, **12**, 185–188.

WETCHATENG T. (2008). *Rickettsia*-like organism (RLO) infection in the abalone *Haliotis diversicolor supertexta*: Histopathology, diagnosis and treatment. PhD. Dissertation, Mahidol University, Bangkok, Thailand, 49 pp.

WETCHATENG T., FRIEDMAN C.S., WIGHT N.A., LEE P.-Y., TENG P.H., SRIURAIRATTANA S., WONGPRASERT K. & WITHYACHUMNARNKUL B. (2010). Withering syndrome in abalone *Haliotis diversicolor supertexta*. *Dis. Aquat. Organ.,* **90**, 69–76.

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NB: Currently (2025) there is no WOAH Reference Laboratory for infection with *Xenohaliotis californiensis* (please consult the WOAH web site: https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3).

NB: FIRST ADOPTED IN 2006. MOST RECENT UPDATES ADOPTED IN 2012.