Report of the Meeting of WOAH Aquatic Animal Health Standards Commission

Original: English (EN)

17 to 24 September 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 17 to 24 September 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*') or WOAH *Manual of Diagnostic Tests for Aquatic Animals* (hereinafter 'the *Aquatic Manual*'): Australia, Canada, Chile, China (People's Rep. of), Chinese Taipei, Japan, Mexico, New Zealand, Norway, Peru, Singapore, Switzerland, Thailand, the United Kingdom (UK), the United States of America (USA), the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of African Members of WOAH, the Members of the WOAH Americas Region (Americas) and the Member States of the European Union (EU) and the QUADS Alliance. The Commission also wished to acknowledge the valuable advice and contributions from numerous experts of the WOAH scientific network.

The Aquatic Animals Commission considered all comments that were submitted prior to the deadline and were aligned with the Guide for WOAH Members and International Organisations on submitting comments during the process for the elaboration of WOAH International Standards (the Guide).

The Aquatic Animals 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.

Annexes

Annex 3 is presented for information only, and presents comments considered by the Aquatic Animals Commission and its responses.

Texts in Annexes 4 to 19 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 must 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

Other relevant reports
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 5 January 2026 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: 11 to 18 February 2026.

List of Annexes

1. Meeting with the 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 17 September 2025. Dr Arroyo thanked the Commission for their commitment and congratulated them on their ambitious agenda. She informed the Commission that Dr Emmanuelle Soubeyran, the WOAH Director General, was unable to meet with the Commission during this meeting as she was on travel duty.

Dr Arroyo informed the Aquatic Animals Commission that the WOAH 8th Strategic Plan (2027-2031) is currently under development and will be presented for adoption at the May 2026 General Session. She noted that feedback from the Specialist Commissions will be important during the consultation phase.

Dr Arroyo highlighted the work of the WOAH Governance Review Committee that held its first meeting on technical governance topics in May 2025 with further meetings scheduled. The technical governance topics included the structure and procedures of the Specialist Commissions, Working Groups and *ad hoc* Groups. Recommendations will be submitted for adoption at the May 2026 General Session.

Dr Arroyo informed the Aquatic Animals Commission that the Standards Online Navigation Tool had been published in April 2025 and provides users with streamlined access to the WOAH Standards (see Item 11.3. in this report). She also noted that the online versions of the WOAH Standards have been updated as of 5 September 2025 to reflect all new and revised texts adopted at the 92nd WOAH General Session in May 2025.

Dr Arroyo noted that the 2024 Quadripartite report on antimicrobial resistance showed that there are concerns regarding antimicrobial usage in aquaculture. She emphasised the importance of the work being done to revise Chapter 6.2.'Principles for responsible and prudent use of antimicrobial agents in aquatic animals' to provide robust standards for Members regarding antimicrobial use in aquatic animals.

Dr Arroyo highlighted current and planned horizontal work with the Terrestrial Animal Health Standards Commission ('Code Commission') and thanked members for their ongoing collaboration. She noted that horizontal work between the Commissions provides consistency which facilitates effective implementation of the standards by Members.

The Aquatic Animals Commission thanked Dr Arroyo for her updates. The Commission noted that work by the Governance Review Committee needs to ensure that the process is methodical and that problems to be addressed are fully defined before solutions are proposed. The Commission also raised the importance of WOAH Aquatic Animal Focal Points to ensure leadership in aquatic issues for Members and encouraged WOAH to continue to strengthen the focal point program.

1.1. Transparency of commenting – phased approach

As originally communicated in the Aquatic Animals 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 considered by the Commission at its February 2024 meeting.

The second step in this process was the publication on the Delegates' and public WOAH websites of comments considered by the Commission at its September 2024 meeting. The Commission also included its responses to comments in Annex 3 for information only. As a result the Commission's report was more concise and focused on providing a short background summary for each agenda item as well as key points discussed and agreed by the Commission.

The third and final step in this process will be to publish the name of the Member or partner organisation who submitted the comment considered by the Commission at its February 2026 meeting, linked with the comment provided in Annex 3.

These new processes are aimed at improving transparency of the standard-setting process and creating a more user-friendly report. Together with the guidance documents (see 'How to submit comments' in this report) for submitting comments that are available for Members and partners WOAH anticipates that this will support more Members to engage in the process for the elaboration of WOAH Standards.

2. Adoption of the agenda

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

3. Cooperation with the Terrestrial Animal Health Standards Commission

A meeting of the Bureaux (i.e., the President and the two Vice-Presidents) of the Code Commission and the Aquatic Animals Commission was held on 18 September 2025 and chaired by WOAH DDG- ISS. The purpose of this meeting was for the two Bureaux to update each other on the relevant work of each Commission on topics of common interest, and to discuss and agree on the planning and coordination on these topics, and to exchange experiences to harmonise approaches to horizontal chapters.

The Bureaux discussed the following topics:

- The approach taken by both Commissions in the planning and progress of their work programme and prioritisation of items,
- Coordination on the amendments to Chapter 1.1. 'Notification of diseases and provision of epidemiological information' of the *Aquatic Code* and *Terrestrial Code* (see Item 7.2.1. in this report),
- Progress of *Aquatic Code* Chapter 4.3. 'Application of Compartmentalisation' and plans to review Chapter 4.2. 'Zoning and compartmentalisation',
- Review of *Terrestrial Code* Chapter 4.4. 'Zoning and compartmentalisation' and new chapter on implementation of zoning (see Item 7.1.1. in this report),
- Development of *Terrestrial Code* Chapter 3.X. 'Emergency Management', considering newly adopted chapters in the *Aquatic Code:* Chapter 4.10. 'Emergency disease preparedness' and Chapter 4.11. 'Outbreak management'
- Progress of *Terrestrial Code* Chapter 4.X. 'Biosecurity' and associated Glossary definitions,
- Work on introduction chapter for Section 5 of the *Aquatic Code* and *Terrestrial Code* (see Item 7.1.2. in this report),
- Progress of *Terrestrial Code* Chapters 5.4. to 5.7. on trade and plans to review *Aquatic Code* Section 5. (see Item 6.4. in this report).

The Bureaux agreed that proposed revisions Chapter 1.1. 'Notification of diseases and provision of epidemiological information' of the *Terrestrial Code* and *Aquatic Code* should be undertaken in parallel to ensure consistency between respective Chapters 1.1. given the importance of alignment. The Bureaux agreed to review each other's draft revised Chapters 1.1. at their February 2026 meetings with the intention to circulate the revised texts at that time so that Members can consider proposed amendments to both Chapters 1.1. to ensure a coordinated process.

The Aquatic Animals Commission encouraged Members to read the Code Commission's report for the details of relevant items.

4. Aquatic Animal Health Strategy

The Aquatic Animals Commission was informed of the key milestones and achievements of the WOAH Aquatic Animal Health Strategy since the last update in February 2025, new activities underway, communication initiatives and key priorities.

The Aquatic Animals Commission confirmed their support for a new Strategy beyond 2025 and discussed the potential for future initiatives regarding aquatic animal health and encouraged WOAH and Members to ensure that the importance of aquatic animal health is reflected in the 8th Strategic Plan, currently under development.

Update on Activity 4.5.: Advancing Aquatic Animal Health Research: WOAH & STAR IDAZ activities

The Aquatic Animals Commission was informed of the joint WOAH–STAR IDAZ IRC initiatives under Activity 4.5. of the WOAH Aquatic Animal Health Strategy for the strategic prioritisation of research areas of importance for the WOAH Community. The Commission noted the successful global consultation and the workshop *Advancing Aquaculture Health Research* held in Paris in February 2025. The outputs of the global consultation for the finfish sector, together with the workshop report and a policy brief on the highest-priority research areas for finfish, are available online for consultation. The Commission acknowledged the importance of the collaboration with STAR IDAZ IRC to identify global research priorities and for its contribution to strengthening synergies between researchers, funders, industry, and WOAH's work in international standard-setting.

The Aquatic Animals Commission agreed to consider further research prioritisation activities on the crustacean section report after a consultation. The Commission also agreed to continue to discuss environmental nucleic acid (e-NA) approaches for environmental surveillance, which could be further addressed in coordination with the Biological Standards Commission.

5. Work programme and priorities

5.1. Comments received on the Work Programme

Comments were received from Canada, Chinese Taipei, Japan, Peru, Singapore, Thailand, the Americas, the EU and the QUADS Alliance.

The Aquatic Animals Commission noted comments expressing support for the Commission's work programme. Comments proposing new work are addressed in Sections 6. and 7.2. of this report; comments on work items discussed in this meeting are addressed in the corresponding items of this report.

The Aquatic Animals 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 and proposed work, 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 Aquatic Animals 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.

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

Texts for comment

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

The WOAH Aquatic Animal Health Code

6. *Aquatic Code* items for Member comment

6.1. Glossary

Background

Chapter 5.12. 'Movement of ornamental aquatic animals' was adopted by the General Assembly at the 92nd General Session in 2025. Chapter 5.12. provides recommendations for managing the disease risks associated with movement of ornamental aquatic animals and complements other provisions of the *Aquatic Code*. To ensure a common understanding of the term 'ornamental aquatic animal' the Aquatic Animals Commission proposed a new definition for 'ornamental aquatic animal' be included in the Glossary of the *Aquatic Code*. The new definition was adopted by the General Assembly at the 92nd General Session in May 2025, including a modification proposed during the session.

September 2025 meeting

Comments were received from Members for the work programme requesting the Aquatic Animals Commission to consider the implications of the revision of the glossary definition for 'ornamental aquatic animal' adopted at the 2025 General Session.

The Aquatic Animals Commission considered comments on the definition for 'ornamental aquatic animals' and revised the definition to align with the proposed definition as it was circulated in its February 2025 report. The Commission agreed that the adopted definition did not distinguish between ornamental aquatic animals that are kept as pets from those that are traded for sale as pets. The Commission noted that aquatic animals kept as pets do not provide a significant risk for disease transmission and should not be included in the definition. The Commission highlighted that the new Chapter 5.12. 'Movement of ornamental aquatic animals' focused on the movement of ornamental aquatic animals and as such the revised definition included the sale of ornamental aquatic animals for use as pets but not pets within households. The definition was revised from '…for sale and use as a pet' to '… to be supplied for sale as a pet'.

The Aquatic Animals Commission's responses to comments (work programme) considered are presented in Annex 3.

Texts for comment

The revised glossary term 'ornamental aquatic animal' is presented as Annex 5 for comment.

6.2. Chapter 4.3. 'Application of compartmentalisation'

Background

At its September 2023 meeting, the Aquatic Animals Commission developed 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 circulated in the Commission's September 2022 meeting report, as well as feedback from WOAH Aquatic Animal Focal Point workshops. 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 Aquatic Animals Commission considered comments received on the discussion paper and noted that responses were generally supportive. The Commission revised the discussion paper to update its proposed approaches to the revision of Chapter 4.3. and it was circulated 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.

At its February 2025 meeting the Commission finalised the revised draft Chapter 4.3. and revised the Glossary definition for 'compartment' for consistent usage in the draft text. The Commission noted that when the revised Chapter 4.3. is adopted the implications on other chapters in the Aquatic Code including surveillance requirements will be reviewed.

The revised Chapter 4.3. and Glossary definition 'compartment' have been circulated once for comment.

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 (item 7.1., page 21)

September 2025 meeting

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

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the revised draft Chapter 4.3. 'Application of compartmentalisation' and revised Glossary definition 'compartment' while proposing some suggestions for clarity and some proposals for content to consider.

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

The Aquatic Animals Commission noted that to account for the many comments received, extensive revisions including the re-ordering of articles were made. Revisions made provide clarity to the categories of independent and dependent compartments and their requirements. The Commission also discussed that surveillance requirements for independent and dependent compartments may need to be considered in Chapter 1.4. 'Aquatic animal disease surveillance'. The Commission agreed to review Chapter 1.4. at its February 2026 meeting and communicate to Members what revisions may be required.

The Aquatic Animals Commission noted that risk analysis is an integral concept within the revised Chapter 4.3. and that revisions were made throughout the text to highlight this concept. Risk analysis should account for the category of compartment, the disease-specific factors of the pathogenic agents of concern as well as environmental factors that may influence disease transmission. Determination of appropriate risk management measures for a compartment will depend on the outcome of the risk analysis being performed.

The rationale for revisions and re-ordering are provided in Annex 3.

Texts for comment

The revised Chapter 4.3. 'Application of compartmentalisation' is presented as Annex 6 for comment.

The revised glossary term for 'compartment' is presented as Annex 7 for comment.

6.3. Chapter 4.7. 'Fallowing in aquaculture'

Background

At its September 2024 meeting, the Aquatic Animals Commission agreed that Chapter 4.7. 'Fallowing in aquaculture', required a review as a consequence of the development of draft new chapters on emergency disease preparedness and disease outbreak management.

At its February 2025 meeting the Aquatic Animals Commission reviewed and revised the text of Chapter 4.7. to align with new draft Chapters 4.10. 'Emergency disease preparedness' and 4.11. 'Disease outbreak management' adopted at the 92nd.

The revised Chapter 4.7. 'Fallowing in aquaculture' has been circulated once for comment.

Previous Commission reports where this item was discussed

September 2024 (Item 7.1.3., page 28), February 2025 (item 7.2., page 22).

September 2025 meeting

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

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the revised Chapter 4.7. 'Fallowing in aquaculture'.

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

The Aquatic Animals Commission noted that due to numerous comments to improve clarity, extensive revisions were made to the revised draft chapter. In addition to a version with track changes, a clean version is also provided in the annex for better readability and easier commenting.

Texts for comment

The revised Chapter 4.7. 'Fallowing in aquaculture' is presented as Annex 8 for comment.

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

Background

At its September 2024 meeting, 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.

At its February 2025 meeting, the Aquatic Animals Commission agreed that the work on Section 5 should focus on providing a clear understanding of how trade should occur and identifying barriers to the implementation of these standards. The objectives of the revision would be to improve transparency and overall confidence between trading partners when implemented. It was agreed that the intention was to work together with the Code Commission on horizontal chapters such as the new introductory chapter (see item 7.1.2.). The Aquatic Animals Commission agreed to finalise its work plan for Section 5 at its September 2025 meeting following the Bureaux meeting with the Code Commission.

Previous Commission reports where this item was discussed

September 2024 report (Item 5.2.2., page 10), February 2025 report (Item 8.2.1., page 27).

September 2025 meeting

The Aquatic Animals Commission discussed Section 5. 'Trade measures, importation/exportation procedures and health certification'. The Commission agreed that the objectives of the proposed approach to the revision of Section 5 would include:

- revision of older standards and improvement of quality as necessary;
- addressing any gaps in the standards for trade;
- improving usability for developing trade measures;
- addressing aquatic specific trade issues while also maintaining alignment with *Terrestrial Code*;
- improving alignment of chapters within Section 5 and between Section 5 and other sections of the *Aquatic Code*.

Considering these objectives the Aquatic Animals Commission proposed a plan for Section 5 with considerations for the trade specific articles in disease-specific chapters and other references to trade in the *Aquatic Code*.

Texts for comment

The Proposed approach to revision of Section 5. 'Trade measures, importation/exportation procedures and health certification' is presented as Annex 9 for comment.

6.5. Article 9.2.2. of Chapter 9.2. 'Infection with *Aphanomyces astaci* (crayfish plague)'

Background

The *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases met in April 2025 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 *Aphanomyces astaci* (crayfish plague)'. This assessment was an update of a previous assessment completed in 2015.

September 2025

The Aquatic Animals Commission considered the *ad hoc* Group report on Susceptibility of Crustacean Species to Infection with *A. astaci* (crayfish plague) and commended the members for their comprehensive work.

The Aquatic Animals Commission agreed to apply Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' using criteria outlined in its September 2024 report (Item 6.5.1., page 18) and to amend the list of susceptible species in Article 9.2.2. in line with recommendations of the *ad hoc* Group.

With the application of Article 1.5.9. the Aquatic Animals Commission agreed that *Faxonius spp.* should be listed at the genus level. The assessment found three species of *Faxonius spp.* were susceptible.

With the application of Article 1.5.9. the Aquatic Animals Commission agreed that *Procambarus spp.* should be listed at the genus level. The assessment found two species of *Procambarus spp.* were susceptible.

The application of the criteria from Article 1.5.9. is shown in the table below. In the table grey highlight is used to indicate whether susceptible species are considered at species or genus level.

Family	Genus	Scientific name
Astacidae	*Astacus*	*Astacus astacus*
	Austropotamobius	*Austropotamobius pallipes*
	Pacifastacus	*Pacifastacus leniusculus*
		Pontastacus leptodactylus
Cambaridae	*Faxonius*	*Faxonius limosus*
		Faxonius obscurus
		Faxonius rusticus
	Procambarus	*Procambarus alleni*
		Procambarus clarkii
Cambaroididae	*Cambaroides*	*Cambaroides japonicus*
Parastacidae	*Cherax*	*Cherax quadricarinatus*
Potamidae	*Potamon*	*Potamon potamios*
Varunidae	*Eriocheir*	*Eriocheir sinensis*

Relevant sections of Chapter 2.2.2. 'Infection with *A. astaci* (crayfish plague)' in the *Aquatic Manual* were also amended in line with recommendations of the *ad hoc* Group (see item 8.1.1.).

The Aquatic Animals Commission encouraged Members to refer to the *ad hoc* Group's April 2025 report available on the WOAH website for details of the assessment conducted by the *ad hoc* Group.

Texts for comment

The revised Article 9.2.2. of Chapter 9.2. 'Infection with *A. astaci* (crayfish plague)' is presented in Annex 10 for comment.

6.6. Article 10.3.5. and 10.3.6. of Chapter 10.3. 'Infection with *Gyrodactylus salaris*'

Background

Following the revision of Chapter 1.4. 'Aquatic animal disease surveillance' the Aquatic Animal Commission reviewed the periods of basic biosecurity conditions (BBC) and targeted surveillance (TS) periods in the disease-specific chapters of the *Aquatic Code*. An assessment on the periods was completed by a WOAH Collaborating Centre expert and informed proposed new periods in Articles X.X.5. to X.X.7. (and 10.4.15. to 10.4.10.) in all disease-specific chapters. These assessments were circulated for comment twice and at its February 2025 meeting the Commission agreed that pathway 2 was not suitable for infection with *Gyrodactylus salaris* as available scientific evidence indicated that clinical disease is not seen in all susceptible species.

At the 2025 General Session some Members expressed that pathway 2 (historical freedom) should be suitable for infection with *G. salaris* because while infection with *G. salaris* may present subclinically in some susceptible species it has at least one susceptible species which shows clinical signs. Thus, some Members indicated it should be possible to use pathway 2 (historical freedom) with appropriate surveillance and early detection systems. In response, the President of the Aquatic Animals Commission agreed that these comments required more consideration and recommended to the Assembly that pathway 2 (historical freedom) be placed under study and discussed by the Commission at its September 2025 meeting.

Previous Commission reports where this item was discussed

February 2025 (Item 6.4., page13 and Annex 3, page 31).

September 2025 meeting

Comments were received under the work programme item requesting that the Aquatic Animals Commission consider the suitability of pathway 2 (historical freedom) for infection with *Gyrodactylus salaris*.

The Aquatic Animals Commission considered comments from the 92nd General Session (May 2025), comments submitted by Members and the Reference Laboratory expert opinion. The Commission agreed that Atlantic salmon (*Salmo salar*) would show clinical disease and pathway 2 (historical freedom) would be suitable for this species. The Commission also noted that other susceptible species may not present clinically and pathway 2 (historical freedom) would not be suitable for those species. The Commission agreed maintain pathway 2 for both Articles 10.3.5. and 10.3.6. adding a text indicating that it could only be used for Atlantic salmon.

The Aquatic Animals Commission's responses to comments considered (on the work programme) are presented in Annex 3.

The Aquatic Animals 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*') can be found on the website. The assessment was updated to reflect the use of pathway 2 (historical freedom) for Atlantic salmon.

Texts for comment

The revised Articles 10.3.5. and 10.3.6. of Chapter 10.3. 'Infection with *G. salaris*' is presented in Annex 11 for comment.

6.7. Article 10.4.9. of Chapter 10.4. 'Infection with infectious salmon anaemia'

Background

Following the revision of Chapter 1.4. 'Aquatic animal disease surveillance' the Aquatic Animals Commission reviewed the periods of basic biosecurity conditions (BBC) and targeted surveillance (TS) periods in the disease-specific chapters of the *Aquatic Code*. An assessment on the periods was completed by a WOAH Collaborating Centre expert and informed proposed new periods in Articles X.X.5. to X.X.7. (and 10.4.15. to 10.4.10.) in all disease-specific chapters. These assessments were circulated for comment twice.

At its February 2025 meeting the Aquatic Animals Commission did not agree with a comment that the period of TS for compartments free of infection with infectious salmon anaemia virus HPR0 should be extended to two years. The Commission noted that shorter periods for compartments take into account the unique characteristics of compartments. TS needs to be sufficiently sensitive to detect the pathogenic agent if present and it includes defensible assumptions about prevalence in the target population.

During the 2025 General Session some Members expressed that the period for a free compartment should be two years. It was noted that ISAV HPR0 is transiently detected in stable populations of Atlantic salmon and most readily during stressful events such as spawning and may not be detected in one year. Also, there is limited understanding of the epidemiology of ISAV HPR0 in land-based establishments and due to this uncertainty, a longer period is required to consider a compartment free from infection with ISAV HPR0.

Previous Commission reports where this item was discussed

February 2025 (Item 6.4., page13 and Annex 3, page 38).

September 2025 meeting

Comments were received under the work programme item requesting the Aquatic Animals Commission to consider targeted surveillance of two years for compartments free from infection with ISAV HPR0.

The Aquatic Animals Commission considered the information provided and reviewed the assessment of BBC and TS and noted that ISAV HPR0 has a very low likelihood of early detection. The Commission consulted Reference Laboratory experts who supported the low likelihood of early detection for ISAV HPR0. Based on this information, the Commission agreed that a minimum period of two years was appropriate for targeted surveillance.

The Aquatic Animals Commission's responses to comments (on the work programme) considered are presented in Annex 3.

The Aquatic Animals 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*') can be found on the website. The assessment was updated to reflect targeted surveillance for ISAV HPR0.

Texts for comment

Article 10.4.9. of Chapter 10.4. 'Infection with infectious salmon anaemia' is presented in Annex 12 for comment.

6.8. Update to the viral names of pathogenic agents for WOAH listed diseases

Background

At its February 2025 meeting the Aquatic Animals Commission noted that several 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.

Previous Commission reports where this item was discussed

February 2025 (Item 8.2.2., page 28).

September 2025 meeting

The Aquatic Animals Commission reviewed the current classifications in ICTV against the names used in the *Aquatic Code* and the *Aquatic Manual* (see Item 8.3.). Of the 18 viral pathogenic agents listed as WOAH listed diseases, 12 needed to be updated.

In the *Aquatic Code* these include:

- Diseases of crustaceans: infection with decapod iridescent virus 1 (Ch 9.3.), infection with hypodermal and haematopoietic necrosis virus (Ch 9.5.), infection with infectious myonecrosis virus (Ch 9.6.) and infection with Taura syndrome virus (Ch 9.8.).
- Diseases of fish: infection with infectious salmon anaemia virus (Ch 10.4.), infection with infectious salmonid alphavirus (Ch 10.5.), infection with infectious haematopoietic necrosis virus (Ch 10.6.), infection with koi herpesvirus (Ch 10.7.), infection with spring viraemia of carp virus (Ch 10.9.), infection with viral haemorrhagic septicaemia virus (Ch 10.10.) and infection with tilapia lake virus (Ch 10.11.).
- Diseases of molluscs: infection with abalone herpesvirus (Ch 11.1.).

The Aquatic Animals Commission informed Members that once these name changes are adopted, relevant changes would be made in the *Aquatic Code* and *Aquatic Manual*.

During the review of viral names for pathogenic agents the Commission noted that infection with yellowhead virus genotype 1 (Ch 9.10.) needed to be updated to the same format as the other viral diseases. Reference to the Order was removed from article 9.10.1.

Texts for comment

The revised scientific names for viral pathogenic agents of WOAH listed diseases is presented in Annex 13 for comment.

6.9. 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 Aquatic Animals 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 Aquatic Animals 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 Aquatic Animals 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 Reference Laboratories could play in enhancing the understanding of emerging diseases.

The Aquatic Animals 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.

6.9.1. 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 Aquatic Animals 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*.

At its September 2024 and February 2025 meetings, the Aquatic Animals 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 for Members to provide information to the Commission 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 (Item 7.3.1., page 23).

September 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.

In its February 2025 report the Aquatic Animals Commission had requested that Members provide feedback and evidence on the importance of CMNV and the Commission noted that no evidence or feedback had been received from Members. With the absence of information and lack of reporting the Commission agreed that infection with CMNV would no longer be recognised by the commission as an emerging disease.

The Aquatic Animals Commission emphasised that any disease events meeting the definition of an emerging disease should be reported by Members in accordance with article 1.1.4.

The Aquatic Animals Commission informed Members that a technical disease card for infection with CMNV remains available on the WOAH website.

6.9.2. 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 Aquatic Animals 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*.

At its September 2024 and February 2025 meetings, the Aquatic Animals Commission noted that there had been no notifications of infection with EHP reported in WAHIS since September 2021. The Commission requested for Members to provide information to the Commission 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 (Item 7.3.1., page 24).

February 2025 meeting

The Aquatic Animals Commission noted that there had been no notifications of infection with Enterocytozoon hepatopenaei (EHP) in WAHIS since its previous meeting. The Commission considered recent scientific information on the impact of infection with EHP.

At its February 2025 report the Aquatic Animals Commission had requested that Members provide feedback and evidence on the importance of EHP and the Commission noted that no evidence or feedback had been received from Members. With the absence of information and lack of reporting the Commission decided that infection with EHP would no longer be recognised by the Commission as an emerging disease.

The Aquatic Animals emphasised that any disease events meeting the definition of an emerging disease should be reported by Members in accordance with Article 1.1.4.

The Aquatic Animals Commission informed Members that a technical disease card for infection with EHP is available on the WOAH website.

7. *Aquatic Code* items for Member Information

7.1. *Aquatic Code* Ongoing work items

7.1.1. Chapter 4.2. 'Zoning and compartmentalisation'

Background

The Aquatic Animals Commission agreed that work to revise Chapter 4.2. 'Zoning and compartmentalisation' will commence following the revision of Chapter 4.3. 'Zoning and compartmentalisation'. The revised Chapter 4.3. has been circulated for comment once.

September 2025 meeting

The Aquatic Animals Commission completed a gap analysis on Chapter 4.2. 'Zoning and compartmentalisation' taking into account work to be done on the zoning chapter in the *Terrestrial Code* and the current situation in the aquatic industry. The Commission decided to consult with Collaborating Centres and work on a revised text to be considered at its next meeting.

7.1.2. Chapter 5.Y. 'Introduction to trade measures, importation/exportation procedures and health certification'

Background

At the 2024 Bureaux meeting the Aquatic Animals Commission and Terrestrial Code Animal Health Standards Commission discussed the need to develop, in collaboration, a new introductory chapter for Section 5 of the *Aquatic Code* and *Terrestrial Code*, respectively to provide clarity on its objectives and how the chapter should be used.

A Task force was formed with two members from the Aquatic Animals Commission and the Code Commission, respectively, which met twice during 2025 to draft the new chapter.

Previous Commission reports where this item was discussed

February 2025 (Item 8.2.1., page 27).

September 2025 meeting

The Aquatic Animals Commission reviewed the new draft Chapter 5.Y. 'Introduction to trade measures, importation/exportation procedures and health certification'. The Commission commended the Task force for their work on the chapter. The Commission noted that the chapter had details which were not normally included in an introductory chapter. The Commission agreed that the Task force should review the chapter again following the introductory chapter template. The Commission considered that the information not included in the introductory chapter could be considered in line with the proposed revisions to Section 5 (see item 6.4.).

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

Background

The WOAH Working Group on Antimicrobial Resistance (Working Group) developed the revised draft 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 to align, as relevant, with Chapter 6.10. of the *Terrestrial Code*.

At its September 2024 meeting, the Aquatic Animals 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 recently adopted Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine' of the *Terrestrial Code*. The Aquatic Animals Commission agreed that revision of the chapters in 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.

At its February 2025 meeting, the Aquatic Animals Commission reviewed a gap analysis prepared by WOAH Secretariat in collaboration with a Collaborating Centre and agreed to start work to update Section 6 of the *Aquatic Code* and requested that an *ad hoc* Group be convened to revise Chapter 6.2.

Previous Commission reports where this item was discussed

September 2024 (Item 7.1.4., page 28), February 2025 (Item 8.1.3., page 26).

September 2025 meeting

The Aquatic Animals Commission were updated that the *ad hoc* Group had met twice in July and August 2025 to propose revisions to Chapter 6.2 'Principles for responsible and prudent use of antimicrobial agents in aquatic animals' utilising the draft created in association with a Collaborating Centre. The proposed revisions were submitted to the Commission and discussed during their last meeting in September 2025. The Commission appreciated the work of the *ad hoc* Group and suggested the inclusion of more examples for aquatic animals raised for purposes beyond human food production.

7.1.4. Section 7. 'Welfare of farmed fish'

Background

At its September 2024 meeting, the Aquatic Animals Commission agreed that a review of the scientific basis of welfare of farmed fish should be completed to ensure that the recommendations in the *Aquatic Code* are scientifically sounds and meet the needs of Members. The Commission noted that this work was aligned with Activity 1.3.'Review of the scientific basis of existing animal welfare standards' under the WOAH Aquatic Animal Health Strategy. The Commission also agreed that the review would be used to inform revisions of the chapters in Section 7. 'Welfare of farmed fish'.

At its February 2025 meeting, the Aquatic Animals Commission was informed that an expert had been contracted to review the scientific justification and recommendations for the chapters in Section 7 that would be completed by August 2025 and provided to the Commission at its September 2025 meeting.

Previous Commission reports where item was discussed

February 2025 (Item 8.1.4., page 26)

September 2025 meeting

The Aquatic Animals Commission considered the review of scientific justification and recommendations for revision to Section 7.'Welfare of farmed fish'. The Commission noted that that this was a very comprehensive review of the available evidence.

The Aquatic Animals Commission agreed that the review of scientific evidence could be used as the basis for revisions to Chapters 7.2. to 7.4. The Commission requested that the service provider prepare revised draft Chapters 7.2 to 7.4. In addition, the Commission requested a revised draft Chapter 7.1. 'Introduction to the recommendations for the welfare of farmed fish' taking into consideration relevant elements of the corresponding Chapter 7.1. 'Introduction to the recommendations for animal welfare' in the *Terrestrial Code*.

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

Assessments have now been completed for all the eleven fish, ten crustacean and seven molluscan listed diseases.

Diseases of amphibians

The Aquatic Animals Commission was informed that the first meeting of the *ad hoc* Group on Susceptibility of Amphibian Species to Infection with WOAH Listed Diseases is planned for 2026 dependent on availability of resources. This *ad hoc* Group will assess susceptible species for the three WOAH listed amphibian diseases.

Maintaining up-to-date susceptible species lists

The Aquatic Animals Commission noted that as new information becomes available on susceptible species the lists in Articles X.X.2. would need to be updated. The Commission agreed that a standing *ad hoc* Group should be proposed to review new evidence of susceptibility to WOAH listed diseases. Evidence assessed would be gathered when submitted by Members, experts and Reference Centres. After the assessments were completed, the Commission would review them and determine when the list of susceptible species would be updated. The Commission requested the Secretariat to report back to the Commission on proposed process and possible members.

7.2. *Aquatic Code* new work items

7.2.1. Chapter 1.1. 'Notification of diseases, and provision of epidemiological information'

The Aquatic Animals Commission considered comments from WAHIAD relevant to Chapter 1.1. 'Notification of diseases, and provision of epidemiological information' and was informed that WAHIAD had also provided comments on the corresponding chapter of the *Terrestrial Code*.

The Bureaux meeting of the Aquatic Animals Commission and the Code Commission agreed to propose revisions to Chapter 1.1. 'Notification of diseases and provision of epidemiological information' of the *Terrestrial Code* and *Aquatic Code* (see Item 3). Given the importance of alignment, the Bureaux agreed that these revisions should be undertaken in parallel to ensure consistency between respective Chapters 1.1. The Bureaux agreed to review each other's draft revised Chapters 1.1. at their respective February 2026 meetings with the intention to circulate the revised texts at that time so that Members could consider proposed amendments to both Chapters 1.1. to ensure a coordinated process.

7.3. *Aquatic Code* other items for consideration

7.3.1. Review of the scientific justification for Article 1.5.9. 'Listing susceptible species at a taxonomic ranking of Genus or higher'

Background

During the 92nd WOAH General Session (May 2025) a Member questioned the appropriateness of listing susceptible species at the Family and/or Genus levels. The President of the Aquatic Animals Commission explained that listing at a Family or Genus level was based on the application of Article 1.5.9. of Chapter 1.5. Criteria for listing species as susceptible to infection with a specific pathogen' and was only applied for diseases with a broad host range. The President agreed that the Aquatic Animals Commission would review the use of Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' at its September 2025 meeting.

September 2025 meeting

The Aquatic Animals Commission discussed the issue raised at the 92nd General Session and emphasised that the scientific justification for Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' has been outlined in previous Commission reports and that this article had been adopted by the World Assembly of Delegates in 2019.

The Aquatic Animals Commission encouraged Members to review these texts which provide the rationale and justifications for Article 1.5.9. including the Aquatic Animals Commission's February 2016 report (item 13, page 12), September 2016 report (item 13, page 11), February 2017 report (item 5, page 8), September 2017 report (item 1.2., page 5), February 2018 report (item 1.5., page 6), September 2018 report (item 1.3., page 5), February 2019 (item 1.3., page 5) and September 2024 report (item 6.5.1., page 16).

7.3.2. Application of model Articles 10.X.10. and 10.X.15. to WOAH listed diseases that affect non-salmonids

Background

During the 92nd General Session (May 2025) model Articles 10.X.10. 'Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with pathogen X' and 10.X.15. 'Importation of gametes and fertilised eggs of fish for aquaculture from a country, zone or compartment not declared free from infection with pathogen X' were adopted. Prior to adoption, a Member noted that the WOAH listed diseases for which model Articles 10.X.10. and 10.X.15. were applied were more relevant to temperate regions than tropical regions. The Member suggested that the application of the model articles should be further reviewed. The President of the Aquatic Animals Commission agreed with this suggestion and informed the Assembly that this would be considered at the Commission's September 2025 meeting.

September 2025 meeting

The Aquatic Animals Commission noted that during its February 2024 meeting an assessment of the suitability of the provisions of Chapter 4.6. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' was performed (see February 2024 report, item 7.2., page 30). This assessment was utilised to determine the suitability of including a cross reference to the provisions of Chapter 4.6. in model Articles 10.X.10. and 10.X.15. in disease-specific chapters. Considerations for the assessment included modes of transmission of the pathogen, relevance of trade in gametes and fertilised eggs and availability of an egg disinfection protocol. As a result of the assessment, the Commission agreed to only include the model articles with cross references for four diseases: infection with salmonid alphavirus, infection with infectious haematopoietic virus, infection with viral haemorrhagic septicaemia and infection with infectious salmon anaemia.

The Aquatic Animals Commission reviewed the previous assessment and agreed that the assessment was still valid and as such the cross-references should only be included in the four diseases: infection with salmonid alphavirus, infection with infectious haematopoietic virus, infection with viral haemorrhagic septicaemia and infection with infectious salmon anaemia. The Commission encouraged Members to provide relevant information to support the addition of a cross-reference to Chapter 4.6. in any other WOAH listed disease-specific chapters for its consideration.

The WOAH *Manual of Diagnostic Tests for Aquatic Animals*

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

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

8. *Aquatic Manual* items for Member comment

8.1. Section 2.2. 'Diseases of crustaceans'

8.1.1. Section 2.2.1. and 2.2.2. of Chapter 2.2.2. 'Infection with *Aphanomyces astaci* (crayfish plague)'

Background

The *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases met in April 2025 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 *Aphanomyces astaci* (crayfish plague)'. This assessment is an update of a previous assessment completed in 2015.

September 2025

The Aquatic Animals Commission amended Sections 2.2.1. and 2.2.2. of Chapter 2.2.2. 'Infection with *Aphanomyces astaci* (crayfish plague)' in line with the recommendations of the *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases (see Item 6.5.).

The Commission agreed to apply Article 1.5.9. 'Listing of susceptible species at a taxonomic ranking of Genus or higher' using criteria outlined in its September 2024 report (Item 6.5.1., page 18) and to amend the list of susceptible species in Article 9.2.2. in line with recommendations of the *ad hoc* Group. With the application of Article 1.5.9. the Commission agreed that *Faxonius* spp. *and Procambarus* spp. should be listed at the genus level.

The Commission encouraged Members to refer to the *ad hoc* Group's April 2025 report available on the WOAH website for details of the assessment conducted by the *ad hoc* Group.

Texts for comment

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.2.2. 'Infection with *A. astaci* (crayfish plague)' are presented in Annex 14 for comment.

8.2. Section 2.4. 'Diseases of molluscs'

8.2.1. Chapter 2.4.2. 'Infection with *Bonamia exitiosa'* and Chapter 2.4.3. 'Infection with *Bonamia ostreae'*

Background

In the 2024/2025 review cycle, the Aquatic Animals Commission updated Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' and Chapter 2.4.3. 'Infection with *Bonamia ostreae',* reformatted them using the new disease chapter template, and proposed them for adoption in May 2025. The chapters were adopted by the Members on the provision that the Commission review the case definitions given in Section 6 'Corroborative diagnostic criteria'.

Previous Commission reports where this item was discussed

September 2024 report (items 8.3.1. and 8.3.2., pages 31–33), February 2025 report (Items 9.3.1. and 9.3.2., pages 31–32).

September 2025 meeting

For this agenda item, the Aquatic Animals Commission was joined by the WOAH Reference Laboratory expert on these two molluscan diseases. The Aquatic Animals Commission explained that the case definition for a confirmed case in either apparently healthy or clinically affected animals should recommend two specific methods. The expert clarified that for these diseases, molecular methods may identify endogenous DNA and therefore should either be combined with another diagnostic method or two species-specific molecular methods targeting non-overlapping regions of the pathogen genome should be used.

The Aquatic Animals Commission agreed to amend the case definition accordingly and, for chapters with this issue, to add a sentence to the introductory text to Section 6 stating that when two molecular methods are used for confirmation of a case, it is preferable to use two species-specific methods targeting non-overlapping regions of the pathogen genome.

Texts for comment

The revised Section 6 'Corroborative diagnostic criteria' of Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' and Chapter 2.4.3. 'Infection with *Bonamia ostreae'* are presented as Annex 15 for comment.

8.2.2. Chapter 2.4.4. 'Infection with *Marteilia refringens'*

September 2025 meeting

Following the discussion on the two *Bonamia* chapters described above (item 8.2.1.), the Aquatic Animals Commission reviewed Section 6 'Corroborative diagnostic criteria' of Chapter 2.4.4. 'Infection with *Marteilia refringens'*.

Texts for comment

The revised Section 6 of Chapter 2.4.4. 'Infection with *Marteilia refringens'* is presented as Annex 16 for comment.

8.2.3. Chapter 2.4.5. 'Infection with *Perkinsus marinus'*

September 2025 meeting

The Aquatic Animals Commission reviewed Chapter 2.4.5. 'Infection with *Perkinsus marinus'*, 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 2.4.5. 'Infection with *Perkinsus marinus*, is presented as Annex 17 for comment.

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

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

Background

At its February 2025 meeting the Aquatic Animals Commission amended Chapter 2.4.6. 'Infection with *Perkinsus olseni'*, which had been updated by a WOAH Reference Laboratory expert and reformatted using the new disease chapter template.

Previous Commission reports where this item was discussed

February 2025 report (Item 10.1.1., page 33).

September 2025 meeting

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the revised Chapter 2.4.6. 'Infection with *Perkinsus olseni'*. The Commission's responses to comments considered are presented in Annex 3.

Texts for comment

The revised Chapter 2.4.6. 'Infection with *Perkinsus marinus'*, is presented as Annex 18 for comment.

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

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

Background

At its February 2025 meeting the Aquatic Animals Commission amended Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis'*, which had been updated by the *ad hoc* Group on susceptibility of mollusc species to infection with WOAH listed diseases and reformatted using the new disease chapter template.

Previous Commission reports where this item was discussed

February 2025 report (Item 10.1.2., page 34).

September 2025 meeting

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the revised Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis'*. The Commission's responses to comments considered are presented in Annex 3.

Texts for comment

The revised Chapter 2.4.7. 'Infection with *Xenohaliotis californiensis'*, is presented as Annex 19 for comment.

8.3. Update to the viral names of pathogenic agents for WOAH listed diseases

Background

At its February 2025 meeting the Aquatic Animals Commission noted that some 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.

Previous Commission reports where this item was discussed

February 2025 (Item 8.2.2., page 28).

September 2025 meeting

The Aquatic Animals Commission reviewed the current classifications in ICTV against the names used in the Aquatic Code (see Item 6.8.) and the Aquatic Manual. Of the 18 viral pathogenic agents listed as WOAH listed diseases, 12 needed to be updated.

In the Aquatic Manual these include:

- Diseases of crustaceans: infection with decapod iridescent virus 1 (Ch 2.3.3.), infection with hypodermal and haematopoietic necrosis virus (Ch 2.2.5.), infection with infectious myonecrosis virus (Ch 2.2.6.), infection with Machrobrachium rosenbergii nodavirus (white tail virus) (Ch 2.2.7.) and infection with Taura syndrome virus (Ch 2.2.8.).

- Diseases of fish: infection with infectious salmon anaemia virus (Ch 2.3.4.), infection with infectious haematopoietic necrosis virus (Ch 2.3.5.), infection with koi herpesvirus (Ch 2.3.6.), infection with infectious salmonid alphavirus (Ch 2.3.8.), infection with spring viraemia of carp virus (Ch 2.3.9.) and infection with viral haemorrhagic septicaemia virus (Ch 2.3.10.).

- Diseases of molluscs: infection with abalone herpesvirus (Ch 2.4.1.).

Texts for comment

The revised scientific names for viral pathogenic agents of WOAH listed diseases is presented in Annex 20 for comment.

9. *Aquatic Manual* items for Member information

9.1. *Aquatic Manual* ongoing work items

9.1.1. *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 September 2025, only 2 of 30 disease-specific chapters are yet to be reformatted and comprehensively revised: infection with *Batrachochytrium dendrobatidis* and infection with *Ranavirus* species. Two new chapters still need to be drafted: infection with tilapia lake virus and infection with *Megalocytivirus pagrus1*.

With regard to the amphibian diseases (*B. dendrobatidis* and Ranavirus), the Secretariat of the Wildlife Working Groups was consulted and kindly facilitated the identification of potential contributors. The Commission wishes to express its sincere appreciation for this valuable collaboration, which will contribute significantly to the development of these chapters.

9.1.2. 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)'. In section 6.1.2. 'Confirmation of cases in apparently healthy animals', 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.

In February 2025, 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

Previous Commission report where this item was discussed

September 2024 (Item 9.1.1., page 34), February 2025 (Item 11.1.2., page 34)

September 2025 meeting

A virtual expert consultation, chaired by the President of the Aquatic Animals Commission, was convened in July 2025. Participants included the two Reference Laboratory experts for IHHNV and four additional subject-matter experts from Americas and Asia. The consultation focused on the proposed diagnostic tests intended to confirm the presence of the pathogen and to determine infection in apparently healthy animals, while excluding endogenous viral elements (EVEs). To address the issue, the experts proposed amendments to the case definition in Section 6.1.2. 'Definition of confirmed case in apparently healthy animals' and added a paragraph in Section 2.1.1 'Aetiological agent' describing IHHNV EVE.

The Commission noted that the proposal did not fully meet its expectations, particularly due to a lack of clarity in the information provided and the need for more precise and concise information. Consequently, the Commission recommended that the Reference Laboratory experts be given clearer instructions on the Commission's expectations, and that any new feedback be discussed at the February 2026 meeting.

Furthermore, the Aquatic Animals Commission extended an invitation to a Reference Laboratory expert for IHHNV to participate virtually during the Aquatic Animal Commission February 2026 meeting to support the development of a revised proposal that could be circulated for comment with the meeting report.

9.1.3. 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.

During the February 2025 meeting, the chair of the Group reported on the progress the Group has made since the first electronic meeting in November 2024: the review the available literature regarding detection methods for *M. pagrus1*; the establishment of an initial short-list of the most appropriate methods of detection of all three genogroups of *M. pagrus1*; and the development of a technical disease card providing preliminary guidance on diagnostic methods for Members.

The inter-laboratory comparability (ILC) study will 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 disease card for infection with *M. pagrus1* is available in the three official languages at: Technical disease card: *Megalocytivirus pagrus1*.

Previous Commission report where this item was discussed

September 2024 (Item 9.1.2., page 34), February 2025 (Item 11.1.3., page 35).

September 2025 meeting

The Chair of the *ad hoc* Group reported the progress with the ILC project. The main output of this phase is the establishment of an interlaboratory comparability panel testing exercise, whereby the results of the initial analysis of interlaboratory data will be used to produce a comparison report. This report will identify reliable assays and outline recommendations to support the development of the *M. pagrus1* chapter for the *Aquatic Manual*.

The Chair of the *ad hoc* Group informed the Commission that preparations have been completed for the three expected genogroups of *M. pagrus1*, and sufficient material has been generated for inclusion in the comparability panel. This work has been undertaken collaboratively among members of the *ad hoc* Group. Prior to shipment, all materials will be subject to inactivation and safety validation processes to ensure biosafety compliance.

The Chair of the *ad hoc* Group also noted that these technical processes, combined with administrative procedures, have delayed the project timeline. A revised timeframe will be shared with the Aquatic Animals Commission

Drafting of the *Aquatic Manual* chapter will begin in parallel with the ongoing ILC test, though the chapter is not expected to be ready for the February 2026 meeting. As an interim measure, the disease card is available as a reference tool and could be updated if necessary. The next *ad hoc* Group meeting is anticipated for the end of 2025, and its report will provide further updates on these developments.

9.1.4. Chapter 2.3.9. 'Infection with spring viraemia of carp virus'

The Aquatic Animals Commission was updated on the ongoing effort to finalise a scientific research paper on real-time PCR assays for this disease. The results are expected in the form of publication or validation report. This updated scientific information will have implications on Tables 4.1 and 4.2, as well as Sections 5 and 6 of the chapter.

9.1.5. Chapter 2.3.5. 'Infection with infectious haematopoietic necrosis virus'

The Aquatic Animals Commission was updated on the ongoing effort to finalise a scientific research paper on real-time PCR assays for this disease. The results are expected in the form of publication or validation report. This updated scientific information will have implications on Tables 4.1 and 4.2, as well as Sections 5 and 6 of the chapter.

9.2. *Aquatic Manual* new work items

9.2.1. Chapter 1.1.2. 'Validation of diagnostic assays for infectious diseases of aquatic animals'

Progress is being made with the revision of Chapter 1.1.2. 'Validation of diagnostic assays for infectious diseases of aquatic animals'. The chapter is being thoroughly revised and adapted to aquatic animal disease validation purposes, namely surveillance of apparently healthy animals, presumptive diagnosis of clinically affected animals and confirmatory diagnosis of a suspect result from surveillance or presumptive diagnosis. The first draft will be ready for review by the Aquatic Animals Commission at the meeting in February 2026.

9.2.2. Section 2.1. 'Diseases of amphibians'

Two chapters in Section 2.1. 'Diseases of amphibians': Chapter 2.1.1. 'Infection with *Batrachochytrium dendrobatidis*' and Chapter 2.1.3. 'Infection with ranavirus' are the last two chapters that need to be revised using the new disease chapter template.

The Aquatic Animals Commission identified amphibian disease experts who will be asked to assist with the revisions of these chapters and to draft a new Chapter 2.1.0. 'General information' (on diseases of amphibians).

9.2.3. Infection with tilapia lake virus

The Aquatic Animals Commission identified an expert who will be asked to complete the draft chapter on infection with tilapia lake virus. It is hoped that the draft will be ready for review at the Aquatic Animals Commission meeting in February 2026.

10. Reference centres or change of experts

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

There were no new applications for Reference Laboratories or Collaborating Centres to be considered at this meeting. No changes of Reference Laboratory experts were assessed.

One change of contact point for the Collaborating Centre for Epidemiology and Risk Assessment of Aquatic Animal Diseases (Americas) was accepted. In line with Article 9 of the Procedures of Designation regarding changes of Contact Point, the institution is required to inform both the WOAH Delegate of the Member Country concerned and WOAH Headquarters. The Commission was informed of the change, and the WOAH database has been updated accordingly.

10.2. Update on the Aquatic Collaborating Centres Network

An update on the activities of this network was provided by a Commission member who also serves as its Chair, in their capacity as contact point of the Aquatic Collaborating Centre for Epidemiology and Risk Assessment of Aquatic Animal Diseases (Europe).

The network meets every 3 months with the objective of establishing a well-structured and coordinated working group. In recent meetings, members have been evaluating the most effective ways to organise activities, ensuring that these remain aligned with statutory responsibilities and that they bring added value to all participants. To this end, draft templates for a Concept Note and Terms of Reference have been circulated and are currently under development as working documents.

The Chair highlighted the need for additional support in managing the network, noting limitations in capacity and human resources. The Commission acknowledged these challenges and proposed that, at its next meeting, the network identify common issues of shared interest on which to focus collective efforts. The Commission also recommended exploring approaches to strengthen the visibility and relevance of aquatic animal health at the international level as a unifying theme.

In terms of outreach, the network actively participated in the 92nd General Session (May 2025), with a dedicated day at the Reference Centres kiosk. On this occasion, the Collaborating Centres of Korea (Rep. of), Chile and Norway presented their activities. This contribution was warmly welcomed and illustrated the value of repeating such initiatives in future General Sessions, extending the opportunity to other Reference Centres.

The Chair expressed appreciation for the Commission's understanding and suggestions and recommended that the leadership of the network be rotated annually among different Collaborating Centres. This would help distribute responsibilities more equitably and sustain motivation across the network. The next meeting of the network is scheduled for the second half of 2025.

11. Updates from WOAH Headquarters

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

At its September 2025 meeting, the Aquatic Animals Commission received a presentation from the World Animal Health Information and Analysis Department (WAHIAD) on notifications related to the occurrence of infections in new host species. The Commission noted the notification by Members of two new host species for infection with *Megalocytivirus pagrus 1* and infection with *Perkinsus olseni*. The Commission welcomed the collaboration between WAHIAD and the Standards Department in applying this process, which ensures that new host species of listed aquatic diseases are systematically identified and recorded.

The Aquatic Animals Commission also considered questions from WAHIAD on Chapter 1.1. of the *Aquatic Code*. The Commission highlighted the importance of holding further discussions with the Code Commission to ensure harmonisation of Chapter 1.1. across both Codes.

11.2. Update on the Taskforce on substandard and falsified veterinary products

The Aquatic Animals Commission was provided with an update on the work of WOAH Headquarters on Substandard and Falsified Veterinary Products (SFVP) and how to incorporate this topic into the WOAH Standards so that Members are better able to prevent, detect and respond to SFVP.

The Aquatic Animals Commission was informed that the Code Commission agreed to the incorporation of SFVP in Chapters 3.2. 'Quality of Veterinary Services', 3.4. 'Veterinary legislation' and Section 6 'Veterinary Public Health' concerning surveillance for antimicrobial resistance. The Code Commission agreed to consider the development of relevant new Glossary definitions after this work has been progressed. The Biological Standard Commission agreed to a relevant revision of Chapter 1.1.8. 'Principles of veterinary vaccine production' by the addition of risk-based post-marketing surveillance into the 'market monitoring' of the *Terrestrial Manual*.

The Aquatic Animals Commission requested to be updated on the proposed amendments to the *Terrestrial Code* and *Terrestrial Manua*l and that they would consider an update of relevant sections of the *Aquatic Code* and *Aquatic Manual* at a later time.

The Aquatic Animals Commission was informed that an *ad hoc* Group would be convened to undertake work which will be presented to relevant Commissions once completed.

11.3. WOAH Navigation Tool

The Aquatic Animals Commission was informed that the online versions of the WOAH *Aquatic Code*, *Terrestrial Code*, *Aquatic Manual* and the *Terrestrial Manual* were updated on 5 September 2025 to reflect all new and revised texts adopted at the 92nd WOAH General Session (May 2025).

The Aquatic Animals Commission was informed that in addition to the dynamic, searchable online version of the WOAH Standards Navigation Tool, first published in April 2025, users can also download PDFs of the entire *Aquatic Code*, *Terrestrial Code*, *Aquatic Manual* or *Terrestrial Manual,* or a specific chapter.

To access WOAH Standards, go to: Codes and Manuals - WOAH - World Organisation for Animal Health.

The Aquatic Animals Commission was also informed about forthcoming addition of a search tool for 'Recommendations for safe international trade by commodity' similar to the tool currently available to search terrestrial animal commodities that members of the Commission had reviewed and approved. All commodities would be integrated into the tool, enabling users to consult trade recommendations by commodity, including those considered safe.

11.4. The Observatory programme products

The Aquatic Animals Commission was updated on the ongoing activities of the WOAH Observatory. The Second Monitoring report will focus on the following sections: trade and sanitary measures, self-declarations and official status, movement control and precautions at borders, zoning and compartmentalisation, antimicrobial use and antimicrobial resistance and implementation of the One Health approach. A preview of the main results may be found on the WOAH website. The full report containing a description of the indicators, interpretation and recommendations for Members and WOAH will be published in late 2025. The findings will be incorporated into the development of the 8th Strategic Plan.

The Aquatic Animals Commission was also informed that in March 2025, the Observatory launched a call for proposals to select the topics for its next Thematic study. The prioritisation process is ongoing and will be guided by established decision-making criteria. The resulting list of priority topics will be submitted to the Observatory Steering Committee for final validation. The next Thematic study is scheduled to be conducted during 2026.

The Aquatic Animals Commission raised the need for fairer messaging in global comparisons between terrestrial and aquatic sectors regarding indicator interpretations. An example highlighted was the need for border precautions for specific aquatic diseases or how AMR surveillance may vary depending on the production volumes and distribution of susceptible species. The Commission also highlighted that the number of self-declarations could double once the data from 2024-2025 are incorporated to the indicator calculation.

11.5. *Ad hoc* Group to update the lists of priority diseases for which vaccination can reduce antimicrobial use

The Aquatic Animals Commission reviewed the terms of references for a planned *ad hoc* Group to update the evidence-based list of priority animal diseases for which vaccines could achieve the greatest reductions in antimicrobial use. This work would build on WOAH lists developed in 2015 and 2018 through two previous *ad hoc* Groups. Using a multi-criteria decision framework, the *ad hoc* Group proposed to rank candidate diseases in three production sectors: pigs, chickens, and cichlids.

The Aquatic Animals Commission recommended expanding the scope to all fish in aquaculture due to emerging bacterial diseases in the sector (e.g. *Piscirickettsia salmonis* in salmonids). The Commission also advised that a review of recent work done in association with STAR-IDAZ in 2025 on advancing aquaculture health research including highest priority areas for vaccines be considered. The Commission highlighted the need to carefully consider and define metrics for success. The drafting of target product profiles that set out desired vaccine characteristics for priority diseases and of a communication, dissemination and exploitation plan (2026–2030) has the potential to strategically direct vaccine R&D and production investment.

The WOAH Secretariat noted these points and agreed to amend the terms of reference accordingly. The Secretariat reported that an *ad hoc* Group would be convened in 2025 and the report would be presented to the relevant Commissions at respective February 2026 meetings.

11.6. Recommendations of the Governance Review Committee

The Code Commission was updated of the work of the WOAH Governance Review Committee in developing recommendations to the Assembly on updates to WOAH's legal framework, institutional, regional, technical and financial governance in accordance with Assembly Resolution

No. 12 (2024) and Resolution No. 5 (2025). Relevant to the work of WOAH Specialist Commissions, the work included a review of the appointment processes of experts to WOAH's Specialist Commissions and other technical bodies, the development of a Technical Procedural Manual on WOAH's technical decision-making processes and distinguishing binding and advisory standards, with final recommendations expected to be presented at the WOAH 93rd General Session. Specialist Commission members were encouraged to engage with their Delegate on the Governance Review Committee's work.

11.7. Animal Health Forum at the WOAH General Session

The Code Commission was updated on the Animal Health Forum held during the 92nd WOAH General Session (May 2025), which focused on veterinary vaccines and vaccination, and addressed barriers to vaccine availability, access, demand and adoption. Discussions covered trade implications, regulatory challenges, public perception, and the role of vaccines in reducing AMR and supporting One Health. The Forum informed the adoption of Resolution No. 29, which outlined 11 recommendations for WOAH and its Members to enhance vaccine availability, quality, and strategic use. The technical report of the session may be found here. The Commission was invited to review the recommendations and provide WOAH Headquarters with feedback on the implementation of the Resolution.

11.8. WOAH Global Conference on Biothreat Reduction

The Code Commission was informed that WOAH's Global Conference on Biological Threat Reduction (Geneva, 28–30 October 2025) will bring together 400 participants from a range of sectors including animal health, public health, and law enforcement to address the evolving landscape of biological threats. Coinciding with key anniversaries of the Biological Weapons Convention and Geneva Protocol, the Conference aims to reflect on historical and current biological threats and anticipate future risks, strengthen international cooperation and secure concrete commitments, foster multi-sectoral collaboration for global health security and promote innovative strategies linking animal health with other sectors. The Conference will feature plenaries, panels, and side events, with expected outcomes including stronger partnerships and improved biothreat awareness.

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…/Annexes

Annex 1. Item 2. – Adopted Agenda

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

17 – 24 September 2025

Agenda

1. MEETING WITH THE DEPUTY DIRECTOR GENERAL

2. ADOPTION OF THE AGENDA

3. COOPERATION WITH THE TERRESTRIAL ANIMAL HEALTH STANDARDS COMMISSIONS

4. AQUATIC ANIMAL HEALTH STRATEGY

5. WORK PROGRAMME OF THE AQUATIC ANIMALS COMMISSION

5.1. Comments received on the Work Programme

5.2. Overview of the Work Programme

6. *AQUATIC CODE* Items for Member comment

6.1. Glossary

6.2. Chapter 4.3. 'Application of compartmentalisation'

6.3. Chapter 4.7. 'Fallowing in aquaculture'

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

6.5. Article 9.2.2. of Chapter 9.2. 'Infection with *Aphanomyces astaci* (crayfish plague)

6.6. Article 10.3.5. and 10.3.6. of Chapter 10.3. 'Infection with *Gyrodactylus salaris'*

6.7. Article 10.4.9. of Chapter 10.4. 'Infection with infectious salmon anaemia'

6.8. Update to the viral names of pathogenic agents for WOAH listed diseases

6.9. Emerging diseases

7. AQUATIC CODE ITEMS FOR MEMBER INFORMATION

7.1. *Aquatic Code* ongoing work items

7.1.1. Chapter 4.2. 'Zoning and compartmentalisation'

7.1.2. Chapter 5.Y. 'Introduction to trade measures, importation/exportation procedures and health certification'

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

7.1.4. Section 7. 'Welfare of farmed fish'

7.1.5. Assessments of susceptible species

7.2. *Aquatic Code* new work items

7.2.1. Chapter 1.1. ‘Notification of diseases, and provision of epidemiological information

7.3. *Aquatic Code* other items for consideration

7.3.1. Review of the scientific justification for article 1.5.9. ‘Listing susceptible species at a taxonomic ranking of genus or higher’

7.3.2. Application of model articles 10.X.10. and 10.X.15. to woah listed diseases that affect non-salmonids

8. AQUATIC MANUAL ITEMS FOR MEMBER COMMENT

8.1. Section 2.2. ‘Diseases of crustaceans’

8.1.1. Section 2.2.1. and 2.2.2. of Chapter 2.2.2. ‘Infection with *Aphanomyces astaci* (crayfish plague)

8.2. Section 2.4. ‘Diseases of molluscs’

8.2.1. Chapter 2.4.2. ‘Infection with *Bonamia exitiosa’* and Chapter 2.4.3. ‘Infection with *Bonamia ostreae’*

8.2.2. Chapter 2.4.4. ‘Infection with *Marteilia refringens’*

8.2.3. Chapter 2.4.5. ‘Infection with *Perkinsus marinus’*

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

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

8.3. Update to the viral names of pathogenic agents for WOAH listed diseases

9. AQUATIC MANUAL ITEMS FOR MEMBER INFORMATION

9.1. *Aquatic Manual* ongoing work items

9.1.1. *Aquatic Manual* reformat

9.1.2. Chapter 2.2.5. ‘Infection with infectious hypodermal and haematopoietic necrosis virus’

9.1.3. Draft new Chapter 2.3.Y. ‘Infection with *Megalocytivirus pagrus1’*

9.1.4. Chapter 2.3.9. ‘Infection with spring viraemia of carp virus’

9.1.5. Chapter 2.3.5. ‘Infection with infectious haematopoietic necrosis virus’

9.2. *Aquatic Manual* new work items

9.2.1. Chapter 1.1.2. ‘Validation of diagnostic assays for infectious diseases of aquatic animals’

9.2.2. Section 2.1. ‘Diseases of amphibians’

9.2.3. Infection with tilapia lake virus

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. Update on the Aquatic Collaborating Centres Network

11. UPDATES FROM WOAH HEADQUARTERS

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

11.2. Update on the Taskforce on substandard and falsified veterinary products

11.3. WOAH Navigation Tool

11.4. The Observatory programme products

11.5. *Ad hoc* Group to update the lists of priority diseases for which vaccination can reduce antimicrobial use

11.6. Recommendations of the Governance Review Committee

11.7. Animal Health Forum at the WOAH General Session

11.8. WOAH Global Conference on Biothreat Reduction

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
(President)
Senior advisor Antimicrobial Stewardship in Aquaculture Centre,
University of Chile,
La Pintana,
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Dr Ingo Ernst
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Director Aquatic Pest and Health Policy,
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Shenzhen Customs District,
General Administration of Customs,
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OTHER PARTICIPANTS

WOAH HEADQUARTERS

Dr Gillian Mylrea
Head of Department
Standards Department

Dr Patricia Kelly
Scientific Coordinator for Aquatic Animal Health
Standards Department

Dr Mariana Delgado
Scientific Secretariat Officer
Science 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 – February 2025

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
Work_1	**Title of the item in the report or item in the work programme annex:** Item 6.4. Assessment of periods of basic biosecurity conditions and targeted surveillance in Articles X.X.5. – X.X.7. for disease-specific chapters **Proposal/Comment:** The Member requests an addition to the work plan, the re-review of the use of Pathway 1, no susceptible species for Infection with DIV1 (Article 9.3.5. point 1 and 9.3.6. point 1) in 2028 after sufficient time for **Rationale:** The Member agrees with the rationale provided by the Commission that as the pathogenic agent, DIV1, is newly identified (2016), and WOAH has only required notification from member states since 2021 and that the full range of susceptible species may be uncertain until more research is completed. However, the Member notes that in the future DIV1 may be suitable for Pathway 1 if there is no further evidence of DIV1 having a broad host range. The Member would like to request that WOAH to place a time limit on the restriction of not allowing freedom through pathway 1 for DIV1. The Member requests that WOAH re-assess the susceptible species, the need to apply a broad host range and a re-review of the use of Pathway 1 for DIV1, 5 years after the initial review of the susceptible species for DIV1 (2023). This will allow time for additional research and Member notification with respect to susceptible species. If at that time (2028), there is no further evidence of a broad host range for DIV1, the Member requests that Pathway 1 be reintroduced into the Articles 9.3.5. and 9.3.6. for infection with DIV1. If a pathogen has a wide host range, the Member would suggest that 5 years of collecting data on outbreaks globally should provide enough evidence to support a wide host range. WOAH should consider providing rationale within Commission reports with respect to the time frame for restricting the use of Pathway 1 for newly identified pathogens, for consistency moving forward.	The Commission discussed how to update the susceptible species lists as new evidence is available. A standing *ad hoc* Group was proposed (see item 7.1.5.) and as sufficient evidence is reviewed for susceptible species for DIV1, a review of the use of pathway 1 would be considered.
work_2	**Title of the item in the report or item in the work programme annex:** On-going review of susceptible species	The Commission discussed how to update the susceptible species lists as new evidence is available. A standing *ad hoc* Group was

	Proposal/Comment: The Member kindly requests a re-review of the susceptibility of *Dicentrarchus labrax* to Viral haemorrhagic septicaemia. The following additional papers were not included within the WOAH Ad hoc Group for susceptible species and should be reviewed for VHS Ia • Castric J & de Kinkelin P, 1984. Experimental study of the susceptibility of two marine fish species, sea bass (*Dicentrarchus labrax*) and turbot (Scophthalmus maximus), to viral haemorrhagic septicaemia. Aquaculture 41: 203-212. • Supporting paper: o De Kinkelin P & Castric J, 1982. An experimental study of the susceptibility of Atlantic salmon fry, *Salmo salar* L., to viral haemorrhagic septicaemia. **5**, 57–65. The following additional papers were not included within the WOAH Ad hoc Group for susceptible species and should be reviewed for VHS IaVHS Ie ▪ Işidan H & Kutlu İ, 2014. Viral Hemorajik Septisemi Virüs Genotip Ie Suşlarının Çipura (*Sparus aurata*) ve Levrek (*Dicentrarchus labrax*) Balıkları Üzerinde Patojenitelerinin Belirlenmesi. *Aquaculture Studies*, **14**, 49–53. We note that Ogut & Altunts 2014 was assessed by the *ad hoc* Group and would provide some additional supporting papers of this original reference. • Altuntaş C & Ogut H, 2010. Monthly occurrence and prevalence of viral haemorrhagic septicaemia virus (VHSV) in whiting Merlangius merlangus. Diseases of Aquatic Organisms 88: 107-113. • Nishizawa T, Savaş H, Işıdan H, Üstündağ C, Iwamoto H & Yoshimizu M, 2006. Genotyping and Pathogenicity of Viral Hemorrhagic Septicemia Virus from Free-Living Turbot (Psetta maxima) in a Turkish Coastal Area of the Black Sea. Applied and Environmental Microbiology 72: 2373-2378.	proposed (see item 7.1.3.). Papers submitted by Members along with any paper submitted by Reference Laboratories, Collaborating Centres and through expert consultation will be provided to this *ad hoc* Group when it convenes for review against the criteria provided in Chapter 1.5. of the *Aquatic Code*.
work_3	**Title of the item in the report or item in the work programme annex:** 6.4. Assessment of periods of basic biosecurity conditions and targeted surveillance in Articles X.X.5. – X.X.7. for disease-specific chapters **Proposal/Comment:** The Member thanks the Commission for taking the information provided by the Members into account and placing the pathway 2 in Articles 10.3.5. and 10.3.6. under study during the 92nd General Session. Atlantic populations or strains of Atlantic salmon would be expected to show clinical expression of Disease if *Gyrodactylus salaris* was present. These populations could be used to claim freedom through pathway 2, historical freedom if the pathogen was present in the zone.	Agreed that pathway 2 is appropriate for use in Atlantic salmon. However, pathway 2 is not appropriate for other susceptible species. Text was revised to highlight that pathway 2 can only be used when declaring freedom if the susceptible species present is Atlantic salmon.

	In addition, Article 1.4.12 indicates that if passive surveillance is not sufficient for some populations of susceptible species (such as those that may not show clinical signs of disease with infestation with *Gyrodactylus salaris*), targeted surveillance may be used to provide additional evidence of freedom for those populations. The Member urges the Commission to reinstate the pathway 2 historical freedom in Articles 10.3.5. and 10.3.6.	See item 6.6. and Annex 11 in this report.
work_4	**Title of the item in the report or item in the work programme annex:** 6.4. Assessment of periods of basic biosecurity conditions and targeted surveillance in Articles X.X.5. – X.X.7. for disease-specific chapters **Proposal/Comment:** The Member thanks the Commission for taking the information provided by the Members into account and placing the time frame for targeted surveillance in Article 10.4.9. point 1 under study during the 92*nd* General Session. ISAV HPR0 is transiently detected in stable populations of Atlantic salmon and most readily detected during physiologically stressful events such as spawning; however, knowledge of the epidemiology of ISAV HPR0 in land-based aquaculture establishments such as compartments is limited. The Member would request that the Commission consider changing the time frame from 1 year to 2 years for targeted surveillance. The Member has experienced a facility that had met the compartmentalization biosecurity requirements, that tested negative 3 times but then had a subsequent positive detection on the 4th survey in year 2. This population had multiple year classes within the same premises, and the year classes were epidemiologically linked. This population was tested at 1% prevalence for HPR0 using gill and sampled proportionately. Under the new time frame proposed for Targeted Surveillance, this facility would have become a compartment, even though HPR0 was present at a low prevalence. When designing a sampling plan, many factors should be considered, such as physiologically stressful events (i.e. spawning or smolting), temperature, season, salinity, life stage, and other stressors. These factors may be used to maximize the chance of detection of disease in a sampling plan and have been shown to be effective for other diseases. Current knowledge of ISAV HPR0 is limited but indicates that the epidemiology of ISAV HPR0 is to some degree different than that of HPR-deleted. With r remaining knowledge gaps in the epidemiology of ISAV HPR0 and evidence of low prevalence infections evading detection until year 2 of sampling, HPR0 may not be detected within a compartment within the proposed 1 year of targeted sampling.	Agreed that for freedom from a compartment for ISAV HPR0 two years for targeted surveillance is required. See item 6.7. and Annex 12 in this report.

work_5	**Category:** General We support this amendment.	Noted.
work_6	**Title of the item in the report or item in the work programme annex:** Work Programme – New proposal. Chapter 2.2.3. Infection with Decapod iridescent virus 1 in *Aquatic Manual* **Proposal/Comment:** The Member requests the Commission to consider reviewing Chapter 2.2.3 Infection with Decapod iridescent virus 1 Apparently, there is an issue in the cycling parameters for DIV1 real-time PCR (incorrect incubation time). We recommend correcting it to avoid confusion. **Rationale:** In the DIV1 manual, there is a section for Real-Time PCR (4.4.1) and all details regarding real-time PCR assays are listed in Table 4.4.1.1 (Primers and probes and cycling conditions for DIV1 real-time PCR). Among the three assays in the Table, the cycling parameters for Method 1 (Qiu *et al.,* 2018a) targeting ATPase seems to be incorrect. The cycling parameter for the assay is stated as follows: 40 cycles of 95°C for 100 sec and 60°C for 30 sec. We believe that the incubation time for the denaturation step is too long (95°C for 100 sec) and should be corrected to 95°C for 10 sec. Apparently, the information originates from the paper published by Qiu LM et al. (2018), which also states 100 sec. This is considerably longer than the typical real-time PCR program. Additionally, we checked the manual for the qPCR enzyme mentioned in the original paper and confirmed that it recommends 10 sec. Just in case, we performed an evaluation experiment to confirm it. As expected, 10 sec incubation produced significantly better results than 100 sec and the detection limit of 10 sec was higher than that of 100 sec. Given the reasons above, we believe that the 100 sec in the WOAH DIV1 manual and the original paper was simply a typo. Therefore, we suggest that the program for detecting DIV1 ATPase by real-time PCR method should consist of 40 cycles of 95°C for 10 sec and 60°C for 30 sec. **References:** Qiu L., M et al. (2018): Detection and quantification of shrimp hemocyte iridescent virus by TaqMan probe based real-time PCR. *J. Invertebr. Pathol.*, **154**, 95–101.	The Commission agreed to request the Reference Laboratory to review the cycling parameters for DIV1 real-time PCR.

work_7	**Título del ítem en el informe o del ítem en el anexo del programa de trabajo**: GENERAL **Propuesta/Comentario**: El miembro, solicita a la comisión revisar la Sección 5. Medidas Comerciales, Procedimientos de Importación y Exportación y Certificación Sanitaria, respecto al Capítulo 5.1: Obligaciones generales en materia de certificación, es específico en el numeral 2 del artículo 5.1.2, ya que este indica *"entre los requisitos en el certificado sanitario internacional aplicable a los animales acuáticos no deberá figurar el de ausencia de agentes patógenos o enfermedades de los animales acuáticos que estén presentes en el territorio del país importador y no sean objeto de un* ***programa oficial de control****. Las medidas impuestas a las importaciones para la gestión de los riesgos asociados a determinado agente patógeno o a determinada enfermedad de los animales acuáticos no deberán ser más rigurosas que aquellas que se aplican como parte del programa oficial de control dentro del país importador*". **Justificación**: Se debe considerar que actualmente no hay una definición de "programa oficial de control" en el Código Acuático de la OMSA, a diferencia del Código terrestre1, por lo cual este término pudiera interpretarse por varios países como un plan oficial de vigilancia de enfermedades o con el Nivel Apropiado de Protección (ALOP). En el caso de los planes y/o programas de vigilancia de enfermedades que se realizan en el país importador, debería también indicarse en este capítulo que la información resultante de estos planes sirva de insumo para establecer medidas sanitarias a las importaciones y por ende en la certificación sanitaria también exigir que las enfermedades estén sujetas a planes de vigilancia en los países exportadores. **Evidencia documentada**, si corresponde: Bondad-Reantaso M.G., Fejzic N., MacKinnon B., Huchzermeyer D., Seric- Haracic S., Mardones F.O., ... & Dall'occo A. (2021). A 12-point checklist for surveillance of diseases of aquatic organisms: a novel approach to assist multidisciplinary teams in developing countries. Reviews in *Aquaculture*, **13**, 1469–1487.	The Commission has proposed a plan to review and where relevant revise the chapters of Section 5. 'Trade measures, importation/exportation procedures and health certification' (see Item 6.4.) which will consider the inclusion of an official control program.

work_8	**Título del ítem en el informe o del ítem en el anexo del programa de trabajo:** GENERAL **Propuesta/Comentario:** El miembro, solicita a la comisión la revisión de la Sección 5. Medidas Comerciales, Procedimientos de Importación y Exportación y Certificación Sanitaria, Capítulo 5.3. 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 respecto al riesgo entre animales acuáticos y productos de animales acuáticos. En el Artículo 5.3.3 Consideraciones generales sobre la determinación de equivalencia de medidas sanitarias indica lo siguiente: *El Código Acuático reconoce el principio de equivalencia mediante la recomendación de medidas sanitarias alternativas para muchas enfermedades. La equivalencia se puede lograr, por ejemplo, reforzando la vigilancia y el seguimiento continuo, utilizando procedimientos de realización de pruebas, tratamiento y aislamiento alternativos, o combinando todos estos elementos. Con el fin de facilitar la determinación de equivalencia, los Países Miembros deberán basar sus medidas sanitarias en las normas y directrices de la OMSA.* **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 muchas veces la rigurosidad que se aplica para el análisis de riesgo de importación (ARI) de animales acuáticos (vivos). Sin embargo, los estándares de la OMSA no hacen referencia a los controles en contenedores (para productos de animales acuáticos congelados) en países importadores, desconociendo el país exportador la metodología de inspección, muestreo y análisis realizado. En esa línea, se evidencia que la interpretación del título 5.3 entre los países miembros no es equivalente lo cual estaría generando medidas restrictivas para el comercio. 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. **Evidencia documentada**, si corresponde: El miembro como parte de los países miembro de la Comunidad Andina, participó en la elaboración de la “Norma sobre categorías de riesgo sanitario, para el comercio intrasubregional y con terceros países de animales acuáticos y sus productos”, aprobada por la Secretaria General de la Comunidad Andina (SGCAN) a través de RESOLUCIÓN N° 2267, en la cual se categorizan los riesgos sanitarios de acuerdo a su naturaleza, para su aplicación en el comercio de mercancías de origen acuático, a nivel intrasubregional y con terceros países. Dicha normativa se enfoca en la gestión del riesgo sanitario asociado al comercio de animales acuáticos y sus productos. https://www.comunidadandina.org/DocOficialesFiles/Gacetas/Gaceta%2044 64.pdf	The Commission has proposed a plan to review and where relevant revise the chapters of Section 5. ‘Trade measures, importation/exportation procedures and health certification’ (see Item 6.4.). The objectives of the review and revision will include to improve the quality of the standards, address any gaps in the standards for trade as well improve the useability for developing trade measures. It was noted that when implementing the standards regarding trade, Members should also be respecting the requirements of the SPS Agreement.

work_9	**Título del ítem en el informe o del ítem en el anexo del programa de trabajo:** GENERAL **Propuesta/Comentario:** El miembro, solicita a la comisión revisar el Capítulo 5.4: Criterios para la evaluación de la inocuidad de las mercancías de animales acuáticos, es específico el título del capítulo, debido a que este hace mención a la "*inocuidad"* de las mercancías de animales acuáticos. **Justificación**: La inocuidad se refiere a que el producto sea seguro para el consumo humano. No obstante, el contenido del capítulo hace referencia a la presencia o ausencia de agentes patógenos en los productos que afectan la salud de los animales acuáticos. Asimismo, la definición de mercancía de acuerdo al glosario del código acuático hace referencia a animales acuáticos, productos e animales acuáticos, productos biológicos y material patológico. Por lo que el miembro, solicita a la Comisión, la revisión del título y la pertinencia de la palabra inocuidad. Asimismo, con respecto al Artículo.5.4.1. ***Criterios para evaluar la seguridad de los productos de animales acuáticos importados (o en tránsito) cualquiera que sea el uso e independientemente del estatus sanitario del país, la zona o el compartimento de exportación con respecto a la enfermedad X.*** El miembro solicita la revisión de los criterios debido a que se cree pertinente realizar una discusión más exhaustiva de la inclusión de este capítulo, toda vez que no se ha demostrado que los productos de animales acuáticos (peces y crustáceos) para consumo humano directo hayan resultado en translocación de enfermedades de un área geográfica a otra. Por el contrario, respecto a animales acuáticos vivos hay amplia evidencia científica, mas no en productos de origen acuático, que muchas veces son sometidos a procesos físicos (por ejemplo: temperatura, secado, ahumado) y/o químicos (por ejemplo: Yodo, PH, sal, humo) y biológicos (fermentación) A la fecha, existen solamente estudios bajo condiciones de laboratorio (nivel experimental) que han demostrado la infecciosidad de agentes patógenos aislados de productos de origen de animales acuáticos. No obstante, faltan estudios epidemiológicos que corroboren la diseminación de la enfermedad a través de productos que son destinados para consumo humano. **Evidencia documentada**, si corresponde: Flegel, TW (2009). Review of disease transmission risks from prawnproducts exported for human consumption. Aquaculture, 290 (3-4),179-189.	The Commission has proposed a plan to review and where relevant revise the chapters of Section 5. 'Trade measures, importation/exportation procedures and health certification' (see Item 6.4.). The objectives of the review and revision will include to improve the quality of the standards, address any gaps in the standards for trade as well improve the useability for developing trade measures. It is noted that while live animals represent the highest likelihood of transmission of pathogenic agents, there is evidence that import of aquatic animal products for human consumption can still pose a risk of transmission. Appropriate risk assessments should be completed on these products to determine the level of risk.

work_10	**Item 5.1. - Work Programme for the Aquatic Animal Health Standards Commission 2025-2027** The Member appreciates the inclusion of the work item to "Review the validation or publication of real-time PCR assays for detection of Spring Viraemia of Carp Virus (SVCV)". The availability of a real-time PCR assay for SVCV, with its higher diagnostic sensitivity and specificity compared to conventional PCR assays, allows for accurate and rapid diagnosis of the disease, while reducing the risk of contamination. We hope that this will be followed by the inclusion of the assay in the chapter, to align with the other WOAH listed fish viral diseases, where real-time PCR assays are listed.	Work is ongoing to update the *Aquatic Manual* chapter with information on the real-time PCR.
work_11	**Category:** General **Topic:** definition of ornamental aquatic animal **Proposed amended text:** We would like to address the amendment and the adoption of the glossary definition of "ornamental aquatic animals" that took place during the 92nd General Session of the World Assembly of National Delegates of the World Organisation for Animal Health (WOAH), held from May 25 to 29, 2025, in Paris, France. The Member proposed an amendment to define "ornamental aquatic animals" as "aquatic animal that is intended for display, exhibition, competition, **supply for sale, or use as a pet**". This proposal was accepted by the President of the Aquatic Animal Health Standards Commission during the Plenary Session. However, we noticed that the amendment recorded in Resolution No. 23 differs slightly from our original proposal. Therefore, we kindly request that WOAH recheck the final text adopted before its publication on the WAOH website.	Did not agree. Ornamental aquatic animals kept as pets in a household do not provide a significant risk for disease transmission. The intention of the new Chapter 5.12. was to focus on the risk of disease transmission through the movement of ornamental aquatic animals such as through sale. See Item 6.1. and Annex 5 in this report.
work_12	**Title of the item in the report or item in the work programme annex: Work programme** **Comment:** The Members, with one exception, request re-evaluation of the change adopted at the General Session for the definition of ornamental aquatic animal from: "an aquatic animal that is intended for display, exhibition, competition, or to be supplied for sale as a pet"; To: "an aquatic animal that is intended for display, exhibition, competition, or to be supplied for sale and use as a pet"	Agreed that the intention of the definition for ornamental aquatic animals was to support new Chapter 5.12. which focuses on the movements of ornamental aquatic animals. As ornamental aquatic animals kept as pets are not a significant risk for disease transmission the definition was revised to focus on the sale for use as pets. See Item 6.1. and Annex 5 in this report.

	which was adopted by the World Assembly of Delegates during the 92nd General Session 25 – 29 May 2025. We note that the definition needs to be suitable to the scope of the new chapter, 'Movement of ornamental aquatic animals', and the use of this defined term within it. The proposal creates ambiguity because it does not distinguish ornamental aquatic animals that are kept as pets from those that are traded for sale as pets. In line with the decision of the Aquatic Animal Health Standards Commission cited in Annex 3, the keeping of pet aquatic animals is outside of the scope of this chapter and should be unambiguously excluded from the definition. We believe the prior definition proposed by the Commission in its February 2025 meeting report for adoption at the 92nd General Session, which removed the wording "kept" (as a pet), achieves this distinction. Therefore, we recommend that the definition be added to the workplan and circulated for Member comment. **Rationale:** A proposal to amend the definition of 'ornamental aquatic animals,' accompanied by detailed rationale (included in Annex 3 of the February 2025 report of the Commission) was previously submitted for consideration. The Aquatic Animal Health Standards Commission reviewed and accepted the proposal, and the original wording proposed for adoption at the 92nd WOAH General Session reflected those contributions. The Members urges the Commission to reconsider the change to the definition that came from the floor of the General Session (which did not allow Members proper time to consider and comment on the proposed change) and revert the definition of 'ornamental aquatic animals' to the form proposed for adoption in the February 2025 report of the Commission. The Members emphasises that the risk of disease spread is negligible when ornamental aquatic animals are kept exclusively within household environments and are not traded or moved. The primary risk arises when these animals are introduced into new populations through trade or other forms of movement (e.g. intentional or accidental release). We recommend that Competent Authorities should not undertake eradication or control measures targeting individual households where ornamental fish are kept solely as pets and are not in contact with other susceptible populations. This principle is consistent with how poultry and other animals kept as pets within households, provided they are not exposed to or interacting with other susceptible populations, are treated. This approach ensures a proportionate response that balances disease control with practical considerations for pet owners, while still mitigating the risk of disease spread through trade and movement, which is the primary objective of the new chapter, 'Movement of ornamental aquatic animals'.	

	Título del punto del informe o punto del anexo del programa de trabajo: Programa de trabajo **Comentario:** Los miembros, con una excepción, solicitan la reevaluación del cambio adoptado en la Sesión General para la definición de animal acuático ornamental de: “un animal acuático destinado a exhibición, competición o para su venta como mascota”; A: “un animal acuático destinado a exhibición, competición o para su venta y uso como mascota” que fue adoptada por la Asamblea Mundial de Delegados durante la 92.ª Sesión General, del 25 al 29 de mayo de 2025. Observamos que la definición debe adecuarse al alcance del nuevo capítulo, “Movimiento de animales acuáticos ornamentales”, y al uso de este término definido en él. La propuesta genera ambigüedad porque no distingue entre los animales acuáticos ornamentales que se mantienen como mascotas y los que se comercializan para su venta como tales. De acuerdo con la decisión de la Comisión de Normas Sanitarias para los Animales Acuáticos citada en el Anexo 3, la tenencia de animales acuáticos de compañía queda fuera del alcance de este capítulo y debe excluirse inequívocamente de la definición. Creemos que la definición previa propuesta por la Comisión en su informe de la reunión de febrero de 2025 para su adopción en la 92.ª Sesión General, que eliminó la expresión "mantenido" (como mascota), logra esta distinción. Por lo tanto, recomendamos que la definición se añada al plan de trabajo y se distribuya para comentarios de los Miembros. **Justificación:** Se presentó previamente para su consideración una propuesta para modificar la definición de "animales acuáticos ornamentales", acompañada de una justificación detallada (incluida en el Anexo 3 del informe de la Comisión de febrero de 2025). La Comisión de Normas Sanitarias para los Animales Acuáticos revisó y aceptó la propuesta, y la redacción original propuesta para su adopción en la 92.ª Sesión General de la OMSA reflejó dichas contribuciones. Los miembros insta a la Comisión a reconsiderar el cambio a la definición propuesto en la Sesión General (que no permitió a los Miembros el tiempo suficiente para considerar y comentar el cambio propuesto) y a revertir la definición de «animales acuáticos ornamentales» a la forma propuesta para su adopción en el informe de la Comisión de febrero de 2025.	

	Los miembros enfatiza que el riesgo de propagación de enfermedades es insignificante cuando los animales acuáticos ornamentales se mantienen exclusivamente en entornos domésticos y no se comercializan ni se trasladan. El riesgo principal surge cuando estos animales se introducen en nuevas poblaciones mediante el comercio u otras formas de traslado (por ejemplo, liberación intencional o accidental). Recomendamos que las Autoridades Competentes no implementen medidas de erradicación o control dirigidas a hogares individuales donde los peces ornamentales se mantienen únicamente como mascotas y no están en contacto con otras poblaciones susceptibles. Este principio es coherente con el trato que reciben las aves de corral y otros animales mantenidos como mascotas en los hogares, siempre que no estén expuestos ni interactúen con otras poblaciones susceptibles. Este enfoque garantiza una respuesta proporcionada que equilibra el control de la enfermedad con consideraciones prácticas para los dueños de mascotas, al tiempo que mitiga el riesgo de propagación de enfermedades a través del comercio y el movimiento, que es el objetivo principal del nuevo capítulo, "Movimiento de animales acuáticos ornamentales".	
work_13	The Members supports the work programme.	Noted.
Work_14	**Title of the item in the report or item in the work programme annex: Work programme** **Proposal/Comment:** The Members does not support the change the definition of ornamental aquatic animal from: “an aquatic animal that is intended for display, exhibition, competition, or to be supplied for sale as a pet”; To: “an aquatic animal that is intended for display, exhibition, competition, or to be supplied for sale and use as a pet” which was adopted by the World Assembly of Delegates during the 92nd General Session 25 – 29 May 2025. We note that the definition needs to be suitable to the scope of the new chapter, ‘Movement of ornamental aquatic animals’, and the use of this defined term within it. The proposal creates ambiguity because it does not distinguish ornamental aquatic animals that are kept as pets from those that are traded for sale as pets. In line with the decision of the Aquatic Animal Health Standards Commission cited in Annex 3, the keeping of pet aquatic animals is outside of the scope of this chapter and should be unambiguously excluded from the definition.	See work_12, Item 6.1. in this report.

	We believe the prior definition proposed by the Commission in its February 2025 meeting report for adoption at the 92nd General Session, which removed the wording “kept” (as a pet), achieves this distinction. Therefore, we recommend that the definition be added to the workplan and circulated for Member comment. **Rationale:** A proposal to amend the definition of ‘ornamental aquatic animals,’ accompanied by detailed rationale (included in Annex 3 of the February 2025 report of the Commission) was previously submitted for consideration. The Aquatic Animal Health Standards Commission reviewed and accepted the proposal, and the original wording proposed for adoption at the 92nd WOAH General Session reflected those contributions. The Members urges the Commission to reconsider the change to the definition that came from the floor of the General Session (which did not allow Members proper time to consider and comment on the proposed change), and revert the definition of ‘ornamental aquatic animals’ to the form proposed for adoption in the February 2025 report of the Commission. The Members emphasises that the risk of disease spread is negligible when ornamental aquatic animals are kept exclusively within household environments and are not traded or moved. The primary risk arises when these animals are introduced into new populations through trade or other forms of movement (e.g. intentional or accidental release). We recommend that Competent Authorities should not undertake eradication or control measures targeting individual households where ornamental fish are kept solely as pets and are not in contact with other susceptible populations. This principle is consistent with how poultry and other animals kept as pets within households, provided they are not exposed to or interacting with other susceptible populations, are treated. This approach ensures a proportionate response that balances disease control with practical considerations for pet owners, while still mitigating the risk of disease spread through trade and movement, which is the primary objective of the new chapter, ‘Movement of ornamental aquatic animals’.	

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**
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**

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. 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 animal 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 diagnostic 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

Draft new Chapter 4.3. 'Application of Compartmentalisation'

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3._1	**Category:** General The Member does not oppose the proposed definitions of "compartment" within the Annex 20. Item 7.1. and new concept of a "dependent" or "independent" compartment. However, the recognition and approval of either dependent or independent compartments must be based on a range of critical factors. These include the outcomes of a robust risk assessment, the proposed end use of the aquatic animal commodity, the characteristics of the pathogen(s) of concern, the susceptibility of relevant species, the species composition of the proposed compartment. In particular, we note that suitability of a dependent compartment may vary significantly depending on the disease agent involved. For example, for pathogens that are not waterborne or for those with limited environmental persistence, a dependent compartment may provide an acceptable and fit-for-purpose level of risk management. We recommend further exploration and clarification of such scenarios, including whether specific aquatic animal pathogens exist that can be considered free in a dependent compartment, to guide the practical application of dependent compartments under the revised standard. The Member supports the inclusion of both types of compartments in the *Aquatic Code* but recommends that the revised text clearly link compartment type to the nature of the disease hazard and risk management requirements, including surveillance intensity and epidemiological separation. In the context of our import risk assessment for prawns intended for human consumption, we require evidence of disease freedom for certain specified disease agents. Compartment status without complete epidemiological separation (i.e. dependent compartments) will not be accepted as sufficient on its own. In such cases, a full risk assessment of the specific dependent compartment is required, including detailed consideration of additional biosecurity and risk management measures to ensure an appropriate level of protection.	Noted first point that approval of a compartment must depend on a range of factors and agreed that this is addressed in Chapter 4.3. However, the Commission kept this as a consideration when reviewing the text to ensure it is clearly reflected. Noted second point that a compartment needs to effectively manage risk and the risk may vary depending on the pathogenic agent and environmental conditions. Did not agree that the chapter should link compartment category to the disease and the specific risk management measures. The risk management measures should be based on a risk analysis and thus cannot be overly prescriptive on what measures are needed in the *Aquatic Code*. Noted that risk assessment is necessary to determine whether a compartment can be accepted.
4.3._2	**Category:** General The Member thanks the Aquatic Animals Commission for the significant work that has gone into the revision of Chapter 4.3. Application of Compartmentalisation. However, we note that there is significant confusion amongst our subject matter experts with respect to the inclusion of the concept of dependent compartments and how dependent compartments would be consistently implemented. The concept of compartmentalisation is well known within our Veterinary Authorities but only as it applies to an independent compartment as is portrayed in this chapter. The inclusion of the concept of dependent compartments within the *Aquatic Code* will	The concept that the disease status of a compartment or zone is dependent on the surrounding environment is not new within the standards. The basis of this is included in the *Terrestrial Code* where freedom may be required in a protection zone around compartments (e.g. Article 8.8.6. 'Compartment free from FMD where vaccination is not practiced' that states the compartment should only approved when there has been no

	create confusion and inconsistency between Terrestrial and Aquatic Competent Authorities. The important distinction is that a dependent compartment does not necessarily have a higher health status as is the generally accepted application of compartmentalisation. We are also concerned with how independent and dependent compartments could be implemented. For example, it is currently unclear when a single facility is located in a zone that is positive for one or more diseases that the cultured species is susceptible to but also in a zone that is negative for other diseases that the species is susceptible to; whether this facility could be both an independent compartment and dependent compartment at the same time? The eventual application of the revised definition of *compartment* within the *Aquatic Code* has also created confusion. The inability to distinguish independent and dependent compartments within the definition has potential impacts on Chapter 1.4. and each disease-specific chapter specifically with regards to the time frames for basic biosecurity conditions (BBC) and targeted surveillance (TS). It is unclear if both independent and dependent compartments will require the same time frames for BBC and TS to support declarations of freedom. These time frames will need to be reviewed, as previously indicated by the Commission, to support Member understanding on the implementation of this revised chapter. There are a significant number of outstanding questions and concerns that must be clarified before the inclusion of dependent compartments can be supported.	infection or transmission of FMDV within a 10 km radius of the compartment for three months). The concept of a dependent compartment is also not excluded from the current chapter on compartmentalisation in the *Aquatic Code* although the concept may not be explicitly described. The revised draft Chapter 4.3. explicitly includes the concept of dependent compartments to provide clarity on a concept that is already utilised in some areas. In response to the concern for whether a compartment can be both independent or dependent – If the compartment is a closed system, then it will be independent regardless of the surrounding disease status. If it is semi-closed it will be dependent and thus influenced by that status of diseases in the environment. A compartment would not be both independent and dependent as the aquaculture establishments can not be both closed and semi-closed. Regarding the concern of the definition and not distinguishing independent and dependent compartments – The decision on the requirements to become a compartment will be hazard specific and depend on the outcome of risk analysis. As noted in its February 2025 report the Commission will review Chapter 1.4. to determine the periods for surveillance and make revisions as required to take into account the provisions of the revised Chapter 4.3. The Commission will consider this at its February 2026 to provide feedback to Members on expected revisions required.

4.3._3	**Category:** General The Member notes that the objectives and principles of this chapter are to provide guidance for Competent Authorities to determine if an "*aquaculture establishment* is **free from** one or more specified *diseases"* and therefore can be considered a compartment. For example: Article 4.3.4. states "Dependent *compartments...*require the application of appropriate *risk* mitigation measures to achieve and maintain **disease-free status** despite epidemiological links to the surrounding environment." Additionally, the Article 4.3.3., Principles for establishing a compartment, point 1) states "A *compartment* must ensure there are effective measures to **prevent the entry or spread of *pathogenic agents*** between the compartment and the external environments (i.e. provide functional epidemiological separation);" However, these objectives and principles seem in conflict with the concept introduced in Article 4.3.4. paragraph 1: 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*. and point 2) e): [Dependent *compartments]* "may not provide sufficient *risk* mitigation for all purposes, *commodity* types and end-uses". In the first example, if the surrounding waters are disease free, what risk mitigations measures are being referred to that would prevent maintenance of disease-freedom? And in point 2e, why is the risk mitigations being linked to purposes, commodity types and end uses". This wording creates confusion regarding the overall concept of a Dependent compartment and questions by importing countries as to whether a dependent compartment can be considered disease-free. Therefore, the Member feels the current concept a Dependent compartment is subjective in relation to disease-free status and opens the understanding of Dependent compartments up to interpretation and potentially conflicting implementation of the standards by member countries. Disease-free health status should be linked to both independent and dependent compartmentalisation. If the Competent Authority is not confident the dependent compartment is disease-free yet then the premises should not be considered a dependent compartment, however the product may still be traded safely using the guidance in the disease-specific chapters Article 10.X.14 (or 10.4.19 for ISA). The Member would like to reiterate that if a premises is not disease free it is not a compartment.	Regarding concerns around epidemiological separation and links - the Commission reviewed the chapter and clarified that the epidemiological separation between populations in the compartment, and the sources of infection (such as infected populations) should be a main point of consideration. Thus, the focus for risk management measures should be on the potential entry of a pathogenic agent. Regarding the question on point 2e, the link to commodities was removed from the chapter as it was noted that risk mitigation should focus on disease introduction rather than end-use commodity type. However, it was noted that risk is not static and fluctuates temporally in relation to a multitude of factors as such the appropriate risk management measures need to be determined by risk analysis. Regarding the concern that a dependent compartment is subjective and has potential to have variable implementation – as highlighted throughout the draft Chapter 4.3. approval of a compartment depends on risk analysis which takes into account many factors, and the implementation of risk management measures based on the analysis. The standards provide a framework and the principles to allow the appropriate risk analysis and to support bilateral negotiation for those compartments that require it. The Commission agreed that compartmentalisation is one option among others and needs to be justifiable. It may not always be feasible or cost-effective to establish and maintain a compartment, so other options to meet importing countries requirements may be preferable.
4.3._4	**Category:** General	1. While the categories of independent and dependent

	1.The current chapter uses the category of “Dependent compartments” and “Independent compartments,” which can easily lead to subjective interpretations of “dependent” or “independent” attributes (such as management capacity, connection with the external environment). As these two types of compartments correspond entirely to “Semi-closed compartments” and “Closed compartments” in Chapter 4.1 respectively, it is recommended to adjust the terminology to “Semi-closed compartments” and “Closed compartments”. This will prevent conceptual confusion and ensure consistency of classification criteria with other chapters of the Code (e.g., Article 4.1.7 of Chapter 4.1). **2.**Supplement with an explanation of compatibility for hybrid or easily confused systems. Although Chapter 4.1 defines four types of aquaculture production systems, the aquaculture practices across different countries, aquaculture production systems with varying degrees of enclosure do not always strictly conform to these definitions. For example, in closed aquaculture systems, although there is no entry or exit of aquatic animals, disease vectors, or water from/to the exterior environment, exchange involving people, production tools, vehicles, and air still occurs; excessively dense surrounding aquaculture activities or high incidences of disease may affect the biosecurity risks of closed compartments; furthermore, in actual production, some aquaculture systems may exhibit both closed and semi-closed characteristics (e.g., recirculating aquaculture systems with intermittent introduction of natural water sources). However, in the current chapter, once classified as a closed system according to the definition, these risks may be overlooked. It is recommended to add transitional category such as “Hybrid compartments” or “Ambiguous compartments” that cannot be categorized in Article 4.3.4, and to require that their applicable biosecurity level be determined through dynamic risk assessment. For example: “For systems that cannot be strictly categorized as closed or semi-closed, the Competent Authority should approve applicable risk management measures based on a risk analysis of pathogen introduction pathways (e.g., water exchange frequency, level of personnel movement control, airborne transmission, etc.).” **3**.**Clarify the management centred on risk analysis.** The current chapter’s categorization of compartments relies excessively on system type, potentially overlooking the diversity of actual risks (e.g., diversity of actual production methods, degree of geographical isolation, density of surrounding wild populations). It is recommended to prioritize emphasizing in Article 4.3.3 (principles article): <u>“The establishment of a compartment should be based on an assessment of the risk of pathogen introduction, including but not limited to:</u> <u>a) Probability of exposure through environmental transmission pathways (water, aerosols, vectors);</u> <u>b) Prevalence rates of diseases and surveillance data in the surrounding area;</u>	compartments do correlate to closed and semi-closed systems, the Commission did not agree to change the terminology as to not introduce further confusion. 2. Agreed that biosecurity is not binary as presented with independent and dependent compartments. Biosecurity is about mitigating risk, and it is considered that this draft chapter and Chapter 4.1. address these issues comprehensively and further information is not required in the draft Chapter 4.3. It was noted that other production categories such as semi-open and open are likely more appropriately addressed through zoning rather than compartmentalisation. 3. Did not agree to addition of text to Article 4.3.3. as the risks of introduction of pathogenic agents are addressed through the development of a biosecurity plan and the risk analysis (which is required to determine the appropriate risk management measures). The Commission did strengthen wording on risk analysis in Article 4.3.5. 4. Article 4.3.5. covers both independent and dependent compartments. However, this article has more detail on dependent compartments as this category requires more risk management due to the link to the surrounding environment. Revisions were made to Article 4.3.5 to provide more clarity on independent and dependent compartments. 5. The text in Article 4.3.5. was revised to clarify that the Competent Authority is responsible for controlling movements and completing the risk analysis. Note that the biosecurity plan is linked to Chapter 4.1. and further information about can be found in that chapter. 6. Self-testing is a good practice for contractors to implement to monitor

	c) Possibility of cross-contamination at various stages of the production chain (referencing the risk assessment template in Appendix 1 of Chapter 4.1 of the Code)." **4.**Specify the biosecurity and other risk-mitigation measures for "independent compartments". Article 4.3.5 only specifies the risk analysis content that the Competent Authority needs to consider for dependent compartments, without imposing requirements for independent compartments. However, there are certain commonalities in some risk control links between the two types of compartments. It is recommended to systematically sort out and integrate the key points of risk analysis for the two types of compartments, clarify the commonalities and differences between the two in risk analysis, supplement the risk analysis content of the "independent compartments", and ensure that the risk management norms can comprehensively cover different types of compartments. **5.**Elaborate on the responsible entities for biosecurity plans. This chapter does not clearly define the responsible entities for formulating, implementing, and supervising the biosecurity plan for the compartments, which affects the implementation of the biosecurity plan for the compartments. In Article 4.3.5, "Biosecurity and other risk mitigation measures", although it mentions that the biosecurity plan should provide a common set of control measures, the responsible entity is not clearly defined. It is recommended to clarify the formulation, implementation and supervision entities of the biosecurity plan for compartments in 4) of Article 4.3.3 "Principles for Establishing a compartment". In addition, it is recommended to add a clause on "capacity building", clarify the qualifications, capabilities and responsibilities of relevant entities, stipulate requirements such as technical training and capacity comparison, and set a transition period to balance the strictness of the standards and the actual capabilities of developing countries. **6.Add the requirements for the self-testing laboratory in compartments in Article 4.3.7.** Article 4.3.7 requires testing laboratories to be "independent of the compartment operator," but it does not stipulate requirements for the compartment's routine self-testing capabilities. Third-party testing independent of the compartment is necessary for official insight and certification, but such third-party testing is often costly and its results lack timeliness, making it difficult to meet the needs of daily biosecurity plan implementation in compartments for aquaculture production. A lack of self-testing capability in compartments is detrimental to their risk assessment and management, and there should also be requirements for the development of self-testing capabilities. It is recommended to add "Compartment operators are encouraged to establish a self-testing laboratory responsible for routine monitoring self-checks. Upon detection of risks and diseases, they should immediately report to the compartment's biosecurity responsible unit."to Article 4.3.7. Given the differences in the economic development levels of each member, a self-testing laboratory is not mandatory here. **7.Add a credit rating mechanism to Article 4.3.10 "Official oversight".** Since the implementation of biosecurity plans and surveillance plans in compartments is, in most cases, managed by the compartments themselves, it is difficult for the regulatory	disease status however this testing cannot be officially recognized by the Competent Authority. Self-testing is not a requirement as to meet official requirements the testing must be completed independently from the operator. 7. It is the responsibility of the Competent Authority to certify that the requirements to be certified as a compartment are being met. The compliance-based system described in the comment may be one way for the Competent Authority to do this however it may not be suitable for all circumstances. The draft chapter is not prescriptive which would allow the Competent Authority to determine the most appropriate way to ensure the requirements are being met.

	authorities to grasp all details, records may be falsified, and disease risks identified during self-testing or production may be concealed and not reported by the compartment. This chapter should establish preventive mechanisms for such issues. It is recommended to add a credit rating mechanism for compartments to assess and investigate evasive regulatory behaviors such as falsification, cheating, and non-reporting in the implementation of biosecurity and surveillance plans, and to make the credit rating mechanism one of the basic prerequisites for compartment recognition. For example, add a credit rating mechanism to Article 4.3.10"Official oversight": "The Competent Authority should establish a credit rating system for compartments and dynamically adjust the intensity of supervision based on the following indicators: a) Timeliness and completeness of historical disease reporting; b) Authenticity of biosecurity records (e.g., random traceability checks); c) Compliance rate with official or third-party audit results. For compartments with a low credit rating, the official audit cycle should be shortened (e.g., adjusted from 24 months to 6 months), and their eligibility for self-declaration of disease-free status should be suspended."	
4.3._5	**Category:** General It is recommended that provide a minimum record keeping period. **Rationale:** Suggest providing a minimum record keeping period for reference by government competent authorities or aquaculture farm.	The record keeping period is addressed in Article 4.3.9. in point 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.'
4.3._6	**Category: General** We thank the Aquatic Animals Commission for the significant work that has gone into the revision of Chapter 4.3. Application of Compartmentalisation. However, we note that there is significant confusion with respect to the inclusion of the concept of dependent compartments and how dependent compartments would be consistently implemented. The concept of compartmentalisation is well known within our Veterinary Authority but only as it applies to an independent compartment as is portrayed in this chapter. The inclusion of the concept of dependent compartments within the *Aquatic Code* will create confusion and inconsistency between Member Terrestrial	See response to 4.3_2.

	and Aquatic Competent Authorities. The important distinction is that a dependent compartment does not necessarily have a higher health status as is the generally accepted application of compartmentalisation. We are also concerned with how independent and dependent compartments could be implemented. For example, it is currently unclear when a single facility is located in a zone that is positive for one or more diseases that the cultured species is susceptible to but also in a zone that is negative for other diseases that the species is susceptible to; whether this facility be both an independent compartment and dependent compartment at the same time? The eventual application of the revised definition of *compartment* within the *Aquatic Code* has also created confusion. The inability to distinguish independent and dependent compartments within the definition has potential impacts on Chapter 1.4. and each disease-specific chapter specifically with regards to the time frames for basic biosecurity conditions (BBC) and targeted surveillance (TS). It is unclear if both independent and dependent compartments will require the same time frames for BBC and TS to support declarations of freedom. These time frames will need to be reviewed, as previously indicated by the Commission, to support Member understanding on the implementation of this revised chapter. These outstanding questions and concerns must be clarified before the inclusion of dependent compartments can be supported.	
4.3._7	**Category:** General The Member would like to commend the Aquatic Animal Health Standards Commission for its work on this important draft new chapter. In general, the Member is of the opinion that the chapter should focus solely on how to establish and maintain a compartment. Commodities are already sufficiently covered in Section 5 and the disease-specific chapters in the *Aquatic Code*. The inclusion of examples may unintentionally narrow interpretation or create uneven applications in trade, as importing countries could selectively adopt measures based on these references rather than on risk-based principles. Therefore, the Member strongly opposes the use of examples of commodities and end-uses in this chapter as they may lead to unintended trade restrictions. The term “epidemiological separation” is used 7 times in the text without being clearly defined. A clear definition or description is needed to ensure a common understanding of how to interpret the exact meaning and associated prerequisites. Additional comments are provided below.	Agreed that the application of compartmentalisation should be used to create a population with a distinct health status regardless of the end-use of that population. The Commission reviewed the chapter and removed references to end-use and commodities. In Annex 6, new Article 4.3.2. (re-ordered from 4.3.3.), point one provides a definition for epidemiological separation – ‘A *compartment* must ensure there are effective measures to prevent the entry or spread of *pathogenic agents* from the external environments into the *compartment* (i.e. provide functional epidemiological separation);’ The use of epidemiological separation is considered clear and does not require further defining.
4.3._8	**Category**: General The Member welcomes the modifications to the chapter.	Noted.

	Nevertheless, we have a comment concerning the term 'external surveillance' (see Article 4.3.3.)	
4.3._9	**Category:** General We observed the terms "end-uses," "possible end-uses," and "intended end-uses" appearing frequently in many articles of Chapter 4.3. We kindly request that WOAH ensure these terms are used correctly and consistently throughout the chapter according to their respective contexts. **Rationale:** For clarity	References to end-uses were removed from the chapter – see response to 4.3._7.
4.3._10	**Category:** General We thank the Commission for their work on this Chapter, and particularly welcome the additional clarity provided on private sector roles in establishing compartments, key variations in dependent and independent compartments, and guidance on various risk analysis steps that can be undertaken. We are curious, however, if the Commission would consider developing text or guidance on how compartmentalisation could be utilised alongside zonation? Also, the current chapter discusses the need for a contingency plan the event of a change in the level of exposure within the compartment, yet that is not addressed here – are there plans to address this topic elsewhere and, if so, can a linked piece of text please be included for clarity as to how it would apply to compartments.	Text was added to Article 4.3.6. regarding external surveillance for a free compartment within a free zone to address the usage of zoning and compartmentalisation in tandem. Contingency planning is discussed in Chapter 4.1. (Article 4.1.9.) and this chapter is cross-referenced in the articles on principles as well as biosecurity in this chapter.
4.3._11	**Category:** General We thank the Aquatic Animals Commission for the significant work that has gone into the revision of Chapter 4.3. Application of Compartmentalisation. However, we note that there is significant confusion amongst our subject matter experts with respect to the inclusion of the concept of dependent compartments and how dependent compartments would be consistently implemented. The concept of compartmentalisation is well known within our Veterinary Authorities but only as it applies to an independent compartment as is portrayed in this chapter. The inclusion of the concept of dependent compartments within the *Aquatic Code* will create confusion and inconsistency between Terrestrial and Aquatic Competent Authorities. The important distinction is that a dependent compartment does not necessarily have a higher health status as is the generally accepted application of compartmentalisation. We are also concerned with how independent and dependent compartments could be implemented. For example, it is currently unclear when a single facility is located in a zone that is positive for one or more diseases that the cultured species is susceptible to but also in a zone that is negative for other diseases that the species is susceptible to; whether this facility be both an independent compartment and dependent compartment at the same time?	See response to 4.3_2.

	The eventual application of the revised definition of compartment within the *Aquatic Code* has also created confusion. The inability to distinguish independent and dependent compartments within the definition has potential impacts on Chapter 1.4. and each disease-specific chapter specifically with regards to the time frames for basic biosecurity conditions (BBC) and targeted surveillance (TS). It is unclear if both independent and dependent compartments will require the same time frames for BBC and TS to support declarations of freedom. These time frames will need to be reviewed, as previously indicated by the Commission, to support Member understanding on the implementation of this revised chapter. There are a significant number of outstanding questions and concerns that must be clarified before the inclusion of dependent compartments can be supported.	
4.3._12	**Category:** General The Members, with one exception, thank the Aquatic Animals Commission for the significant work that has gone into the revision of Chapter 4.3. Application of Compartmentalisation. However, we note that there is significant confusion amongst our subject matter experts with respect to the inclusion of the concept of dependent compartments and how dependent compartments would be consistently implemented. The concept of compartmentalisation is well known within our Veterinary Authorities but only as it applies to an independent compartment as is portrayed in this chapter. The inclusion of the concept of dependent compartments within the *Aquatic Code* will create confusion and inconsistency between Terrestrial and Aquatic Competent Authorities. The important distinction is that a dependent compartment does not necessarily have a higher health status as is the generally accepted application of compartmentalisation. We are also concerned with how independent and dependent compartments could be implemented. For example, it is currently unclear when a single facility is located in a zone that is positive for one or more diseases that the cultured species is susceptible to but also in a zone that is negative for other diseases that the species is susceptible to; whether this facility could be both an independent compartment and dependent compartment at the same time? The eventual application of the revised definition of *compartment* within the *Aquatic Code* has also created confusion. The inability to distinguish independent and dependent compartments within the definition has potential impacts on Chapter 1.4. and each disease-specific chapter specifically with regards to the time frames for basic biosecurity conditions (BBC) and targeted surveillance (TS). It is unclear if both independent and dependent compartments will require the same time frames for BBC and TS to support declarations of freedom. These time frames will need to be reviewed, as previously indicated by the Commission, to	See response to 4.3_2.

	support Member understanding on the implementation of this revised chapter. There are a significant number of outstanding questions and concerns that must be clarified before the inclusion of dependent compartments can be supported. **Comentario:** General Los Miembros, con una excepción, agradecen a la Comisión de Animales Acuáticos por el importante trabajo realizado en la revisión del Capítulo 4.3. Aplicación de la compartimentación. Sin embargo, observamos que existe una gran confusión entre nuestros expertos en la materia con respecto a la inclusión del concepto de compartimentos dependientes y la forma en que se aplicarían sistemáticamente los compartimentos dependientes. El concepto de compartimentación es bien conocido por nuestras Autoridades Veterinarias, pero solo en la medida en que se aplica a un compartimento independiente, como se describe en este capítulo. La inclusión del concepto de compartimentos dependientes en el Código Acuático generará confusión e inconsistencia entre las Autoridades Competentes Terrestres y Acuáticas. La distinción importante radica en que un compartimento dependiente no necesariamente tiene un estatus sanitario superior, como se acepta generalmente en la aplicación de la compartimentación. También nos preocupa cómo se podrían implementar los compartimentos independientes y dependientes. Por ejemplo, actualmente no está claro cuándo una misma instalación se ubica en una zona positiva para una o más enfermedades a las que la especie cultivada es susceptible, pero también en una zona negativa para otras enfermedades a las que la especie es susceptible; ¿podría esta instalación ser a la vez un compartimento independiente y un compartimento dependiente? La eventual aplicación de la definición revisada de compartimento en el Código Acuático también ha generado confusión. La imposibilidad de distinguir compartimentos independientes y dependientes en la definición tiene posibles repercusiones en el Capítulo 1.4 y en cada capítulo específico de enfermedad, en particular en lo que respecta a los plazos para las condiciones básicas de bioseguridad (BBC) y la vigilancia específica (ET). No está claro si los compartimentos independientes y dependientes requerirán los mismos plazos para que la BBC y la ET respalden las declaraciones de ausencia de enfermedad. Estos plazos deberán revisarse, como indicó previamente la Comisión, para facilitar la comprensión de los Miembros sobre la aplicación de este capítulo revisado. Existe un número significativo de preguntas e inquietudes pendientes que deben aclararse antes de que se pueda respaldar la inclusión de compartimentos dependientes.	

4.3._13	**Category:** General The Members in general supports this new chapter. The Members welcomes the confirmation that Chapter 1.4. on "Aquatic disease surveillance" and the Articles in disease-specific chapters for declaration of compartment freedom will be reviewed when the new Chapter 4.3. has been adopted. The main concern is about dependent compartments. If the concept of 'dependent' compartment is included in this draft chapter, the Members considers that the higher risk of introducing a disease from the surrounding waters associated with these entities must be taken into account when setting out the period of time required to gain disease-freedom, in the disease-specific chapters i.e. in our view, this is likely to be longer that the 1-year period which is currently proposed. Specific comments are inserted in the text below.	Noted, the Commission will consider Chapter 1.4. at its February 2026 meeting.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.1._1	**Categoría: Cambio** **Texto modificado propuesto:** Este capítulo brinda recomendaciones para establecer y mantener *compartimentos* libres de *enfermedades* específicas, con la finalidad de facilitar el comercio ~~o~~ **y** la prevención y el control de *enfermedades*. **Justificación:** El fin del compartimento es la prevención y el control de *enfermedades.* El texto citado debe estar en concordancia con lo que más abajo se indica en la finalidad del compartimento *"Los compartimentos pueden establecerse con el propósito principal de facilitar el comercio* ***y*** *también la prevención y el control de enfermedades"*	Agreed to change, the purpose of a compartment is for facilitate trade, and disease prevention and control. Thus, the word 'and' is more appropriate than 'or'.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.1._2	**Category:** Change **Proposed amended text:** 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~~ one or more *aquaculture establishments* containing a population of aquatic animals	Did not agree to added text. 'Compartment' is a defined term linked to the glossary and so it is not necessary to define within the text.

	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 in accordance with this chapter. **Rationale:** The **Glossary** defines a compartment as "one or more aquaculture establishments…with a distinct health status for a specific disease…". Article 4.3.1. should use the same wording as the one in Glossary or the definition should change to the proposed text in Article 4.3.1.	
4.3.1._3	**Category:** addition/deletion **Proposed amended text:** 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~~ epidemiologically linked *aquaculture establishments* that operate under a common set of *risk management* measures in accordance with this chapter. **Rationale:** Replace "interrelated" with "epidemiologically linked" so it is clear that the group of establishments are related from a disease management perspective (and not related for other reasons).	Agreed to delete interrelated but not to add epidemiologically linked as neither word is necessary to understand the text.
4.3.1._4	**Category of comments:** General **Proposed amended text:** Compartmentalisation **also** 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. **Rationale**: Compartmentalization is not limited to the private sector only. Addition of the word 'also' indicates this as there are several public sector establishments involved in the production, distribution and trade & research of aquatic animals.	Agreed that compartmentalisation is not limited to the private sector, although it is often a significant stakeholder. The word 'private sector' was changed to operator throughout the text to take into account that the operator may not always be within the private sector.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.1._5	**Category:** Change **Proposed amended text:** 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~~ are essential. **Rationale:** There's a grammatical error. It should be plural.	Agreed to editorial change.
4.3.1._6	**Category**: deletion **Proposed amended text**: ~~Investment by the private sector and~~ oversight by the relevant *Competent Authorities* is essential. **Rationale:** To begin with, “investment” is not appropriate for the content of the WOAH Code. The Code should deal with the manner and methods of testing, harvesting and producing. In addition to it, the present draft is misleading, negatively implying that the high-cost investment is always necessary regardless of the effectivity in disease prevention and control. The intent of the phrase “investment by the private sector” is unclear, and it seems unnecessary to mention in the introduction.	Did not agree to remove reference to investment, as investment is necessary to meet the requirements of a compartment. The text does not indicate that this investment needs to be significant as it would depend on the circumstances of the compartment and would be variable. Note that ‘private sector’ was changed to ‘operator’; see response to comment 4.3.1._5.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.1._7	**Category:** addition/deletion **Proposed amended text:** A *competent authority* can make 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. **Rationale:** It needs to be clear that the official *self-declaration of freedom from disease* and establishment of a *compartment* must ultimately be made by the Competent *Authority,* not private enterprise.	Agreed to proposed change as it needs to be clear that a self-declaration of freedom from disease will be made by the Competent Authority.
4.3.1._8	**Category:** Addition **Proposed amended text:** A *self-declaration of freedom from disease* for a *compartment* from specified *listed diseases* can be made by the Competent Authority 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. **Rationale:** While the definition of self declaration of freedom is given in the glossary (and will be linked), given the references to the private sector in the paragraph above, would it be worth clarifying that such a declaration is made by the Competent Authority rather than a self-declaration by the private sector.	Agreed, see response 4.3.1._7.
4.3.1._9	**Category:** Addition **Proposed amended text:** A *self-declaration of freedom from disease* for a *compartment* from specified *listed diseases* can be made by the Competent Authority 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. **Rationale:** We want to clarify that the official self-declaration should come from the Competent Authority (not made by industry themselves). As written, this is not clear and should be emphasized.	Agreed, see response 4.3.1._7.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.2._1	**Category:** Addition **Proposed amended text**: There may be a range of *commodities* produced by a *compartment* and a range of 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. **Rationale**: Change for clarity of sentence.	The second paragraph was deleted to remove references to commodities and end-uses as the focus of a compartment should be to have populations of aquatic animals of a distinct health status regardless of commodity produced or potential end-uses.
4.3.2._2	**Category:** change **Proposed amended text:** ~~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.~~ **Rationale:** Both 4.3.2 and 4.3.3 , even in 4.3.4 (the paragraph after point 2) mention the need to consider the type and ultimate use of commodities in risk management. However, there is no further description in this chapter on how to consider and what applicable risk management measures are required for different types of products. To streamline repetitive content and improve the clause system, two suggestions are put forward: First, delete the paragraph on "Commodity type and ultimate use" in Article 4.3.2 and supplement its examples to point 2) of Article 4.3.3. Second, add a new clause in this chapter to elaborate in detail on the risk management measures corresponding to different commodity types.	See response 4.3.2._2.
4.3.2._3	**Category:** Deletion **Proposed amended text**:	See response 4.3.2._2.

	~~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.~~ **Rationale:** The first paragraph of this article sufficiently describes the purposes of a compartment. Commodity types are sufficiently covered in Section 5 and the disease-specific chapters.	

Article 4.3.3.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3._1	**Category:** General The introduction of the concept of internal and external surveillance is difficult to understand. External factors are to be taken into account in the surveillance system of any dependent compartment.	Internal and external surveillance are a concepts that are already included in the current Chapter 4.3. of the *Aquatic Code* which was adopted in 2010 as well as Chapter 4.5. 'Application of compartmentalisation' of the *Terrestrial Code* adopted in 2008. The text of the draft chapter was reviewed, and edits were made to provide clarity on the usage of internal and external surveillance.
4.3.3._2	**Category:** General The Members queries the use of 'External Surveillance', both in the terminology, which is not commonly used and does not have a glossary definition, and in the concept itself. In our view, such 'external surveillance' is unnecessary provided the surveillance, which is carried out within the compartment itself, is sufficiently robust. This includes during the period of TS which precedes a declaration of disease-freedom, and in the period during which that freedom is maintained. It is our view that surveillance to maintain the freedom of a dependent compartment should be at a higher level than that which applies to an independent compartment.	Internal and external surveillance are concepts that are already included in the current Chapter 4.3. of the *Aquatic Code* which was adopted in 2010 as well as Chapter 4.5. 'Application of compartmentalisation' of the *Terrestrial Code* adopted in 2008. In revised Article 4.3.6. (Annex 6) the usage of internal and external surveillance have been described. Text was added in Article 4.3.6. point 2, that external surveillance may be passive or targeted and in line with the disease-specific chapters and Chapter 1.4. The Commission will review Chapter 1.4. at its February 2026 meeting to discuss whether revisions are required for consistency with the draft Chapter 4.3.

Principles for establishing a compartment

The following principles should be applied to establish and maintain a *free compartment*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3._3	**Categoría:** Adición **Texto modificado propuesto:** Los compartimentos deben estar claramente definidos y deberán documentar todos los componentes de este, así como todas aquellas unidades que tengan una relación epidemiológica. **Justificación:** Es importante definir y documentar los límites y ubicación, así como cualquier componente que eventualmente pueda influir en el estatus sanitario del compartimento (ejemplo: empresas de servicio externas como plantas de alimento y empresa retiro de mortalidad).	Agreed that compartments should be clearly defined and all components should be documented. This is addressed in revision of Article 4.3.1. paragraph 2 – 'A *compartment* may comprise a single *aquaculture establishment* or a group of *aquaculture establishments* that operate under a common set of *risk management* measures in accordance with this chapter.' The need for a biosecurity plan that takes into account the different components that may influence the health status of a compartment is outlined in Article 4.3.5.

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);

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3._4	**Category:** Change **Proposed amended text**: 1) A *compartment* must ensure there are effective measures to prevent the entry or spread of *pathogenic agents* from the ~~between the compartment and~~ external environments into the *compartment* (i.e. provide functional epidemiological separation); **Rationale:** This principle is to prevent the movement of disease from the environment into the compartment. Movement of disease out of the compartment is not a concept that should be addressed in this chapter, as that would essentially equate compartments to quarantines and require additional effluent controls which is a potential barrier for businesses interested in becoming a compartment. Additionally, movement of disease within an epidemiologically distinct population within a compartment is expected and beneficial for disease surveillance.	Agreed to edit text to focus on the measures to prevent entry of pathogenic agents from the environment. The primary objective of a compartment is to maintain a distinct health status which would be lost by the entry of a pathogenic agent.
4.3.3._5	**Category:** addition/deletion **Proposed amended text:** A *compartment* must ensure there are effective measures to prevent the entry or spread of *pathogenic agents* between the external environments and the	See response 4.3.3._4.

	compartment ~~and external environments~~ (i.e. provide functional epidemiological separation); **Rationale:** The use of the word "between" infers potential for two-way spread of pathogenic agents between the compartment and the external environment. However, if the primary objective is for compartments to be established to maintain disease freedom (as outline in Article 4.3.1 Objective and introduction), then the emphasis here should be the prevention of the entry or spread of *pathogenic agents* from the external environment to the *compartment*, and suggest by swapping the order of these two terms that this more strongly inferred.	
4.3.3._6	**Category:** Change **Proposed amended text:** 1) A *compartment* must ensure there are effective measures to prevent the entry or spread of *pathogenic agents* between ~~the *compartment* and~~ external environments and the *compartment* (i.e. provide functional epidemiological separation); **Rationale:** The primary concern should be spread from an unknown health status (the environment) into the compartment (known health status).	See response 4.3.3._4.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3._7	**Category:** Addition **Proposed amended text**: 3) ~~the purpose of a~~ A *compartment* should be clearly defined ~~(*disease(s)* for which freedom will be claimed, species and *commodities* produced, intended end-uses of *commodities*)~~ by the owner/operator and the Competent Authority, as this will have implications for the design of risk management measures, as described in Article 4.3.2. The following must be clearly defined: i) purpose of the compartment (disease(s) for which freedom will be claimed, species and commodities produced, intended end-uses of commodities) ii) category of compartment (independent or dependent)	The objective of this article is to provide principles which are expanded upon in the rest of the chapter, such as the points proposed. This article was re-ordered to become new Article 4.3.2. (Annex 6). The proposed points are all already addressed in the text: - The new Article 4.3.3. (old Article 4.3.2.) was renamed 'Purposes and scope of compartments' to better reflect its content. - Category of compartment is addressed in point 3 of new Article 4.3.2. - Text on having a defined area around a dependent compartment was added to

	iii) for dependent compartments the boundaries of the zone upon which the health status is determined. **Rationale:** Many aspects of the compartment need to be defined. The owner and Competent Authority need to agree on all aspects of the definition to ensure appropriate application of the standards and a common understanding of the approach, potential limitations and potential implications of decisions.	Article 4.3.6. in relation to external surveillance to address point iii of proposed text.
4.3.3._8	**Category:** change **Proposed amended text:** 2) the purpose of a *compartment* should be clearly defined (e.g. *disease(s)* for which freedom will be claimed, species and *commodities* produced (e.g. *aquatic animals*, *aquatic animal products*), intended end-uses of *commodities* (e.g. for *aquaculture*, stocking of natural water bodies, human consumption, *ornamental aquatic animals*)) as this will have implications for the design of *risk management* measures, as described in Article 4.3.2.; **Rationale:** Both 4.3.2 and 4.3.3 , even in 4.3.4 (the paragraph after point 2) mention the need to consider the type and ultimate use of commodities in risk management. However, there is no further description in this chapter on how to consider and what applicable risk management measures are required for different types of products. To streamline repetitive content and improve the clause system, two suggestions are put forward: First, delete the paragraph on "Commodity type and ultimate use" in Article 4.3.2 and supplement its examples to point 2) of Article 4.3.3. Second, add a new clause in this chapter to elaborate in detail on the risk management measures corresponding to different commodity types.	Did not agree, re-ordering of articles (see response to 4.3.3._7) allowed the principles to be outlined in this article while the proposed additional text is covered by existing text in other articles following the principles. References to end-uses and commodities was removed – see response to 4.3._7.
4.3.3._9	**Category:** Deletion **Proposed amended text**: 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.; **Rationale:** The principles for establishing a compartment should be related to the required risk management measures, including any disease-specific risks as per the disease-specific chapters. This includes much more than species, commodities and intended end uses, and the text should be amended for clarity.	Removed references to commodities and end-uses (see response to 4.3._7.). Other examples remained as they provide clarity to point 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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3._10	**Category:** General It is unclear where the line is between a 'compartment' versus a 'zone' based on the language in 3) above.	External surveillance aims to identify relevant changes in the level of exposure, which will allow timely management measures Further as outlined in additional text to Article 4.3.6. if a free compartment is in a free zone, the surveillance of a zone may provide the external surveillance of the compartment.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3_11	**Category:** Change **Proposed amended text:** 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. 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.; ~~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.; **Rationale:** Suggest describing biosecurity measures and surveillance as two separate principles. The biosecurity plan is included in the principle of biosecurity measures. This is because the biosecurity plan provides the basis and	Did not agree, the intention of point 3 is to provide a distinction between independent and dependent compartments and their requirements for surveillance and biosecurity. Revisions were made to point 3 for more clarity to its purpose and to emphasise the categories.

	operational guidelines for implementing biosecurity measures. So it is recommended that the content related to the biosecurity plan in point 4) be moved to point 3), and delete the word " surveillance " in point 3.	
4.3.3._12	**Categoría:** Modificación / Editorial **Texto modificado propuesto:** La ~~clara~~ descripción detallada de las medidas de *vigilancia* orientadas a demostrar que el *compartimento* está libre de *enfermedades* específicas, y para mantener ~~que se mantiene~~ su estatus libre conforme al ~~acuerdo con el~~ Capítulo 1.4., incluye ~~incluidos~~ ~~los~~ elementos de *vigilancia* interna y externa, en cumplimiento ~~de conformidad~~ con lo dispuesto en el Artículo 4.3.6.; **Justificación:** El texto presenta una estructura redundante y con frases que dificultan la lectura. El término “detallado” es más técnico y adecuado en documentos normativos, ya que implica una descripción específica, documentada y verificable; mientras que “clara” es más subjetiva.	Agreed to change for clarity in Spanish version.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3._13	**Categoría:** Cambio **Texto modificado propuesto:** 6) Las pruebas de *vigilancia* deberán estar respaldadas por pruebas de laboratorio fiables ~~o~~ y realizadas en laboratorios independientes del operador del *compartimento* y que estén aprobadas por la *autoridad competente*, tal y como se describe en el Artículo 4.3.7.; 7) **Justificación:** Las pruebas de laboratorio no son independientes sino los laboratorios donde se realizan estas pruebas.	Agreed to change for clarity in Spanish version.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.3._14	**Category**: Addition **Proposed amended text**: 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 within the compartment or for dependent compartments in the defined surrounding waters upon which the health status has been established, or for other *diseases* relevant to trade from the *compartment*, as described in Article 4.3.12.; **Rationale:** The compartment must be prepared for the notification and response procedures for both detections within the compartment and in the defined zone surrounding the compartment.	Agreed that a compartment must notify when there is an event that may lead to a breach of the biosecurity measures and potentially threaten the health status of the compartment. As point 10 is a basic principle text reflecting this was not added to this point but was added to Article 4.3.12. - 'the operator of a compartment should report any event which could lead to a breach of biosecurity measures to the Competent Authority. A review should be initiated by the Competent Authority to determine whether a breach of biosecurity measures has occurred which could impact the health status of the compartment.'

4.3.3._15	**Category:** Addition **Proposed amended text**: 11) 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.; **Rationale:** This principle is proposed to be removed from Traceability Article 4.3.8.as it is not related to traceability and should be s a general principle of a compartment and therefore included in this section.	Agreed that Article 4.3.8. was not the appropriate location for text outlining that movements into a free compartment should come from free country, zone or compartment. The Commission did not agree that it should be listed as a principle and instead the text was added to Article 4.3.5. on biosecurity.
4.3.3._16	**Categoría:** Modificación / Editorial **Texto modificado propuesto:** La instauración de medidas de notificación y respuesta ~~en caso de~~ ante la detección de la e*nfermedad* para la cual ~~que~~ el *compartimento* se ha declarado libre, o de otras *enfermedades* relevantes ~~pertinentes~~ para el comercio a partir del *compartimento*, como se describe en el Artículo 4.3.12. **Justificación:** El uso de “Ante” en lugar de “en caso de” es más formal y conciso, adecuado para textos normativos, y refleja una relación directa de casualidad entre la detección de la enfermedad y la activación de las medidas. Sustitución de “pertinentes” por “relevantes”: Relevantes es un término más técnico y preciso en el contexto de sanidad animal, ya que subraya la importancia de las enfermedades en función de su impacto en el comercio internacional, conforme a los criterios de la WOAH.	Agreed to editorial change to Spanish version.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._1	**Category**: Clarification **Proposed amended text**: Dependent *compartments* do not have complete epidemiological separation from the surrounding environment and may 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 surrounding waters to be established as disease free~~ **Rationale:** This sentence seems to indicate that risk mitigation is required however the last paragraph before table 1 indicates that risk mitigations that may be required based on risk analysis. That paragraph is clearer about what risk mitigations may be required and what those mitigations may be. Removal of this text allows simplification of the Article and ensures consistency with the last paragraph.	Agreed that the application of risk management measures is dependent on risk analysis. Proposed text was not incorporated as the text in Article 4.3.4. was extensively revised to improve clarity on the use of risk analysis and risk management measures for independent and dependent compartments.
4.3.4._2	**Original version** **Categoría:** General **Texto modificado propuesto:** El compartimento dependiente debe aplicar solo con fines de comercialización de productos de animales acuáticos. **Justificación:** En vista que los compartimentos dependientes no están completamente separados epidemiológicamente del entorno circundante, no proporcionando suficientes garantías de mitigación de riesgo para todos los fines, resulta necesario que solo podrá ser aplicado para productos de los animales acuáticos.	Did not agree that dependent compartments should only be used for producing aquatic animal products. A dependent compartment can be used to create a distinct health status and should be informed by risk analysis accounting for disease-specific and environmental factors.
4.3.4._3	**Category:** change **Proposed amended text:** 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	Agreed to change from ‘applied successfully’ to ‘implemented effectively’ for more clarity.

	achieve and maintain disease-free status despite epidemiological links to the surrounding environment. If such *risk* mitigation measures cannot be ~~applied successfully~~ implemented effectively, a dependent *compartment* cannot be approved by the *Competent Authority*. **Rationale:** This way of expressing logic is clearer and more accurate.	
4.3.4._4	**Category:** general **Proposed amended text:** n/a **Rationale:** Suggest adding the terms "dependent compartment" and "independent compartment" to the glossary, either as part of main definition of "compartment"	Did not agree, to add independent and dependent compartment to the glossary. The terms are defined as they are used in the draft Chapter 4.3. and not used in other parts of the *Aquatic Code*. Text in the draft Chapter 4.3. was revised to provide greater clarity on these terms.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._5	**Category:** Deletion **Proposed amended text**: d) provide levels of *risk* mitigation suitable for all purposes~~, *commodity* types and end-uses;~~ **Rationale:** Deletion to improve clarity and focus.	Agreed, see response 4.3._7.

   e) are often preferred for high value *aquatic animals* (e.g. genetically improved lines, brood stock).

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._6	**Category:** Change **Proposed amended text:** e) ~~are often preferred for~~ typically houses high value *aquatic animals* (e.g. genetically improved lines, brood stock). **Rationale:** Suggested change for clarity.	Point e was deleted. Independent compartments are often preferred for high value aquatic animals however the inclusion of the point was not considered necessary to understand the concept of an independent compartment.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._7	**Category of comments:** General **Proposed amended text:** 2) Dependent compartments: a) are **semi-open and** semi-closed production system types only (as described in Chapter 4.1.); … d) meet the additional biosecurity criteria and risk mitigation measures for transmission via **both** intake **and effluent** water which the Competent Authority may approve in accordance with Article 4.3.5.; **Rationale**: The reason for adding *'semi-open'* to *(2a)* above is that most of the commercial aquaculture production in the region is done in semi-open systems (notably cages) both within the inland fresh-water and marine environments.	Point a - Did not agree to add semi-open production systems. Semi-open systems are usually better addressed through zoning rather than compartmentalisation due to risk levels and associated surveillance required. Point b – Did not agree to added text as the objective of a compartment is to prevent the entrance of a pathogenic agent and as such the focus is on the intake of water.

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).

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._8	**Category:** Deletion **Proposed amended text:** 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)~~. **Rationale:** The list of examples that are not applied to dependent compartments may be confusing. Suggest deletion of examples.	Point e was deleted due to removal of commodities and end-uses from the chapter – see response to 4.3._7.
4.3.4._9	**Category**: deletion **Proposed amended text**: 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)~~. **Rationale:** The Member opposes indicating "live aquatic animals for aquaculture" as possible inappropriate example in 2) e). The current text is misleading that the dependent compartment cannot be applied for supplying "live aquatic animals for aquaculture". However, the Member thinks it may be applicable to such case if appropriate risk mitigation measures are implemented in accordance with Article 4.3.5. If examples are absolutely necessary in 2) e), the Member requests the Commission to make clear for each example in what respects sufficient risk mitigation may not be achieved, so that bilateral discussions on the application of dependant compartment for such inappropriate examples will be facilitated.	See response 4.3.4._8.
4.3.4_10	**Category:** Deletion, addition **Proposed amended text**: 2) Dependent compartments: a) are semi-open or 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~~ biosecurity and surveillance to mitigate the risk of introduction of specific pathogenic agents into the compartment in accordance with Article 4.3.5.; ~~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)~~ d) may not provide sufficient *risk* mitigation for all purposes~~, *commodity* types and end-uses (e.g. supplying~~	Point a – see response 4.3.4._7. Point c – Agreed to clarify biosecurity and surveillance use to mitigate risk. Edits were made to reflect the suggestion. Point d – Did not agree to delete but was revised to differentiate from point c. Point c is to prevent introduction of pathogenic agent for which the compartment has a distinct health status, while point d is to prevent introduction of other hazards. Point e was deleted, see response 4.3.4._8.

	~~live *aquatic animals* for *aquaculture* or restocking, for high value *aquatic animals* such as genetically improved lines).~~ **Rationale:** The Member encourages the Commission to reconsider whether there could be situations where a semi-open system may be able to fulfil the criteria to become a dependent compartment. If a semi-open system should be able to fulfil the requirements it would be inappropriate to exclude it. While semi-closed systems are much more likely to be able to fulfil the requirements, there may be situations where the characteristic of the pathogenic agent in question and the environmental conditions allows a semi-open system to have sufficient biosecurity and surveillance measures to be eligible for status as a dependent compartment. Biosecurity measures, surveillance and risk mitigation are key aspects for dependent compartments and related text changes are suggested.	

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).

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._11	**Category**: Change **Proposed amended text**: …, and their end-uses (e.g. products for human consumption versus *aquatic animals* for aquaculture ~~stocking~~ in semi-open systems). **Rationale:** The Member requests the Commission to clarify the difference between “aquatic animals for stocking in semi-open systems” and “aquatic animals for aquaculture in semi-open systems”, since the assumed situation is equal.	References to end-use have been removed from the chapter (see response 4.3._7). This paragraph along with others in Article 4.3.4. have been extensively revised for clarity and improved understanding of dependent and independent compartments.
4.3.4._12	**Category:** Deletion **Proposed amended text**: 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).~~ **Rationale:** The suitability of a dependent compartment to achieve the required level of risk mitigation is the key aspect, based on risk analysis. As previously mentioned, commodities are sufficiently covered in Section 5 and the disease specific chapters.	Agreed, see response to 4.3._7.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._13	**Category**: Deletion **Proposed amended text**: 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* (e.g. influent screens or filtration). 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*.~~ **Rationale:** For the first sentence, it is suggested to include an example such as influent screens to indicate that influent treatment is not required for dependent compartments. If the compartment health status is dependent on the health status of the water in the surrounding zone, then risk mitigation measures such as water treatment sufficient for pathogens of concern would likely only be implemented for independent compartments. Movement of disease out of the compartment is not a concept that should be addressed in this chapter, as that would essentially equate compartments to quarantines and require additional effluent controls which is a potential barrier for businesses interested in becoming a compartment. Additionally, movement of disease within an epidemiologically distinct population within a compartment is expected and beneficial for disease surveillance.	Did not agree to add example of influent screen for a risk management measure. This example may lead to a misunderstanding that an influent screen can prevent the entrance of infection from the environment. Agreed to remove risk mitigation measures to prevent transmission if the disease into the environment. The main purpose of a compartment is to prevent entrance of disease transmission, and these measures are not relevant to that purpose.
4.3.4._14	**Category**: Deletion **Proposed amended text**: ~~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*.~~	Agreed that last paragraph is more relevant to Article 4.3.5. on biosecurity. Text from this paragraph was revised and integrated into Article 4.3.5 to include this concept in that article.

	Rationale: This paragraph should be in the next article 4.3.5. based on the content.	

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

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.4._15	**Category:** Change **Proposed amended text:** ~~Only~~ Closed and semi-closed systems are a suitable production system type **Rationale:** More than one aquaculture establishments combining closed and semi-closed systems can be recognised as a dependent compartment.	Table 1 was deleted as it was confusing and that information was integrated into other areas of the chapter. Note that if a system is a part of a dependent compartment, it would not closed system.
4.3.4_16	**Category:** Deletion, addition **Proposed amended text**: In the table under the “Independent” heading: Suitable for all ~~*commodities* and~~ pathways In the table under the “Dependent” heading: ~~Only~~ Semi-open and semi-closed systems ~~are~~ ~~a~~ may be suitable production system ~~type~~ types May not meet the required level of *risk* mitigation for all ~~*commodities* and~~ pathways **Rationale:** See comment earlier about potential eligibility of semi-open systems and commodities being sufficiently covered in Section 5 and the relevant disease-specific chapters. The Commission is also encouraged to reconsider whether this table is needed given the easy-to-read list of characteristics earlier in this article.	Table 1 was deleted as it was confusing and that information was integrated into other areas of the chapter.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.5._1	**Category**: Addition **Proposed amended text**: For *compartments* comprising more than one *aquaculture establishment* with a common purpose and category of compartmentalisation, 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*. **Rationale:** For compartments that consist of more than one aquaculture establishment, all aquaculture establishments should be of one category only, either dependent or independent. Otherwise, the biosecurity plan would not consist of comment management and physical measures as these would be different for dependent and independent compartments.	Did not agree to proposed text. In a compartment aquaculture establishments do not need a common purpose but rather a common disease status. Further if multiple aquaculture establishments are a part of a compartment they are by definition in the same category.

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:*

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.5._2	**Category**: Editorial **Proposed amended text**: 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~~ to inform the development of appropriate *risk management* and *surveillance* measures to mitigate the identified *risks*. The *Competent Authority* should consider in the *risk analysis:* **Rationale:** The risk assessment should inform the development of risk mitigations.	Agreed to editorial revision.

1) characteristics of the *pathogenic agent*;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.5._3	**Category:** Addition **Proposed amended text:**	Agreed to plural as a compartment may have a health status for more than one pathogenic agent. The chapter was

	1) characteristics of the pathogenic agents." **Rationale:** A compartment may declare freedom from multiple diseases, so this should be reflected in pluralisation here.	reviewed, and other instances were made plural where appropriate.

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:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.5._4	**Categoría:** Modificación / Editorial **Texto modificado propuesto:** 2) la ausencia de *especies susceptibles* y de vías de *infección* en el entorno debido a la ~~situación~~ ubicación geográfica, las condiciones medioambientales o la implementación ~~a la aplicación~~ de medidas de *bioseguridad*. Deberá prestarse especial atención a: **Justificación:** "ubicación" es más específico y técnico, refiriéndose a la posición espacial del compartimento en relación con factores de riesgo como la proximidad a áreas endémicas, este término es común en los estándares de la WOAH. Cambio de aplicación a implementación, "implementación" denota una acción planificada y sistemática, más adecuada para describir medidas de bioseguridad (ejemplo, barreras físicas, protocolos de desinfección) que requieren de diseño y monitoreo continuo.	Agreed to editorial change for Spanish version.
4.3.5._5	**Category:** Change **Proposed amended texts:** 2) presence or absence of *susceptible species* and pathways of ~~*infection*~~ exposure in the surrounding environment due to geographical location, environmental conditions or the application of *biosecurity* measures. Specific consideration should be given to: **Rationale:** We should be interested in both the presence or absence of susceptible species, as well as pathways that could lead to exposure to a given pathogen.	Agreed that point 2 should focus on the presence of susceptible species. Absence was removed, as the presence of susceptible species is the risk factor of concern. Absence was revised to presence in point 3 as well, as presence of infection is the risk factor.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.5._5	**Category**: Addition **Proposed amended text**: 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*. **Rationale:** This paragraph should be in the article 4.3.5., not in the article 4.3.4, based on the content.	Agreed, see response 4.3.4._14.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.5._6	**Category:** Deletion **Proposed amended text:**	Did not agree to delete this paragraph. It is an important point to emphasise, that if it is not possible to mitigate risks from the external environment than

	~~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*.~~ **Rationale:** This text is repetitive and could be deleted.	aquaculture establishments cannot be recognised as a dependent compartment.
4.3.5._7	**Category:** Addition **Proposed amended text**: For some semi-open and 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* **Rationale:** Text needs to be amended if semi-open aquaculture establishments are included for dependent compartments.	Did not agree, see response 4.3.4_7.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.6._1	**Categoría:** Editorial **Texto modificado propuesto:** Para el reconocimiento de un *compartimento libre*, deberá presentarse una *autodeclaración de ausencia de enfermedad* que cumpla con los requisitos enumerados en el Artículo 1.4.4. Los requisitos de *vigilancia* necesarios para establecer una *autodeclaración de ausencia de enfermedad* relativa a un *compartimento* y para mantener un *compartimento libre* deberán ajustarse a lo dispuesto en el Capítulo 1.4. **Justificación:** Se debe indicar primero el capítulo y luego el artículo.	Did not agree as the ordering of chapter and article is the accepted format used throughout the *Aquatic Code*.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.6._2	**Category**: Clarification **Proposed amended text**: *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*. [under study] **Rationale:** The Member proposes that this paragraph be put under study as the AAC has committed to review Chapter 1.4. and articles on compartments in the disease-specific chapters to determine the implications of the revised Chapter 4.3. Putting this paragraph understudy means that upon adoption that the current periods for targeted surveillance for compartments are not used to establish disease freedom for dependent compartments until that review of implications can be completed.	Did not agree, the Commission will review Chapter 1.4. at its February 2026 meeting and consider what revisions need to be made at that time.

Surveillance requirements should be developed in accordance with factors as described in Article 4.3.5.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.6._3	**Category:** Addition **Proposed amended text**: *Surveillance* requirements for dependent compartments should be developed in accordance with risk factors identified in the risk analysis as described in Article 4.3.5. **Rationale:** For independent compartments, there should be no introduction risk therefore surveillance design in not dependent on risk mitigation strategies of biosecurity. This sentence was modified to specifically describe dependent compartments and the need to consider the identified risks in building an internal and external surveillance plan.	The sentence was deleted and was addressed under point 2 on external surveillance.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.6._4	**Category**: clarification **Proposed amended text**: 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. [under study] **Rationale:** The Member proposes that this paragraph be put under study as the AAC has committed to review Chapter 1.4. and articles on compartments in the disease-specific chapters to determine the implications of the revised Chapter 4.3. Putting this paragraph understudy means that upon adoption that the current periods adopted for targeted surveillance for compartments are not used to establish disease freedom for dependent compartments until that review of implications can be completed.	See response to 4.3.6._2.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.6._5	**Category:** Addition **Proposed amended text:** External *surveillance* is required for dependent *compartments* if populations of *susceptible species* are present in the environment surrounding the *compartment*. External surveillance may be used for independent compartments to inform their biosecurity measures. **Rationale:** Surveillance is required to determine the health status of the surrounding environment.	Agreed that external surveillance can be used by either category of compartment. The paragraph was split into two paragraphs for more clarity. The first paragraph is a general paragraph on what external surveillance is. The second paragraph is specific to how external surveillance is used with dependent compartments.

4.3.6._6	**Category:** Addition **Proposed amended text**: All compartments must support freedom with internal with or without external surveillance, as described below: 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*. External surveillance may be passive or targeted based on the specific situation in accordance with the relevant disease-specific chapters and Chapter 1.4. **Rationale:** Added sentence to external surveillance definition to include passive and targeted surveillance and refer to the relevant disease specific chapters and chapter 1.4, since freedom in an external environment may apply principles on zone freedom such as absence of susceptible species or absence of pathogen in a discrete area. As disease freedom claims in the surrounding waters of dependant compartments could be based on historical freedom (pathway 2) at the country or zone level or historical freedom claims supplemented by targeted surveillance, all options should be available for demonstration of freedom prior to definition of the compartment.	Did not agree to add a sentence before the points, as it is stated in point 1 that internal surveillance is required for all compartments and is not necessary to repeat here. Agreed to add to point 2 that external surveillance may be passive or targeted and should take into account provisions in the disease-specific chapters and Chapter 1.4.
4.3.6._7	**Category:** editorial **Proposed amended text:** 1. Internal surveillance Internal *surveillance* (i.e. ~~for~~ of 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.	Agreed to editorial revision.

	2. External surveillance External *surveillance* (i.e. ~~for~~ of 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*. **Rationale:** Edited to improve accuracy – surveillance "for" populations suggests that surveillance is being carried out to determine presence/abundance of *susceptible species*, whereas surveillance "of" more accurately denotes that the populations of susceptible species are undergoing surveillance for disease.	
4.3.6._8	**Category:** General **Proposed amended text**: The description of "external surveillance" in the *Aquatic Code* is limited compared to that for "internal surveillance". The Member requests the Commission to consider whether additional details should be given to improve clarity on how external surveillance should be conducted. **Rationale:** Further description should ensure a uniform understanding of the requirements related to "external surveillance".	Noted, will be considered when the Commission reviews Chapter 1.4.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.7._1	**Category:** Editorial **Proposed amended text:** 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:	Agreed to editorial revision.

	1) … 2) ~~is required to~~ conducts testing in accordance with the recommendations of the *Aquatic Manual*; **Rationale:** Removed words that do not add meaning to the text.	

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.7._2	**Category:** Change **Proposed amended text:** 3) can confirm or exclude cases of ~~*disease*~~infection as described in Article 1.4.18.; **Rationale:** The aim of testing should be to confirm/exclude cases of 'infection' rather than 'disease'.	Agreed, testing is to exclude cases of infection rather than disease.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.8._1	**Category**: Addition **Proposed amended text**: be appropriate for the nature of supply chains of the *aquatic animal* species ~~and~~ for application to individual or groups of *aquatic animals* or *aquatic animal products*, as necessary; **Rationale:** When applied aiming for disease control, the traceability "appropriate" in terms of "species" is unclear. The Member requests the Commission to clarify the meaning by adding some phrase as proposed, or if not possible, delete "for the aquatic animal species".	Agreed that traceability needs to be appropriate to the nature of the supply chain rather than just the aquatic animal species.
4.3.8._2	**Category:** Deletion, addition	Did not agree. While commodities were removed

	Proposed amended text: 1) be appropriate for the *aquatic animal* species and for application to individual or groups of *aquatic animals* ~~or *aquatic animal products*~~, as necessary; **Rationale:** Compartments are relevant for trade with live aquatic animals, for which traceability systems are important to ensure safe trade. The example of "aquatic animal products" is inappropriate as it could indicate traceability requirements for the compartment operator all the way to the final consumer, including for Ready-to-Eat products based on aquatic animal species. This would cause an unreasonable burden on the operator and is in contradiction to the provisions for trade with aquatic animal products for human consumption in the disease specific chapters in the *Aquatic Code*.	from the chapter, it does not exclude the inclusion of aquatic animal products in the context of this article.

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.;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.8._3	**Category:** Change **Proposed amended text**: ~~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.;~~ 2) record all *aquatic animal* movements into and out of the *compartment including origin and destination.* **Rationale:** This statement was deleted because it does not speak to tracing guidelines. Ensuring all animal introductions are disease free is an over aching principle of biosecurity or compartmentalisation and is suggested to be moved to Article 4.3.3. A basic principle of tracing is recording all animals movements. Added wording for basic tracing.	Agreed to revise point 2 to focus on the traceability of movements. Revisions were made to reflect this consideration.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.9._1	**Category:** Addition **Proposed amended text:** 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, vaccination records, and health investigations; **Rationale:** Vaccination is an important tool for disease control but also one of great trade concern to many countries, so it should be included here given the purpose of the compartments are to facilitate trade.	Agreed to the addition of vaccination records as the use of vaccination is relevant to risk analysis for surveillance requirements.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.9._2	**Category:** Change **Proposed amended text:** 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. Or utilize digital tools to enhance traceability and ensure the integrity of records. Electronic records shall be recognized as legally valid and enforceable under applicable national and	Did not agree to add text on digital records. The intention is to ensure appropriate records are being kept, not prescribe the format in which the records should be kept. Different format of record keeping could be utilized depending on the circumstance. Did not agree to added text around data sharing as the second paragraph of this article indicates that records should be available by request which covers this point.

	international regulations, provided they are securely stored and tamper-evident; Data shall be shared with the Competent Authority through secure digital platforms, ensuring timely access to critical information (e.g., biosecurity logs, surveillance results, movement records) for compliance monitoring and emergency response. **Rationale:** Digitization is the trend of the future. Digital records help to trace in real-time and quickly, and prevent data from being modified or supplemented. It is recommended to combine digital technology with modern traceability and explicitly recognize the legal validity of electronic records. And electronic records and data exchange with regulatory authorities ensure regulatory transparency and efficiency. Given the potential technological or financial constraints of small and medium-sized farms in digitalization, it is recommended to classify relevant digital requirements as optional to allow flexible implementation based on practical conditions.	

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.10._1	**Category:** Change **Proposed amended text**: 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~~	Agreed to remove the term accredited as it may have different meaning for different Members. Agreed to replace it with text that third party auditors must be approved by the Competent Authority for clarity.

	a third party auditors approved by the Competent Authority. **Rationale:** The term accredited does not mean the same thing in all member countries. Suggesting wording to standardize that third parties must be approved by the CA.	
4.3.10._2	**Category:** Editorial **Proposed amended text**: A *Competent Authority* must have the authority to approve the operation of the *aquaculture establishment(s)* that ~~compromise~~ comprise the *compartment*. **Rationale:** Editorial change.	Agreed, editorial revision.
4.3.10._3	**Category:** Editorial **Proposed amended text:** A *Competent Authority* must have the authority to approve ~~the operation of the~~ *aquaculture establishment(s)* that comprises ~~compromise~~ the *compartment*. **Rationale:** For the sake of clarity.	Agreed, editorial revision.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.11._1	**Category:** Change **Proposed amended text:** The quality of *Aquatic Animal Health Services* relevant to the self-declaration of *compartment* freedom should be documented (reviewed), including how they meet the requirements of Chapter 3.1 by the Competent Authority. **Rationale:** This should indicate that the quality should be evaluated by the higher-level official regulatory agency.	Agreed, the quality of Aquatic Animal Health Services must be documented by the Competent Authority.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.12._1	**Category**: Change **Proposed amended text**: Deletion In the event of ~~suspicion of~~an 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. **Rationale:** Deletion to mirror the wording in Article 1.1.3. that Veterinary Authorities shall notify the occurrence of a listed disease. Competent Authorities should not be required to notify importing countries of the suspicion of disease, they should only be notifying upon confirmation of the detection.	Agreed to change for consistency with Article 1.1.3. that notification occurs on the suspicion of disease.
4.3.12_2	**Category:** Addition **Proposed amended text:** In the event of suspicion of occurrence of the disease for which the *compartment* was defined, the management of the *compartment* should immediately notify the *Competent Authority*. The *Competent Authority* should then determine whether the disease-free status of the *compartment* should be immediately suspended and *importing countries* should be notified following the provisions of Chapter 1.1, while the occurrence of the disease is confirmed or ruled out. **Rationale:** The management of the *compartment* should notify the *Competent Authority* at the first suspicion of the disease, as the *Competent Authority* be responsible for suspending the status of the compartment and notifying importing countries.	Agreed to emphasise that an operator should notify upon suspicion of disease. Text was revised to reflect this suggestion.
4.3.12._3	**Category:** Deletion **Proposed amended text:** ~~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.~~ **Rationale:** We disagree with this statement as written because “suspicion" implies that every FAD investigation would trigger status suspension and notification; however, Chapter 1.1 does not indicate notification	Did not agree to delete the paragraph that suspicion should be reported. Potential disease introduction regardless of disease may indicate a breach of biosecurity measures and the integrity of the compartment may be compromised. Text was revised to clarify that on notification the Competent Authority should complete a review a determine whether status of the

	based on "suspicion". We therefore propose that the compartment should report to the Competent Authority if there is suspicion, and then after the Competent Authority has reviewed the situation they make the final decision regarding reporting. If the pathogen is confirmed, then it should be reported by the Competent Authority to WOAH.	compartment should be suspended depending on the circumstances.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.12._4	**Category:** Deletion/Addition **Proposed amended text:** In the event of ~~detection~~ suspicion of the occurrence 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. **Rationale:** The management of the *compartment* should notify the *Competent Authority* at the first suspicion of the disease which may indicate a breach of *biosecurity* measures, to allow pre-emptive investigation to determine whether a breach of *biosecurity* measures has occurred, and hopefully prevent the future occurrence of the disease for which the *compartment* was defined.	Agreed to change detection to suspicion of disease as it may represent a breach of biosecurity measures. Other revisions were made to this article to emphasise that a potential breach of biosecurity measures should be considered.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.12._5	**Category**: Addition **Proposed amended text**: In the event of suspicion of occurrence of disease within surrounding waters upon which the health status was established, the dependent compartment should be notified by the Competent Authority. There should be an immediate suspension of trade from the dependent compartment to disease-free areas until disease investigation and response as described in Chapter 4.Y is completed. Disease free status of the dependent compartment may only be reinstated if the suspicion of disease is not confirmed.	Paragraph 3 was revised to clarify that an operator should report on any potential event that may cause a breach in biosecurity measures, this may include disease outbreak as well as events such as natural disasters or other emergencies. It is then the responsibility of the Competent Authority to then determine whether the breach is a risk to the status of the compartment.

	Rationale: For dependent compartments if there is a disease incursion in the surrounding waters upon which the health status was established, they may not be aware if it was detected through activities not associated with the compartment. The Competent Authority should make them aware as soon as possible as their health status would be considered automatically affected. In addition, as the health status of the surrounding waters provides the health status for the compartment, the dependent compartment would also lose their health status and all trade must be suspended until the disease is confirmed. If the disease is confirmed that compartment would not be able to remain a dependent compartment and if they want to remain a disease free zone, would have to transition to an independent compartment with the additional infrastructure and disease freedom testing required for that designation.	

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.3.12._6	**Category:** Change **Proposed amended text:** In the event of suspicion of occurrence of the disease for which the *compartment* was defined, the *Competent Authority* should be notified by the management of the *compartment* and the investigation of the cause should be instigated. The trade should voluntarily be suspended by the management of the *compartment* until the disease status of the *compartment* is confirmed. ~~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 confirmation of the disease for which the compartment was defined, the free status should immediately be suspended. In the event of confirmatory 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.	Proposed addition to the first paragraph had been addressed by revisions. These revisions were regarding the role of the Competent Authority in determining the impact of an event on the status of a compartment. Note that voluntary suspension of trade may not be done by the operator of the establishment. Agreed to add 'In the event of confirmation of the *disease* for which the *compartment* was defined, the free status should immediately be suspended.' Did not agree to add 'confirmatory' to second paragraph as it is not required for understanding. Did not agree to add surveillance to demonstrate freedom for return to disease-free status. This would only apply if the disease detected was that for which the compartment held

	If a significant breach in *biosecurity* is identified as the cause of the confirmatory detection, ~~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 including surveillance to demonstrate freedom from a *disease* of concern 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. **Rationale:** There appears to be a gap in the sequence of events outlined in the article, specifically from disease suspicion to confirmation, notification, and the implementation of response measures. This gap affects various levels of stakeholders and the chain of command, and should be addressed in the right order to ensure a coordinated and effective response. A suspected case should be notified to the Competent Authority (CA), and the cause should be investigated. The free status should not be suspended during the investigation. The compartment owner may voluntarily suspend trade; this is a commercial decision made during confirmatory testing. A confirmed case should be notified to the CA, and since the cause is known, the free status should be suspended immediately. Necessary emergency response activities should be undertaken, including depopulation, disposal of animals, and disinfection. Following this, a review of biosecurity measures should be conducted, and the status of the compartment should be re-evaluated, including surveillance. However, a period of maintaining basic biosecurity conditions must be observed, and basic biosecurity conditions must be continuously met prior to the commencement of targeted surveillance, which would be difficult to meet.	status. Other disease detections may lead to suspension of status because they represent a biosecurity breach not introduction of the disease of concern.

4.3.12_7	**Category:** Addition **Proposed amended text:** 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. The *surveillance* requirements to demonstrate and maintain freedom outlined in Article 4.3.6 should be consulted, including the relevant disease-specific chapters, to confirm that *basic biosecurity conditions* have continued to be in place in the *compartment* uninterrupted for the required period prior to commencement of *targeted surveillance*. The minimum period that *targeted surveillance* should be conducted prior to making a *self-declaration of freedom from disease* should also be re-evaluated, if required, prior to the disease-free status of the *compartment* being reinstated **Rationale:** The re-evaluation needs to confirm that the *basic biosecurity conditions* have continued to be in place (and not interrupted) for the minimum amount of time relevant to the disease, to maintain the integrity of the targeted surveillance, that is required to demonstrate and maintain the status of the compartment. If there has been a breach in the biosecurity conditions, the clock may need to be "re-started" once the conditions have been re-established, prior to the status of compartment being reinstated.	Text was added to the last paragraph to address this comment. The text outlines that basic biosecurity conditions needs to be reviewed and modified prior to reinstatement of status due to concerns on breach of biosecurity.

Glossary – Compartment

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
glossary_1	**Category:** General The Member continues to be concerned with the implications of having one definition for compartments but 2 categories, independent and dependent compartments, as outlined in the revised Chapter 4.3. The implications of the use of this definition within Chapter 1.4. and the disease-specific articles for compartmentalisation specifically for the periods for basic biosecurity and targeted surveillance are unclear. If this definition is used within the *Aquatic Code* for both dependent and independent compartments with no other qualifications, it will lead to inconsistent interpretation and application. The Member cannot support the new definition until additional clarity is provided regarding the implications of application of the definition are addressed.	Did not agree that independent and dependent compartments require a definition. The terms are defined within Chapter 4.3. and Member comments on that chapter were taken into account to clarify the usage of these terms in the chapter (see Annex 6).
glossary_2	**Category:** General We support this amendment.	Noted.
glossary_3	**Category:** General The Members support this new definition.	Noted.

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)*.~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
glossary_4	**Category:** Change **Proposed amended text**: means one or more *aquaculture establishments* containing a population of *aquatic animals* ~~with a distinct health status for a~~ free of specific disease or *diseases* that is established and maintained through the application of a common *biosecurity* system, appropriate *surveillance* and *disease* control measures. **Rationale:** The definition of a compartment should be linked to freedom status not just a distinct health status. A facility that maintains biosecurity and disease control measure but has inhouse endemic disease should not be called a compartment for that disease.	Did not agree to include concept of freedom rather than distinct health status. When a compartment is being established there may be a transition stage where it is not free of a specific disease. The wording a 'distinct health status' allows for this transition time during the establishment of the compartment.
glossary_5	**Categoría:** General **Texto modificado propuesto:** designa uno o varios *establecimientos de acuicultura* que contienen una población de *animales acuáticos* con un estatus sanitario diferenciado respecto de una o varias *enfermedades* específicas, establecido y mantenido mediante la aplicación de un sistema común de *bioseguridad* y de medidas apropiadas de *vigilancia* y *control* de *enfermedades* con un fin específico según el tipo de compartimento. **Justificación:** En vista que los compartimentos dependientes no están completamente separados epidemiológicamente del entorno circundante, no proporcionando suficientes garantías de mitigación de riesgo para todos los fines, resulta necesario que solo podrá ser aplicado para productos de los animales acuáticos.	Did not agree to add text that control measures need to be related to the end-use of the compartment. The risk management in a compartment needs to focus on the aspects under the control of the operator to allow it to maintain a distinct health status. In Chapter 4.3. references to end-uses have also been removed and are not needed in the definition.
glossary_6	**Category:** change **Proposed amended text:** means one or more *aquaculture establishments*, documented by the *Competent Authority(ies)*, containing ~~a population of~~ *aquatic animals* population(s) 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. **Rationale:** The insight of a compartment by the Competent Authorities plays a very crucial role, which is clearly stipulated in both compartmentalization and the application of compartmentalization. This point should not be removed from the definition.	Did not agree to add wording including the Competent Authorities as this aspect of compartmentalisation is covered in the revised Chapter 4.3. and is not necessary for inclusion in the definition of a compartment. Agreed to the second point that there may be more than one population of aquatic animals and added 'each' before containing to address this component.

	In addition, a compartment usually has more than one population of aquatic animals, and the concept of a population has not been clearly defined in the Code. The plural form should be used here.	
glossary_7	**Category:** general **Rationale:** We suggest that this definition should also reference *dependent* and *independent* compartments, or these terms should be added to the glossary separately.	Did not agree, see glossary_1.
glossary_8	**Category:** addition **Proposed amended text:** means one or more *aquaculture establishments* containing a population of *aquatic animals* with ~~a distinct health status~~ freedom from ~~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. Or, alternatively means one or more *aquaculture establishments* containing a population of *aquatic animals* with a distinct health status (usually freedom) 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. **Rationale:** The objective and introduction to Chapter 4.3: Application of compartmentalisation contains frequent reference to compartmentalisation being used to establish disease freedom, and it is understood that this is the most common reason compartmentalisation is applied in disease management. The definition here in contrast references “distinct health status”, rather than “disease freedom”. We propose that the definition be updated to replace “distinct health status” with “freedom”. Alternatively, if the Commission intends to keep the option of compartments being used for a purpose other than establishing disease freedom, then we propose adding “usually freedom” in parentheses to at least link the definition more definitively to Chapter 4.3	Did not agree to remove distinct health status, see glossary_4. Free compartment is a defined term in the glossary meaning ‘a compartment that fulfils the requirements for self-declaration of freedom from disease with respect to the disease(s) under consideration in accordance with the relevant chapter(s) in the *Aquatic Code*’. As this is a defined term the inclusion of freedom in the definition is not necessary.
glossary_9	**Category:** Addition **Proposed amended text:** means one or more *aquaculture establishments* containing a population of *aquatic animals* with a distinct health status for a specific *disease* or *diseases* approved and supervised by the *Competent Authority* that is established and maintained through the application of a common *biosecurity* system, appropriate *surveillance* and *disease* control measures.	Did not agree, the role of the Competent Authority is outlined in the revised Chapter 4.2. and is not necessary to include in the definition.

	Rationale: Establishments wishing to become a compartment will require the Competent Authority to submit their self-declaration/s of disease freedom, and therefore the compartment should be under the Competent Authority's supervision.	
glossary_10	**Category:** Deletion **Proposed amended text:** 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. **Rationale:** Delete 'that is' and 'the application of' to remove repetition and improve clarity of the statement.	Agreed to editorial edits.

[…]

Chapter 4.7. ‘Fallowing in Aquaculture’

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7._1	**Category:** General **This chapter should add rotational Aquaculture schemes.** Due to the great differences in the diversity and susceptibility of aquatic animals, rotational Aquaculture is more feasible than fallowing in many cases. In addition, non-susceptible species can be used for rotational Aquaculture, and infected susceptible species may be preyed on through the effect of the food chain, which has been confirmed in aquaculture practice. For example, fish can prey on shrimp infected with WSSV. This method can be considered as an alternative to fallowing, so Fallowing or Alternate Farming in Aquaculture can be used as the title of this chapter, and the corresponding content can be added.	Did not agree. Voluntary fallowing is a discretionary option. Thus, rotational aquaculture can be utilised if the Competent Authority determines that it is the best option for the circumstances. The cultivation of alternative species as an option is considered in Article 4.11.9.’Recovery phase’ and does not need to be re-iterated in this chapter as it may cause confusion.
4.7._2	**Category:** General It is recommended to specify a minimum fallowing period and provide practical fallowing procedures. **Rationale:** Suggest providing a minimum fallowing period and practical fallowing operational procedures for reference by government competent authorities or aquaculture farm.	Did not agree. The revised Chapter 4.7. provides principles for fallowing. Thus, it indicates that fallowing periods should be determined based on risk assessment. Minimum fallowing periods are considered too prescriptive as the Competent Authority will need to determine them based on the specific circumstance. The chapter was reviewed, and links were provided to Chapter 4.1.’Biosecurity for aquaculture establishments’ where appropriate.
4.7._3	**Category:** General The Member supports the modifications to the chapter. Nevertheless, we have one comment (see Article 4.7.2.)	Noted.
4.7._4	**Category:** General The Members in general supports and welcomes the update of this chapter, in particular, the differentiation between the standards which apply to compulsory fallowing and those which apply to voluntary fallowing Comments are inserted in the text below.	Noted.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.1._1	**Category:** Deletion **Proposed amended text**: ~~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. **Rationale:** editorial	Agreed, editorial revision.

4.7.1._2	**Categoría:** editorial **Texto modificado propuesto:** En *acuicultura*, el *vacío sanitario* ~~como~~ constituye una medida de rutina de gestión de enfermedades ~~regular de control de *enfermedades* es frecuente en *acuicultura*~~, ~~ya sea como una mejor practica~~ especialmente antes de volver a introducir poblaciones de *animales acuáticos* en un sitio previamente pobladas ~~de~~ ~~repoblación~~ ya utilizado como parte de un *plan de bioseguridad* conforme a lo dispuesto en el Capítulo 4.1., o siguiendo las instrucciones de la *autoridad competente*, a raíz de un brote de una *enfermedad* que es objeto de medidas de gestión de emergencia según lo descrito en el Capítulo 4.Y. **Justificación:** Mejorar la redacción	Agreed that wording could be confusing, revisions were made to text to reflect this proposal. Note: The Commission extensively revised Article 4.1. to improve clarity.
4.7.1._3	**Category:** change **Proposed amended text:** ~~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 susceptible *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. **Rationale:** 1. Fallowing should be limited to operations on “susceptible” aquatic animals. 2. A "used" error is a printing issue.	Added ‘certain’ in place of proposed susceptible to be consistent with later articles where both susceptible species and vector species are noted. Re-stocking does not need to be restricted to susceptible species.

4.7.1._4	**Categoría:** Modificación / Editorial **Texto modificado propuesto:** En *acuicultura*, el *vacío sanitario* ~~como~~ constituye una medida rutinaria de control ~~de rutina de gestión~~ de enfermedades ~~regular de control de *enfermedades es frecuente en acuicultura*~~, ~~ya sea~~ implementada como ~~una~~ mejor práctica ~~especialmente~~ antes de reintroducir ~~volver a introducir~~ poblaciones de *animales acuáticos* en un sitio previamente utilizado para ~~de~~ repoblación, conforme al Capítulo 4.1 del ~~ya utilizado como parte de un *plan de bioseguridad* conforme a lo dispuesto en el Capítulo 4.1~~., o siguiendo las instrucciones de la *autoridad competente*, a raíz de un brote de una *enfermedad* que es sujeta a ~~objeto de~~ medidas ~~de gestión~~ de emergencia según lo establecido ~~descrito~~ en el Capítulo 4.Y. **Justificación:** La oración es demasiado larga y carece de claridad en algunos puntos. El término “control de enfermedades” es más apropiado y comúnmente aceptado en manuales de bioseguridad y planes sanitarios, en comparación con “gestión de enfermedad” el cual puede resultar más ambiguo. La frase **“**sitio previamente de repoblación ya utilizado" es redundante y confuso. La expresión “como parte de un plan de bioseguridad conforme a lo dispuesto en el Capítulo 4.1” fue reorganizado como “conforme al Capítulo 4.1 del plan de bioseguridad” para alinear la estructura gramatical con el lenguaje técnico-normativo, como el utilizado por organismos como la OIE (WOAH) o la FAO.	Did not agree to change position of reference to Chapter 4.1. as the original position is more appropriate and clear. Did not agree to reference disease control as reference to Chapter 4.11. provides this detail.
4.7.1._5	**Category:** Editorial **Proposed amended text:** *Fallowing* is a routine ~~carried out as a regular~~ *disease* management measure in aquaculture. It is ~~either as~~ a best practice measure especially employed 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. **Rationale:** Edited to make sentence easier to read as it was very long to begin with. Also deleted the word “used” as assumed “stocked” will replace it.	The Commission extensively revised Article 4.1. to improve clarity.
4.7.1._6	**Category:** Deletion **Proposed amended text:** *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.	Agreed to remove ‘routine’ and editorial revision. The Commission extensively revised Article 4.1. to improve clarity.

	Rationale: We request the deletion of 'routine' because not all aquaculture production systems utilize fallowing. We recommend deletion of 'used' for grammatical reasons.	
4.7.1._7	**Category of comments:** Deletion **Proposed amended text:** *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~~ establishment, as part of a *biosecurity plan* in accordance with Chapter 4.1. *Fallowing* is also used as a mandatory action ~~or on the instructions of~~ by the *Competent Authority*, following an outbreak of a *disease* which is subject to emergency management measures as described in Chapter 4.Y. **Rationale**: To improve clarity of the statemen	The Commission extensively revised Article 4.1. to improve clarity.

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:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.2._1	**Category of comments:** General **Proposed amended text:** *Fallowing* is used to provide a temporal break in the transmission cycles of *pathogenic agent*/agents ~~transmission cycles~~ between susceptible populations of *aquatic animals* or through *disease* vectors. It should be implemented with careful consideration given to:" **Rationale:** The proposed revision improves technical accuracy and clarity by explicitly acknowledging that disease transmission in aquatic systems may occur not only directly between susceptible animal populations, but also indirectly through disease vectors. Many aquatic pathogens can persist in the environment or be transmitted through intermediary hosts (e.g. molluscs, crustaceans, or wild fish), biofilms, or water currents. Replacing "pathogenic agent transmission cycles between susceptible populations" with the broader formulation "transmission cycles of pathogenic agent(s) between susceptible populations or through disease vectors" ensures the definition captures both direct and indirect transmission pathways, which is crucial for fallowing to be applied effectively as a risk mitigation strategy.	Agreed. The Commission extensively revised this article to improve clarity.

	Additionally, introducing "careful consideration given to" strengthens the language to reflect the need for context-specific decision-making, including factors such as pathogen biology, environmental persistence, vector presence, and biosecurity conditions. This aligns with the risk-based principles of aquatic animal health management and enhances the practical applicability of the recommendation across diverse aquaculture settings.	

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*;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.2._2	**Category:** Deletion/Addition **Proposed amended text:** the objective of *fallowing* such as preventing transmission between ~~sequential production cycles~~ successive cohorts, suppression of *pathogenic agent infection* pressure, or to eradicate a *pathogenic agent* from an *aquaculture establishment*; **Rationale:** Terminology – suggest replacing "sequential production cycles" with "successive cohorts".	Agreed, added 'successive cohorts' to reflect the proposal.
4.7.2._3	**Category:** Addition **Proposed amended text:** *Fallowing* is used to provide a temporal break in *pathogenic agent* transmission cycles between susceptible populations of *aquatic animals*, which may be voluntary or compulsory. It should be implemented with consideration given to: **Rationale:** We believe it would be important to highlight there are 2 options (which are discussed later in the chapter). These could be inserted here or in the introduction above.	Agreed, revision of Article 4.7.1. took this comment into account to reflect that fallowing can be voluntary or compulsory.

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;

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.2._4	**Category:** change **Proposed amended text:**	Agreed. The terms obligate and facultative could be confusing. Points 3 and 4 were combined to focus on the characteristics

	3) survival and stability of *a pathogenic agent* outside the host; ~~whether the *pathogenic agent* is obligate or facultative;~~ ~~4) for obligate *pathogenic agents*, the period that they may remain viable in the environment;~~ **Rationale:** Pathogenic agents should include bacteria, fungi, viruses, parasites, etc. Bacteria include aerobic, obligate anaerobic, and facultative anaerobic types. However, point 3) of the original text only considers the obligate and facultative characteristics of pathogens, which is incomplete. In addition, according to the WOAH Aquatic Manual, pathogenic factors in each disease chapter should include the survival and stability of pathogenic agents outside the host, such as spores, parasite life cycles, and pathogen inactivation methods. However, point 4) of the original text only emphasizes the survival time of pathogens without considering pathogen stability, which is also incomplete. Since both point 3) and point 4) of the original text describe pathogen-related factors but are insufficiently comprehensive, and the "obligate or facultative" content emphasized in point 3) also falls within the category of pathogen survival and stability in vitro, it is recommended to merge point 3) and point 4) into one point and revise it to "survival and stability of a pathogenic agent outside the host".	of the pathogenic agent which should be considered and provide more clarity.
4.7.2._5	**Category:** General The definition of an obligate or facultative pathogenic agent should be described.	Agreed, see response to 4.7.2._4.
4.7.2._6	**Category:** Change **Proposed amended text:** 3) the ~~whether the~~ *pathogenic agent* characteristics (i.e., survival and stability outside the host); ~~is obligate or facultative;~~ ~~4) for obligate *pathogenic agents*, the period that they may remain viable in the environment;~~ **Rationale:** The terminology used in 3) and 4) is more specific to bacteriology, but fallowing could be used for more than just bacterial pathogens. The proposed language is in alignment with the language in pathogen-specific manual chapters (under the disease information).	Agreed, see response to 4.7.2._4.
4.7.2._7	**Category:** General For the sake of clarity, it should be specified what an obligate or facultative pathogenic agent is.	Agreed, see response to 4.7.2._4.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.2._8	**Proposed amended text**: 4) ~~for obligate *pathogenic agents*,~~ the period that they~~r~~ pathogenic agents 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 of time, the length of which should be based on a *risk assessment*. 7) the level of risk to the local aquaculture industry and wider aquatic resources **Rationale:** Point 4: The time pathogenic agents remain viable in the environment is important information with making a fallowing plan for both obligate or facultative organisms. The Member recommends removing "obligate pathogenic agents" from point 4 to allow the statement to apply to any pathogenic agent. Point 6: The length of time for effective fallowing is based on more than the infectious period, incubation period or the stability in the environment. It may also be based on the temperature, salinity, organic load, and many other factors. Therefore, the length of time for fallowing should always be based on a risk assessment. Point 7, the level of risk to the local aquaculture industry and wider aquatic resources was a consideration of both voluntary and compulsory fallowing and as such should be included in 4.7.2. as a general consideration	4 - Agreed, see response to 4.7.2._4. 6 – Agreed, the time period of fallowing will depend on risk assessment. 7 – The level of risk to the local environment and other aquatic resources would be taken into account in risk assessment and did not need to be repeated.
4.7.2._9	**Category:** Change **Proposed amended text:** 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*. 7) the balance between the benefit and costs, such as the risk of disease transmission, burden of the disease, cost of fallowing, the loses of production suspension, and the possible effect of fallowing.	Did not agree to add point on the cost-benefit ratio. The cost-benefit considerations are referenced in Article 4.7.3. The Commission made revisions to this article to provide more clarity to these considerations in relation to fallowing.

	Rationale: Cost-effectiveness should be considered in any biosecurity measures taken and this is a prerequisite before considering fallowing. Aquatic Animal Health Services will need to assess and explain this issue when encouraging or persuading aquaculture farms to fallow. This issue is also addressed in 4.7.3.	
4.7.2._10	**Category:** Deletion/addition **Proposed amended text:** 6) when the infective period is not known, the ~~farm~~ production site may be fallowed for a period, the length of which should be based on a *risk assessment*. **Rationale:** Terminology – suggest using term "production site" rather than "farm" for consistency.	Changed 'farm' to 'aquaculture establishment' as this is a defined term in the Glossary.
4.7.2._11	**Category:** Addition **Proposed amended text:** We propose that the Commission add additional consideration points that are not disease related, such as the ecological and environmental impacts of fallowing. **Rationale:** Fallowing, as stated above, can be undertaken at various stages of production and, indeed, for various reasons. Although it is the primary directive of WOAH to focus on animal disease, in the spirit of One Health and viewing animal health as intimately connected to that of the environment, particularly for aquatic animals, we feel considerations related to the impacts of fallowing on the surrounding ecosystem warrant being included here.	Did not agree to add additional points such as ecological and environmental impacts. These considerations are outside the scope of the *Aquatic Code* and the intention of Chapter 4.7. is to provide principles for controlling the transmission of pathogenic agents.
4.7.2_12	**Category of comment:** General and Addition **Proposed amended text:** 3) whether the *pathogenic agent* is obligate or ~~facultative~~ opportunistic; (preferably use opportunistic) 6) when the infective period is not known, the farm may be fallowed for a period determined by ~~, the length of which should be based on a~~ a risk assessment. 7) Type of aquaculture system- **Rationale:** Fallowing guidelines should be system-specific and reflect differences in control measures and environmental exposure. For example, fallowing in pond-based or land-based systems allows for complete drainage, drying, and disinfection, while in open-sea cage systems cannot be "emptied" or disinfected easily. The hydrodynamics, water exchange, and proximity to other farms differ significantly, affecting pathogen persistence and fallowing strategies.	3 - Agreed, see response to 4.7.2._4. 6 – see response 4.7.2._8. 7 – Agreed that type of production system should be considered and it integrated into new point 4 in Annex 8.

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.3._1	**Category:** Deletion **Proposed amended text**: 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 *Aquatic Animal Health Services* ~~*Competent Authority*~~ should emphasise the likely beneficial effects of *fallowing* in proportion to the economic costs involved. **Rationale:** For consistency within the paragraph as Aquatic Animal Health Services is indicated as the encouraging body in the first sentence. The advice on the beneficial effects of fallowing could come from other owners in the same area, industry associations or actors other than the Competent Authority.	Agreed that the Aquatic Animal Health Services should be the body to encourage the beneficial effects of fallowing. This is consistent with the text in the first sentence of the paragraph.

4.7.3._2	**Categoría:** Modificación **Texto modificado propuesto:** Al impulsar a los operadores acuícolas a implementar ~~aplicar~~ un *vacío sanitario* en sus instalaciones, la *autoridad competente* deberá hacer hincapié en los probables efectos beneficiosos del *vacío sanitario* en proporción a los costos económicos que conlleva. **Justificación:** En el contexto de la sanidad acuícola y la gestión de bioseguridad, el verbo "implementar" se utiliza con mayor frecuencia en documentación técnica, normativa y científica para referirse a la acción de medidas, protocolos o estrategias operativas. Además "implementar" refuerza la idea de un proceso sistemática y documentado, que es coherente con los estándares internacionales de bioseguridad. Por el contrario "aplicar" puede ser más general y no refleja la naturaleza operativa, planificada y sostenida del vacío sanitario como práctica estructurada.	Agreed, revision in Spanish version. Note that this article has been extensively revised to improve clarity.
4.7.3._3	**Category:** Deletion **Proposed amended text:** 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. **Rationale:** We request the deletion of "common" because not all aquaculture production systems utilize fallowing. We propose deleting the last sentence of this paragraph because, while fallowing helps to reduce carry over of pathogens between populations (as a risk management tool), there may be costs associated with both fallowing and disease response, so it doesn't seem appropriate to highlight whether one or the other is more economical.	Did not agree to delete 'common'. The word 'common' is used in the context that fallowing is a measure that should be used by a number of aquaculture establishments at the same time. Did not agree to remove the last sentence. The beneficial effect of fallowing is an important consideration. Note that this article has been extensively revised to improve clarity.

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*.~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.3._4	**Category:** Change **Proposed amended text:** In addition to the considerations outlined in Article 4.7.2. t~~T~~he *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*.~~ **Rationale:** This paragraph should also include a cross-reference to the overarching considerations for fallowing to prevent duplication.	Agreed it is important link to Article 4.7.2. and reduce unnecessary duplication. Revisions were made to text to reflect this proposal. Note that this article has been extensively revised to improve clarity.
4.7.3._5	**Category:** Change **Proposed amended text:** 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, including the economic affordability and the sustainability of small-scale farms~~,~~ ~~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*.~~ **Rationale:** Small-scale farmers in some developing countries may fall into difficulties due to the interruption of income during the fallowing period, and need to balance disease prevention and control with livelihood protection.	Agreed that socioeconomic considerations should be considered. Note that this article has been extensively revised to improve clarity.

4.7.3._6	**Categoría:** Modificación **Texto modificado propuesto:** El Servicio de Sanidad de los Animales Acuáticos también deberá tener en cuenta el nivel de riesgo que una determinada enfermedad supone para las operaciones acuícolas locales, el periodo infeccioso ~~de infecciosidad~~ de la enfermedad en cuestión, así como las condiciones socioeconómicas cuando se evalúan los beneficios potenciales para los recursos acuáticos del área. **Justificación:** La palabra “infecciosidad” no es incorrecta, pero su uso es poco común y ambiguo en textos técnicos o científicos. Sustituir “infecciosidad” por “periodo infeccioso” mejora la precisión científica y comprensión técnica, además se alinea con estándares internacionales.	Agreed to revision in Spanish.
4.7.3._7	**Category:** Editorial **Proposed amended text:** 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~~ The *Aquatic Animal Health Service* should assess the potential benefits to aquatic resources in the area and ~~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*.~~ When encouraging aquaculture operators to fallow their establishments, the *Competent Authority* can then ~~should~~ emphasise the likely beneficial effects of *fallowing* in proportion to the economic costs involved and should also stress that spatial coordination is needed to maximise its effectiveness. ~~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,~~	Note that this article has been extensively revised to improve clarity readability.

	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*. **Rationale:** Changed the order of the content – benefits of voluntary fallowing should be assessed first, and will give more credibility when the competent authority is emphasizing the benefits and encouraging uptake. Also suggest adding reference to "spatial coordination" emphasize its importance and link it to Article 4.7.2 Considerations for fallowing.	
4.7.3._8	**Category:** Change **Proposed amended text:** The *Aquatic Animal Health Service* should also consider such factors as take into account the level of *risk* a particular *disease* pathogen poses to the local and national *aquaculture* operations, previous knowledge of the severity of a *disease(s)*, the infective period of the *disease* pathogen in question, and distribution of the *pathogenic agent(s)*, as well as the ability to apply biosafety measuresrelevant 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*. **Rationale:** We believe the appropriate term that should be used here is 'pathogen' not 'disease'. If the purpose of including 'relevant socioeconomic conditions' in this article as because some operations may not be able to fallow, then we suggest rewording to 'ability to apply biosafety measures'.	Agreed to change disease to pathogenic agent. Added reference to Article 4.7.2. to account for consideration of ability apply biosecurity measures. Did not agree to remove socioeconomic considerations. Due to cost involved socioeconomic considerations are important when considering voluntary fallowing. Note that this article has been extensively revised to improve clarity.

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*.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.4._1	**Category:** Addition **Proposed amended text**: 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 *aquaculture establishments* in the *infected zone* should this be indicated by the *risk assessment*. **Rationale:** The glossary term should be used to provide specificity to the use of 'establishments'.	Agreed to use glossary term 'aquaculture establishments'.
4.7.4._2	**Category:** Editorial **Proposed amended text:** 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 epidemiologically linked ~~relevant~~ *aquaculture establishments* in an officially declared ~~established~~ *infected zone*, are ~~be~~ subjected to a required period of *fallowing*~~, if necessary synchronised~~. A risk assessment will indicate the required period of *fallowing* ~~This *fallowing* will be carried out for a period of time~~ which is prescribed by the *Competent Authority*, ~~following *risk assessment*. A~~ and whether a period of synchronous *fallowing* may be required in epidemiologically linked ~~relevant~~ establishments in the *infected zone*. ~~should this be indicated by the *risk assessment*.~~ **Rationale:** Suggest replacing "relevant" with "epidemiologically linked" for clarity. Edited final sentences to remove repetition of term "risk assessment".	Agreed that 'epidemiologically' linked is a clearer term than 'relevant' regarding the aquaculture establishments. Additional revisions were made on this article to remove repetition and improve clarity, to reflect suggestions.
4.7.4._3	**Category of comments:** Deletion and Addition **Proposed amended text:** Compulsory *fallowing* may be required ~~in accordance with~~ based on the instructions of the *Competent Authority* following an outbreak of ~~an important~~ a significant *disease* ~~which has been subject to the measures described~~ as outlined 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~~ mandate that an infected *aquaculture establishment*, and ~~all~~ other relevant *aquaculture establishments* in an officially declared	Revisions were made to the text to account for suggestions and add clarity. However, an 'important disease' was not changed to a 'significant disease' because the former wording is used in Chapters 4.10. and 4.11.

	~~established~~ *infected zone*, ~~are~~ be ~~subjected~~ to a required period of *fallowing*. This *fallowing* will ~~be carried out for a period of time~~ last a duration ~~which is prescribed~~ determined by the *Competent Authority*, following conducting a *risk assessment*. A period of synchronous *fallowing* may be required in relevant establishments ~~in~~ within the *infected zone* ~~should this be indicated by the *risk assessment*~~. **Rationale:**The proposed amendment enhances clarity and legal consistency by aligning terminology with WOAH standards, specifying the authority of the Competent Authority, and ensuring decisions on compulsory and synchronous fallowing are based on risk assessment. It promotes a science-based, proportionate approach to disease control that considers local epidemiological conditions, avoids unnecessary disruption, and supports effective implementation across diverse aquaculture systems.	

Article 4.7.5~~2~~.

Legal powers

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.5._1	**Category:** General We recommend moving Article 4.7.5. after 4.7.2. Moving this article earlier in the chapter after 'considerations' would have better flow before the chapter starts to get into more technical details.	The requirement for legal powers is related to compulsory fallowing. Thus Articles 4.74. and 4.7.5. were combined to ensure a better flow and more clarity.
4.7.5._2	**Category:** Editorial **Proposed amended text:** **~~Legal powers~~Competent Authority responsibilities or oversight** **Rationale:** We recommend changing the title of this Article as 'Legal Powers' is a less commonly used term.	Articles 4.7.4. and 4.7.5. were combined (see response 4.7.5._1) and thus title no longer used.

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:~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.5._3	**Category:** Change **Proposed amended text**: In the cases referred to in Article 4.7.~~1~~4. 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:~~ **Rationale:** Article 4.7.4. is the more appropriate reference for compulsory fallowing.	Articles 4.7.4. and 4.7.5. were combined (see response 4.7.5._1), and reference is no longer relevant.
4.7.5._4	**Category:** Editorial **Proposed amended text**: In the cases referred to in Article 4.7.~~1~~ 4. 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:~~ **Rationale:** Article 4.7.4 seems to be the appropriate Article to refer to.	Articles 4.7.4. and 4.7.5. were combined (see response 4.7.5._1), and reference is no longer relevant.

1) define ~~defining~~ the ~~*disease*~~ circumstances when *fallowing* or synchronised *fallowing* is required;

Reference	Comment	Aquatic Animals Commission Response
4.7.5._5	**Category:** change **Proposed amended text:** 1) define ~~defining~~ the ~~*disease*~~ circumstances when *fallowing* or synchronised *fallowing* is required, and specific implementation steps for synchronous fallowing if needed. **Rationale:** "Synchronous fallowing" has been mentioned many times, but there is a lack of specific implementation steps, such as time window demarcation and responsibility division. The complexity of synchronous fallowing requires clear process design to avoid loopholes in prevention and control caused by differences in implementation. It is suggested to add specific implementation steps for "synchronous fallowing".	Agreed that need clarity on specific implementation steps, revisions were made to the text to reflect this suggestion.

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*.~~;~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.5._6	**Category of comments:** Editorial **Proposed amended text:** In the cases ~~referred to~~ mentioned 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~~ that determine individual disease-specific measures ~~may be determined~~, including when *fallowing* should commence ~~*disinfection*~~ and the ~~length~~ duration of the *fallowing* period prior to the re-introduction of *susceptible species*.~~;~~ **Rationale:** Improve readability and clarity	Revisions were made to the text to improve clarity and readability and reflect the suggestions.

~~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*.~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.5._7	**Category:** Change **Proposed amended text:** ~~3) following permission by the *Competent Authority* to restock with *susceptible species*,~~ ~~define~~ing ~~a period of *surveillance* and *diagnostic* to verify freedom from the specified *disease*~~, following permission by the *Competent Authority* to restock with *susceptible species*. **Rationale:** This is required by the legal power and does not overlap with the content in 4.7.8.	Revisions were made to the text to indicate that the Competent Authority should ensure there are the legal provisions including – 'conditions under which the re-introduction of aquaculture species will be permitted, once the fallowing period has been completed'.

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 *aquaculture 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:

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.6._1	**Category:** Change **Proposed amended text:** 1) removal of infected stocks in a biosecure manner:~~destruction of and biosecure disposal:~~ **Rationale:** We suggest leaving as "removal" because you could have harvest-ready animals that can be securely removed from the premises, as well as depopulation. Also, all removal should be done in a biosecure manner, and not all compulsory fallowing is based on the destruction of livestock.	Revision to say, 'removal and biosecure disposal of'. Removal to indicate that stock can be removed without destruction. However, all removal must be completed in a biosecure manner and is important to emphasise. Did not agree to 'infected stocks' because not all stocks removed will necessary be infected such as in the case of synchronous fallowing.

a) ~~removal~~ of all *susceptible species* of *aquatic animals* for the *disease* of concern; and

b~~2~~) ~~removal~~ of all species of *aquaculture* animals which are capable of acting as *vectors* of the *disease* of concern; and

c~~3~~) ~~if appropriate, removal~~ of other species, if indicated by *risk assessment*; ~~and~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.6._2	**Category:** Editorial **Proposed amended text:** 1) destruction of and biosecure disposal of: a) ~~removal of~~ all *susceptible species* of *aquatic animals* for the *disease* of concern; and b~~2~~) ~~removal of~~ all species of *aquaculture* animals which are capable of acting as *vectors* of the *disease* of concern; and c~~3~~) ~~if appropriate, removal of~~ other species, if indicated by *risk assessment*; ~~and~~ **Rationale:** Edits to remove repetition	Agreed with editorial revisions.

2~~4~~) removal of water in which infected stocks have been held, where feasible; and

3~~5~~) 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*.~~

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.6._3	**Category:** Change **Proposed amended text**: appropriate *disinfection* measures have been completed on equipment and other contaminated materials in accordance with Article 4.7.4., under ~~supervision~~oversight of the ~~*Aquatic Animal Health Services*~~ *Competent Authority*. ~~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*.~~ **Rationale:** In the case of compulsory fallowing during disease response which is ordered by the competent authority, while the Member agrees that the cleaning and disinfection can be completed by the Aquatic Animal Health Services, there needs to be oversight of the process by the Competent Authority prior to the commencement of fallowing.	Agreed that cleaning and disinfection requires oversight by the Competent Authority and revisions were made to reflect the proposal.
4.7.6._4	**Category:** Change **Proposed amended text:** ~~3~~5) 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*.~~ 4)Environmental monitoring: a) During the fallowing period, the Competent Authority may mandate regular monitoring of water quality and sediment for residual pathogenic agents, using standardized methods (e.g., PCR, culture-based assays). Results shall be documented and submitted to the Competent Authority for review. b) Ecological restoration measures (e.g., natural sediment flushing, reintroduction of native microbial communities) shall be implemented to rehabilitate the production site' s environmental conditions prior to restocking. **Rationale:** It is recommended to add requirements for environmental monitoring. First, environmental monitoring ensures that residual pathogens are eradicated during fallowing, reducing re-infection risks. Standardized methods (e.g., PCR) align with WOAH guidelines for consistency. Second, ecological	Did not agree. Proposed point 4a – The *Aquatic Manual* does not provide validated methods for monitoring pathogenic agents in the environment, as such cannot require these measures in the *Aquatic Code.* Proposed point 4b - These considerations are outside the scope of the *Aquatic Code* and the intention of Chapter 4.7. is to provide principles for controlling the transmission of pathogenic agents.

	restoration addresses global concerns about sustainable aquaculture. Restoring natural ecosystems enhances long-term productivity and aligns with the UN Sustainable Development Goals (SDG 14: Life Below Water).	

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.6._5	**Category:** Change **Proposed amended text:** In addition to the considerations outlined in Article 4.7.2. the Competent Authority should consider that. 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.~~ **Rationale:** This paragraph should also include a cross-reference to the overarching considerations for fallowing where some of these points are already made. Edits have been made to remove duplication.	Agreed that this article should include reference to Article 4.7.2. 'Considerations for fallowing'.
4.7.6._6	**Category of comments:** General **Proposed amended text:** In accordance with ~~Taking into account~~ the categories of *aquaculture* production systems outlined ~~referred to~~ in Article 4.1.5., *fallowing* of an *aquaculture establishment* ~~*Fallowing* of a farm~~ should take paragraph 5 of Article 4.X.7. into account and start immediately after the following actions are taken:	First paragraph – did not agree, proposal did not provide improved clarity, with the exception of adding 'the following actions are taken'. 1 – Agreed to reference Article 7.4.2.

	1) destruction of and biosecure disposal (according to Article 7.4.2): a) ~~removal~~ of all *susceptible species* of *aquatic animals* for the *disease* of concern; and b~~2~~) ~~removal~~ of all species of *aquaculture* animals that are capable of acting as *vectors* of the *disease* of concern; and ~~2c~~3) control and/or if appropriate, the removal of other species that are capable of acting as *vectors* of the *disease* of concern, ~~if~~ as indicated by *risk assessment*; ~~and~~ 3~~2~~4) removal of water in which infected stocks have been held, where feasible; and 4~~3~~5) appropriate *disinfection* measures have been completed on equipment and other contaminated materials in accordance with Article 4.7.4., This process should occur 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~~ duration of the compulsory ~~statutory~~ *fallowing* period should be based on scientific evidence of the likelihood of a free ~~a~~ *pathogenic agent* remaining infective ~~outside its aquaculture host(s)~~ in the local environment, at a level ~~likely to cause~~ that poses an unacceptable risk of re-*infection* of the *aquaculture establishment*. ~~Account should be taken of~~ Factors to be considered include 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~~ relevant climatological, geographical and hydrographical ~~factors~~ conditions. In addition, the level of *risk* to the local *aquaculture* industry and ~~wider~~ the broader 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. **Rationale**: Recommended changing 1(c) to point 2 because it may not be ecologically feasible to destroy all species in the system but rather control them or remove the only if appropriate to do so. The rest of the text have been edited for clarity.	1c – Did not agree as the current wording provides the Competent Authority more flexibility. 4 – Agreed. Final paragraph – Agreed to term 'duration' for consistency. Revisions were made to the paragraph to increase clarity

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.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.7._1	**Category:** Deletion **Proposed amended text**: ~~*Competent Authorities*~~ Aquatic animal Health Services ~~Countries~~ establishing *fallowing* procedures should develop a detailed set of instructions for *disinfection* of *aquaculture establishments* prior to *fallowing*~~,~~ for approval by the Competent Authority. These instructions should be ~~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. **Rationale:** The instructions for disinfection need to be developed by industry or the Aquatic Animal Health Services to ensure that all specific aspects of the aquaculture establishment are taken into account. These instructions may need to be different based on the situation, location, pathogen, infrastructure and there may be different disinfectants approved which could be used depending on the environment for in which it will be used. Then the Competent Authority should be responsible for approving any instructions.	Agreed that procedures for disinfection needs to be developed by Aquatic Animal Health Services with approval for the Competent Authority.
4.7.7._2	**Category:** change **Proposed amended text:** 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~~	See response to 4.7.1._3.

	infected zone, are ~~be~~ subjected to a required period of *fallowing* of relevant susceptible species~~,~~ ~~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*. **Rationale:** Compulsory fallowing of all aquaculture farms in infected areas should be limited to operations with susceptible aquatic animals.	

Article 4.7.8~~5~~.

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~~.

Reference	Comment (in language submitted)	Aquatic Animals Commission Response
4.7.8._1	**Category:** change **Proposed amended text:** An ~~No~~ *aquaculture establishment* that has been subjected to~~under~~ compulsory *fallowing* should not be restocked with the susceptible species 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 susceptible *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.~~	Did not agree. See response to 4.7.1._3. The current wording gives the Competent Authority flexibility to make their own rules on re-stocking subject to risk assessment.

	Rationale: The fallowing period should be limited to susceptible species only and should be unrestricted for non-susceptible species.	
4.7.8._2	**Category:** Editorial **Proposed amended text:** 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* administered by the *Competent Authority* 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~~. **Rationale:** It may be unclear what "official" surveillance means so we recommend clarifying that it should surveillance overseen by the competent authority.	Did not agree. The reference to Chapter 1.4. implies that the surveillance programme must be overseen by the Competent Authority.

CHAPTER 2.4.6.

INFECTION WITH *PERKINSUS OLSENI*

Reference	Comment	Aquatic Animals Commission response
2.4.6_1	**Category:** General The Member supports the revision of this chapter and has inserted some comments within the text for consideration.	**EN**: Noted. **FR** : La Commission a pris note de ce commentaire. **SP**: Anotado.
2.4.6_2	**Category:** General The Member supports the revised chapter.	**EN**: Noted. **FR** : La Commission a pris note de ce commentaire. **SP**: Anotado.
2.4.6_3	**Category:** General The Member supports this updated chapter.	**EN**: Noted. **FR** : La Commission a pris note de ce commentaire. **SP**: Anotado.

1. Scope

Infection with *Perkinsus olseni* is considered to be infection with the pathogenic agent *Perkinsus. olseni* of the ~~(~~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

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	no common name
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
	Leukoma jedoensis	Jedo venus
	Paratapes undulatus	undulate venus
	Protapes gallus	rooster venus
	Proteopitar patagonicus	no common name
	Ruditapes decussatus	grooved carpet shell
	Ruditapes philippinarum	Japanese carpet shell

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
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

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; forit can start being deleterious and lethal at densities of 10^6 parasite cells/g wet tissue (Dang *et al.,* 2013; Waki *et al.,* 2018).

Reference	Comment	Aquatic Animals Commission response
2.4.6_2.3.1_1	**Category:** editorial **Proposed amended text (or precise suggested deletion)** Infections in ~~clam hosts~~ shellfish 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; for example, in clam hosts 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). **Rationale** Minor edits to this paragraph – start with general statement and end with specific example, and make it clear the lethal intensity of infection of infection is a specific example from clams.	**EN**: Agreed. **FR** : La Commission a souscrit au commentaire. **SP**: Aceptado.

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 produce 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.

Reference	Comment	Aquatic Animals Commission response
2.4.6_3.1_1	**Category:** editorial **Proposed amended text** Bivalves that are gaping, ~~clams~~ that are found at the sediment surface ~~instead of being~~ when they would normally be 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. **Rationale** Minor edits to this paragraph to ensure it is clear that this can apply to other bivalves not just clams.	**EN**: Agreed. **FR** : La Commission a souscrit au commentaire. **SP**: Aceptado.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.6_4_1	**Category:** General At the end of this chapter, it is stated that "There are currently no WOAH Reference Laboratory for *Perkinsus olseni*". But here in Section 4. Diagnostic methods, it is mentioned that "WOAH Reference Laboratories welcome feedback on diagnostic performance of recommended assays, in particular PCR methods", and "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". The statements before and after are contradictory. It is recommended to specify which laboratories the WOAH reference laboratories in Article 4 specifically refer to.	**EN**: Disagreed. The introductory text to Table 4.1 is standard text from the chapter template. It is the intention to designate Reference Laboratories for all listed diseases, so the current lack should not be a permanent situation. **FR** : La Commission n'a pas souscrit à cette observation. Le texte introductif du tableau 4.1 correspond au texte standard du modèle de chapitre. L'intention est de désigner des Laboratoires de Référence pour toutes les maladies listées ; par conséquent, l'absence actuelle ne devrait pas constituer une situation permanente. **SP**: En desacuerdo. El texto introductorio de la tabla 4.1 corresponde al texto estándar del modelo de capítulo. La intención es designar Laboratorios de Referencia para todas las enfermedades listadas, por lo que la ausencia actual no debería considerarse una situación permanente.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.6_TABLE4.1_1	**Category:** General Table 4.1 lists "N/A" for the level of validation for histopathology, real-time PCR, and conventional PCR. However, the level of validation should be available for real-time PCR and conventional PCR for the presumptive diagnosis of clinically affected animals. Information should be available for clinically affected animals, as validation in these cases would be easier to perform than for apparently healthy animals, which is listed as level 3.	**EN**: Disagreed. The methods for the assays presented in Section 4.4 were validated either on cultures or in wild populations of naturally infected hosts. No indication was provided to suggest sampling was targeted at clinically affected animals.
		FR : La Commission n'a pas souscrit au commentaire. Les méthodes des essais présentées dans la section 4.4 ont été validées soit sur des cultures, soit sur des populations sauvages d'hôtes naturellement infectés. Aucune indication n'a été fournie suggérant que l'échantillonnage ait été ciblé sur des animaux cliniquement affectés.
		SP: En desacuerdo. Los métodos de los ensayos presentados en la sección 4.4 fueron validados ya sea en cultivos o en poblaciones silvestres de hospedadores naturalmente infectados. No se proporcionó ninguna indicación que sugiriera que el muestreo se dirigiera a animales clínicamente afectados.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.6_4.4_1	**Category:** General For tables 4.4.1 and 4.4.2 the template is incomplete with unknown GenBank Accession numbers for four added assays.	**EN**: Partially agreed: given the number of GenBank Accession numbers concerned, the Commission added a footnote to the tables directing the reader to the original publication for GenBank Assession numbers.
		FR : La Commission a partiellement souscrit au commentaire : compte tenu du nombre de numéros d'accession GenBank concernés, la Commission a ajouté une note de bas de page aux tableaux renvoyant le lecteur à la publication originale pour les numéros d'accession GenBank.
		SP: Parcialmente de acuerdo: dado el número de números de acceso de GenBank implicados, la Comisión añadió una nota a pie de tabla remitiendo al lector a la publicación original para consultar los números de acceso de GenBank.
2.4.6_4.4_2	**Category:** General The accession number of *P. olseni* reference sequences are missing within the table. **Rationale:** Strengthens preparedness for abalone-related diseases with **cross-border trade implications**, particularly in regions with wild abalone fisheries.	**EN**: See above.
		FR : Voir ci-dessus.
		SP: Véase arriba.

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 / ITS 2	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 ???			
P. olseni / ITS	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 / ITS	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 / 5.8S & ITS2	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:

Reference	Comment	Aquatic Animals Commission response
2.4.6_6.1.2_1	**Category:** Addition **Proposed change:** The presence of infection with *P. olseni* is considered to be confirmed if at least one of the following ~~criterion~~ criteria is met: **Rationale:** For consistency with other recently adopted chapters (B.exitiosa, B. ostrea) for confirmed case in apparently healthy animals. Positive results from all of the tests outlined in points below should not be required to confirm a positive test, only positive results from at least one of following criteria.	**EN**: Agreed. **FR** : La Commission a souscrit au commentaire. **SP**: Aceptado.

[1] For example transboundary commodities.

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.

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

Reference	Comment	Aquatic Animals Commission response
2.4.6_6.3_2	**Category:** Addition Please add the DSe and DSp for both presumptive diagnosis of clinically affected animals and surveillance of apparently health animals as determined by the validation studies required for stage 2 and stage 3 validation for those tests outlined in Table 4.1. **Rationale:** Table 4.1 indicates that there are a number of tests which have been validated to Stage 2 and Stage 3. Validation stage 2 and above requires that estimation of diagnostic sensitivity and diagnostic specificity be completed. These details should be provided to member countries, so that appropriate sample sizes can be calculated and to ensure alignment between information provided in the chapter.	**EN**: Partially agreed. Revised the validation levels in Table 4.1 based on the populations sampled as described in the published references. As a result, Table 6.3.1 remains empty as the published references gave no indication that clinically affected samples were targeted. Table 6.3.2. for surveillance of apparently healthy animals has, however, now been completed. **FR** : La Commission a partiellement souscrit au commentaire : les niveaux de validation du tableau 4.1 ont été révisés sur la base des populations échantillonnées, telles que décrites dans les références publiées. En conséquence, le tableau 6.3.1 reste vide, car les références publiées n'ont fourni aucune indication que des échantillons cliniquement affectés aient été ciblés. En revanche, le tableau 6.3.2 concernant la surveillance d'animaux apparemment sains a été complété.

		SP: Parcialmente de acuerdo. Se revisaron los niveles de validación de la tabla 4.1 en función de las poblaciones muestreadas, según lo descrito en las referencias publicadas. Como resultado, la tabla 6.3.1 permanece vacía, ya que las referencias publicadas no aportaron ninguna indicación de que se hubiera dirigido el muestreo a animales clínicamente afectados. Sin embargo, la tabla 6.3.2, relativa a la vigilancia de animales aparentemente sanos, ha sido completada.
2.4.6_6.3_2	**Category:** General Tables under Section 6.3 should be completed based on the level of validation stated in Table 4.1 of the real-time PCRs.	**EN**: See above. **FR** : Voir ci-dessus. **SP**: Véase arriba.

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.

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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.

CHAPTER 2.4.7

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Reference	Comment	Aquatic Animals Commission response
2.4.7_1	**Category:** General The Member supports the revision of this chapter and has inserted some comments within the text for consideration.	**EN**: Noted. **FR**: La Commission a pris note de ce commentaire. **SP**: Anotado.
2.4.7_2	**Category:** General The Member supports the revised chapter.	**EN**: Noted. **FR**: La Commission a pris note de ce commentaire. **SP**: Anotado.
2.4.7_3	**Category:** General The Member supports the revised chapter.	**EN**: Noted. **FR**: La Commission a pris note de ce commentaire. **SP**: Anotado.
2.4.7_4	**Category:** General The Member supports this updated chapter.	**EN**: Noted. **FR**: La Commission a pris note de ce commentaire. **SP**: Anotado.

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.

2.4.7_2.1.3_1	**Category:** Deletion **Proposed deletion:** 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.~~ **Rationale:** We request these deletions because there is no information to date regarding vector involvement for this pathogen of concern	**EN**: Agreed. **FR** : La Commission a souscrit au commentaire. **SP**: Aceptado.

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

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 *X. californiensis* according to Chapter 1.5. of the *Aquatic Code* is:

Family	Scientific name	Common name
Haliotidae	*Haliotis gigantea*	giant abalone

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
Haliotidae	*Haliotis discus hannai*	Japanese disc abalone

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).

2.4.7_2.3.4_1	**Category:** Addition **Proposed addition:** 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; 2007; Moore *et al.*, 2000; 2001; Rosenblum *et al.*, 2008). 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). **Rationale:** We request the list of references to include some of the other papers referenced in 2.1.3. above, which also apply to 2.3.4.	**EN**: Agreed. **FR** : La Commission a souscrit au commentaire. **SP**: Aceptado.

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.

2.4.7_3.5.2_1	**Category:** Deletion **Proposed deletion:** ~~Tissue samples for PCR testing should be preserved in 80% (v/v) molecular 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~~ **Rationale:** We wish to note that other manual chapters only include the information provided in the second paragraph of 3.5.2. We therefore suggest updating this section so that it is aligned with other manual chapters.	**EN**: Agreed. **FR** : La Commission a souscrit au commentaire. **SP**: Aceptado.

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.

Reference	Comment	Aquatic Animals Commission response
2.4.7_4_1	**Category:** General At the end of this chapter, it is stated that “There are currently no WOAH Reference Laboratory for *Xenohaliotis californiensis*”. But here in Section 4. Diagnostic methods, it is mentioned that “WOAH Reference Laboratories welcome feedback on diagnostic performance of recommended assays, in particular PCR methods”, and “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”. The statements before and after are contradictory. It is recommended to specify which laboratories the WOAH reference laboratories in Article 4 specifically refer to.	**EN**: Disagreed. The introductory text to Table 4.1 is standard text from the chapter template. It is the intention to designate Reference Laboratories for all listed diseases, so the current lack should not be a permanent situation. **FR** : La Commission n’a pas souscrit au commentaire. Le texte introductif du tableau 4.1 correspond au texte standard du modèle de chapitre. L’intention est de désigner des Laboratoires de Référence pour toutes les maladies listées ; par conséquent, l’absence actuelle ne devrait pas constituer une situation permanente. **SP**: En desacuerdo. El texto introductorio de la tabla 4.1 corresponde al texto estándar del modelo de capítulo. La intención es designar Laboratorios de Referencia para todas las enfermedades listadas, por lo que la ausencia actual no debería considerarse una situación permanente.

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	D. Surveillance of apparently healthy animals				E. Presumptive diagnosis of clinically affected animals				F. 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[2]

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

Reference	Comment	Aquatic Animals Commission response

[2] For example transboundary commodities.

2.4.7_6.3_1	**Category:** General Information should be available to fill the table 6.3.1 and 6.3.2 based on the level of validation stated in Table 4.1. for the real-time PCR method.	**EN**: Partially agreed. Revised the validation levels in Table 4.1 for presumptive diagnosis of clinically affected animals as the published papers gave no indication that clinically affected samples were targeted but rather sampled farmed and wild populations of apparently healthy animals. The data in Table 6.3.1 has thus been deleted and moved to Table 6.3.2.
		FR : La Commission a partiellement souscrit au commentaire : les niveaux de validation du tableau 4.1 pour le diagnostic présomptif des animaux cliniquement affectés ont été révisés, car les articles publiés n'indiquaient pas que l'échantillonnage avait ciblé des animaux cliniquement affectés, mais plutôt des populations d'animaux d'élevage et sauvages apparemment sains. Les données du tableau 6.3.1 ont donc été supprimées et déplacées vers le tableau 6.3.2.
		SP: Parcialmente de acuerdo. Se revisaron los niveles de validación de la tabla 4.1 para el diagnóstico presuntivo de animales clínicamente afectados, ya que los artículos publicados no indicaban que el muestreo se hubiera dirigido a animales clínicamente afectados, sino más bien a poblaciones de animales de granja y silvestres aparentemente sanos. En consecuencia, los datos de la tabla 6.3.1 se eliminaron y se trasladaron a la tabla 6.3.2.
2.4.7_6.3_2	**Category:** Addition Please add the DSe and DSp for surveillance of apparently health animals for real time PCR as Table 4.1. indicates stage 3 validation has been completed. **Rationale:** Table 4.1 indicates real time PCR has been validated to Stage 2 and Stage 3. Validation stage 2 and above requires that estimation of diagnostic sensitivity and diagnostic specificity be completed. These details should be provided to member countries, so that appropriate sample sizes can be calculated and to ensure alignment between information provided in the chapter.	**EN**: See above.
		FR : Voir ci-dessus.
		SP: Véase arriba.

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

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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.

Annex 4. Item 5.2. – Work Programme for the Aquatic Animal Health Standards Commission 2025–2027

Chapter	Subject	Summary of the work	Status – September 2025		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Aquatic Code					
Ch. 1.1.	Notification of diseases, and provision of epidemiological information	Discussed with Code Commission to ensure consistency and clarity on revisions.	Revisions to be further considered at next meeting	Refer to Sept 2025 AAHSC report	**1**
Ch. 1.4.	Aquatic animal disease surveillance	Review Ch. 1.4. to consider if revision required following the update of Ch. 4.3.	Preparatory work	Refer to Sept 2025 AAHSC report	**2**
Ch. 4.2.	Application of zoning	Revision of the chapter following the update to Ch. 4.3. to focus on the application of zoning.	Preparatory work	Refer to Sept 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 Sept 2025 AAHSC report (Feb 2025/2)	**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 Sept 2025 AAHSC report (Feb 2025/2)	**1**
Section 5	Trade measures, importation/exportation procedures and health certification	Revision of chapters in Section 5 to ensure useability for trade purposes	Proposed plan for revision circulated for comments	Refer to Sept 2025 AAHSC report (Sept 2025/1)	**1**

Chapter	Subject	Summary of the work	Status – September 2025		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 5.Y.	New introductory chapter to Section 5	Taskforce between AAC and TCC convened and drafting chapter.	Preparatory work.	Refer to Sept 2025 AAHSC report	**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. 6.2.	Principles for responsible and prudent use of antimicrobial agents in aquatic animals	*Ad hoc* Group provided Commission with recommendations and will review Commission's responses to provide a draft chapter.	Preparatory work	Refer to Sept 2025 AAHSC report	**1**
Section 7	Welfare of farmed fish	Commission review report on current science for welfare of farmed fish and proposed a consultant produce revisions of all 4 chapters.	Preparatory work	Refer to Sept 2025 AAHSC report	**2**
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 Sept 2025 AAHSC report	**3**

Chapter	Subject	Summary of the work	Status – September 2025		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
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 Sept 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 Sept 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'.	Circulated for comment	Refer to Sept 2025 AAHSC report (Sept 2025/1)	**1**
Ch. 10.3.	Infection with *Gyrodactylus salaris*	Revise the usage of pathway 2 to declare freedom from disease, following discussion at 2025 General Session	Circulated for comments	Refer to Sept 2025 AAHSC report (Sep 2025/1)	**1**
Ch. 10.4.	Infection with salmon anaemia virus	Revise the targeted surveillance required for HPR0 for declaring a free compartment.	Circulated for comments	Refer to Sept 2025 AAHSC report (Sep 2025/1)	**1**

Chapter	Subject	Summary of the work	Status – September 2025		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Disease-specific chapters	Update viral names in X.X.1.	Update the viral names of relevant pathogenic agents based on current information in ICTV	Circulated for comments	Refer to Sept 2025 AAHSC report (Sep 2025/1)	**1**
N/A	Emerging diseases	Review emerging diseases	Standing agenda item	Refer to Sep 2025 AAHSC report	**1**
Aquatic Manual					
Ch. 1.1.2.	Validation of diagnostic assays for infectious diseases of aquatic animals	New chapter for validation of diagnostic assays for infectious diseases of aquatic animals.	Preparatory work – revision of chapter ongoing.	Refer to Sept 2025 AAHSC report	**1**
Ch. 2.1.0.	General Information	To create a general information chapter.	Not started	Refer to Sept 2025 AAHSC report	3
Ch. 2.1.1.	Infection with *Batrachochytrium dendrobatidis*	Update the chapter to the new template for disease-specific chapter.	Preparatory work	Refer to Sept 2025 AAHSC report	2
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 Sept 2025 AAHSC report	**3**

Chapter	Subject	Summary of the work	Status – September 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 Sept 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 Sept 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 Sept 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'.	Circulated for comment	Refer to Sept 2025 AAHSC report (Sept 2025/1)	**1**
Ch. 2.2.5.	Infection with infectious hypodermal and haematopoietic necrosis virus	Expert consultation to update EVE in chapter.	Expert consultation	Refer to Sept 2025 AAHSC report	**1**

Chapter	Subject	Summary of the work	Status – September 2025		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 2.3.5.	Infection with infectious haematopoietic necrosis virus	Update the real-time PCR assays following publication of new peer-reviewed validated methods.	Preparatory work	Refer to Sept 2025 AAHSC	**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 – interlaboratory comparison	Refer to Sept 2025 AAHSC report	**2**
Ch. 2.3.9.	Infection with spring viraemia of carp virus	Update the real-time PCR assays following publication of new peer-reviewed validated methods	Preparatory work	Refer to Feb Sept AAHSC report	**1**
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 Sept 2025 AAHSC report	**3**
Ch. 2.4.2.	Infection with *Bonamia exitiosa*	Update the case definition	Circulated for comments	Refer to Sept 2025 AAHSC report (Sep 2025/1)	**1**
Ch. 2.4.3.	Infection with *Bonamia ostreae*	Update the case definition	Circulated for comments	Refer to Sept 2025 AAHSC report (Sep 2025/1)	**1**
Ch. 2.4.5.	Infection with *Perkinsus marinus*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments	Refer to Sept 2025 AAHSC report (Sep 2025/1)	**1**
Ch. 2.4.6.	Infection with *Perkinsus olseni*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments	Refer to Sep 2025 AAHSC report (Feb 2025/2)	**1**
Ch. 2.4.7.	Infection with *Xenohaliotis californiensis*	Update the chapter to the new template for disease-specific chapter.	Circulated for comments	Refer to Sept 2025 AAHSC report (Feb 2025/2)	**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. – Glossary

GLOSSARY

[...]

ORNAMENTAL AQUATIC ANIMAL

means an *aquatic animal* that is intended for display, exhibition, competition, or to be supplied for sale ~~and use~~ as a pet.

[...]

Annex 6. Item 6.2. – 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 and ~~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 operator ~~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 operator~~private sector~~ and oversight by the relevant *Competent Authorities* are~~is~~ essential.

A *Competent Authority* can make 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* including compliance with *basic biosecurity conditions* and *surveillance* requirements as described in Chapter 1.4. and in the relevant disease-specific chapters have been met.

Article 4.3.2.

Principles for establishing a compartment

The following principles should be applied to establish and maintain a *free compartment.* The principles should be addressed in a *self-declaration of freedom from disease* as described in Chapter 1.4.

1) A *compartment* must ensure there are effective measures to prevent the entry or spread of *pathogenic agents* from the external environments into the *compartment* (i.e. provide functional epidemiological separation);

2) The purpose and scope of a *compartment* should be clearly defined (e.g. *disease(s)* for which freedom will be claimed species produced and *aquaculture establishments* that comprise the *compartment*) as described in Article 4.3.3.;

3) There are two categories of *compartments* (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.) and *biosecurity* and *surveillance* measures should be appropriate for the category of *compartment*;

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 4.3.3~~2~~.

Purpose~~s~~ and scope 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*. The *disease(s)* for which freedom will be claimed and the species produced should be clearly defined.

~~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.

Independent and dependent ~~Dependent and independent~~ compartments

There are two categories of *compartments* that are determined by the degree of epidemiological separation from the surrounding environment: independent and dependent *compartments*. ~~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 may 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 compartments

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*.

~~Independent and dependent *compartments* and have the following characteristics:~~

~~1)~~ Independent *compartments* have the following characteristics:

1~~a~~) are closed production system types only (as described in Chapter 4.1.);

2~~b~~) have control over all transmission pathways and complete epidemiological separation from surrounding environments;

3~~c~~) have appropriate levels of *biosecurity* and *surveillance* to mitigate the *risk* of introduction of specific *pathogenic agents* into the *compartment* in accordance with Article 4.3.5.~~physical and management measures to maintain effective *biosecurity* for all pathways;~~

~~d) provide levels of *risk management* 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*

Dependent *compartments* do not have complete epidemiological separation from the surrounding environment but conditions exist which create an effective disease-specific separation between the *compartment* and other *aquatic animal* populations that may be infected. The possibility of achieving such disease-specific separation will be determined by the *Competent Authority*, based on *risk analysis*.

The concept of dependent *compartments* broadens the application of compartmentalisation to a wider range of production systems and *aquaculture establishments*, creating additional opportunities for trade in disease-free commodities where such *compartments* ensure an appropriate level of *risk management*.

Dependent compartments have the following characteristics:

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 *biosecurity* and *surveillance* to mitigate the *risk* of introduction of ~~specific~~ the *pathogenic agent(s)* (for which the *compartment* has been established) in accordance with Article 4.3.5.~~physical and management measures to maintain effective *biosecurity* for all pathways~~;

d) meet the additional *biosecurity* and *surveillance* requirements to mitigate transmission *risk* from the surrounding environment as informed by a *risk analysis* ~~via intake water 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* should be assessed against the minimum *risk* factors outlined in Article 4.3.5. If these measures cannot be effectively implemented, the *Competent Authority* cannot grant approval. Where effective disease-specific separation is possible, approval may be granted provided that specific *risk management* measures are applied. Both the *risk analysis* and the specified measures must be documented in the dossier of evidence referred to in Article 1.4.16.

~~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 management~~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 management*~~mitigation~~ across all elements of the *compartment*.

The *Competent Authority* should require~~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.

For dependent *compartments*, the *risk analysis* described in Article 4.3.4.~~4.1.8.~~ should include the assessment of *risks* within the environment surrounding the *compartment* to inform ~~and~~ the development of appropriate *risk management* and *surveillance* measures to mitigate *disease* transmission from the environment. The *risk* mitigation measures should be developed in accordance with Article 4.1.8. and may include the application of specific *biosecurity* measures, a higher level of internal *targeted surveillance* and external *surveillance* to monitor for changes in *disease risk*. ~~the identified *risks*.~~

~~The *Competent Authority* should consider in~~ At a minimum, the following factors should be addressed within the *risk analysis:*

1) characteristics of the *pathogenic agent(s)*;

2) presence~~absence~~ of *susceptible species* and pathways of exposure~~*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) presence~~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* as well as the requirements to maintain that freedom in accordance with Article 1.4.15.

~~*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. off~~or~~ 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. offfor 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* may be passive or targeted based on the specific situation in accordance with the relevant disease-specific chapters and Chapter 1.4.

For dependent *compartments*, externalExternal *surveillance* is required for dependent *compartments* if populations of *susceptible species* are present in the environment surrounding the *compartment*. The *surveillance* should be developed taking into account the factors described Article 4.3.5. The area for which external *surveillance* is required must be defined and should take into account any *surveillance* which is carried out on adjacent *aquaculture establishments* keeping *susceptible species*. For a dependent *compartment* occurring within a *free zone* or *free country*, the *surveillance* to establish and maintain a *free zone* or *free country* constitutes the external *surveillance* for 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 conducts testing in accordance with the recommendations of the *Aquatic Manual*;

3) can confirm or exclude cases of *infectiondisease* 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 nature of the supply chains of the *aquatic animal* species and for application to individual or groups of *aquatic animals* or *aquatic animal products*, as necessary;

2) record all *aquatic animal* movements into and out of the *compartment* including origin and destination. 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, vaccination records 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 comprise~~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 approved by *Competent Authorities*.

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 by the *Competent Authority*, 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 operator of the *compartment* should immediately notify the *Competent Authority*. The *Competent Authority* should then determine whether the disease-free status of the *compartment* should be immediately suspended and *importing countries* should be notified following the provisions of Chapter 1.1., while the occurrence of the disease is confirmed or ruled-out.

In the event of confirmation of the *disease* for which the *compartment* was defined, the free status should immediately be suspended.

The operator of a *compartment* should report any event which could lead to a breach of *biosecurity* measures to the *Competent Authority*. ~~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 by the *Competent Authority* to determine whether a breach of *biosecurity* measures has occurred which could impact the health status of the compartment.

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 by the *Competent Authority* after the depopulation, decontamination and *fallowing* have been completed, previously existing *basic biosecurity conditions* have been reviewed and modified as necessary, and *surveillance* in accordance with Chapter 1.4. and the relevant disease-specific chapter(s) has been completed. ~~*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 7. Item 6.2. – Glossary - Compartment

GLOSSARY

[…]

COMPARTMENT

means one or more *aquaculture establishments* each 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 8. Item 6.3. – Chapter 4.7. 'Fallowing in Aquaculture'

[Followed by clean version]

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*, which is employed either: ~~as a best practice especially prior to the introduction of new populations of *aquatic animals* into a previously stocked used site,~~

1) voluntarily, prior to the introduction of certain new populations of *aquatic animals* into a previously stocked *aquaculture establishment* as part of a *biosecurity plan* constructed in accordance with Chapter 4.1., or

2) compulsorily, on the instructions of the *Competent Authority*, following an outbreak of a *disease* which is subject to emergency management measures as described in Chapter 4.11~~Y~~.

In the case of the voluntary *fallowing*, the objectives are to prevent transmission of *pathogenic agents* between successive production cycles and suppress *pathogenic agent infection* pressure.

In the case of compulsory *fallowing*, the objective is to eradicate a *pathogenic agent* from an *aquaculture establishment* or in the case of synchronous *fallowing*, from a group of epidemiologically connected *aquaculture establishments*.

Article 4.7.2.

Considerations for fallowing

Fallowing is used to provide a temporal break in the transmission of a *pathogenic agent* ~~transmission cycles~~ between successive cohorts of *susceptible species* or where relevant vector species ~~populations~~ of *aquatic animals*. It should be implemented taking the following factors into account ~~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*;~~

1~~2~~) the possible sources of *infection* at the *aquaculture establishment* ~~production site~~ such as farmed or wild populations of *susceptible species* ~~*aquatic animals*~~, *vectors*, fomites or *pathogenic agents* in the environment (e.g. water or sediment);

23) characteristics of the relevant *pathogenic agent*, including its survival and stability outside the host and its infective period ~~whether the *pathogenic agent* is obligate or facultative~~;

~~4) for obligate *pathogenic agents*, the period that they may remain viable in the environment;~~

35) the need for spatial coordination to synchronously fallow epidemiologically connected *aquaculture establishments*;

4) the type of *aquaculture* production system taking into account its design, extent and application of *biosecurity* measures;

56) *aquaculture establishment(s)* should ~~when the infective period is not known, the farm may~~ be fallowed for a period of time, the length of which should be based on a *risk assessment*.

Article 4.7.3.

Voluntary fallowing

When assessing the potential benefits of recommending voluntary *fallowing*, the *Aquatic Animal Health Services* in a country should in addition to the considerations outlined in Article 4.7.2. take the following factors into account:

1) the level of *risk* a particular *pathogenic agent* poses to local *aquaculture* operations, and to other aquatic resources in the area;

2) the relevant socioeconomic conditions and ~~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 mandated by ~~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 4.10~~X~~. and 4.11~~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 epidemiologically linked ~~relevant~~ *aquaculture establishments* in an officially declared ~~established~~ *infected zone*, are ~~be~~ subjected to a ~~required~~ period of *fallowing*~~, if necessary synchronised~~. The duration of the ~~this~~ *fallowing* period will be ~~carried out for a period of time which is~~ prescribed by the *Competent Authority*, following *risk assessment*. *Risk assessment* will also be used to determine if a ~~A~~ period of synchronous *fallowing* is ~~may be~~ required in epidemiologically linked ~~relevant~~ *aquaculture establishments* in the *infected zone* as well as the duration of such *fallowing* ~~should this be indicated by the *risk assessment*.~~

The *Competent Authority* should ensure compulsory *fallowing* is underpinned by legal provisions that set out the following details;

~~Article 4.7.52.~~

~~**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~~ conditions under which ~~*disease* circumstances when~~ *fallowing* or synchronised *fallowing* is required including specific implementation steps for each;

2) specific point at which *fallowing* should commence;

3) duration of the *fallowing* period;

4) conditions under which the re-introduction of *aquaculture* species will be permitted, once the *fallowing* period has been completed.

~~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 4.7.5~~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., as well as the measures described in paragraph 5 of Article 4.10.7., *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 the following actions are taken:

1) removal ~~destruction of~~ and biosecure disposal of:

   a) ~~removal of~~ all *susceptible species* of *aquatic animals* for the *disease* of concern; and

   b~~2~~) ~~removal of~~ all species of *aquaculture* animals which are capable of acting as *vectors* of the *disease* of concern, if indicated by *risk assessment*; and

   c~~3~~) ~~if appropriate, removal of~~ other species, if indicated by *risk assessment*; ~~and~~

2~~4~~) removal of water in which infected stocks have been held, where feasible; and

3~~5~~) appropriate *disinfection* measures have been completed on equipment and other contaminated materials in accordance with Article 4.7.4., under the oversight of the *Competent Authority* ~~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*.~~

In addition to the considerations outlined in Article 4.7.2., the *Competent Authority* should consider that the duration~~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~~ Factors to be considered include 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 relevant ~~local~~ climatological, geographical and hydrographical conditions~~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 4.7.6~~7~~4.

~~Instructions for disinfection~~ Disinfection prior to fallowing

Aquatic Animal Health Services ~~Competent Authorities~~ ~~Countries~~ establishing *fallowing* procedures should develop a detailed set of instructions for *disinfection* of *aquaculture establishments* prior to *fallowing* for approval by the *Competent Authority*. These instructions should be~~, where~~ appropriate for the type of production system and circumstances. This should be completed in accordance with Chapter 4.4. and in the case of~~or~~ compulsory *fallowing*, in accordance with Chapters 4.10~~X~~. and 4.11~~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 disinfectants~~treatments~~ for the *pathogenic agent* of concern.

Article 4.7.7~~8~~5.

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~~.

CLEAN VERSION

CHAPTER 4.7.

FALLOWING IN AQUACULTURE

Article 4.7.1.

Introduction

Fallowing is a *disease* management measure in *aquaculture*, which is employed either:

1) voluntarily, prior to the introduction of certain new populations of *aquatic animals* into a previously stocked *aquaculture establishment* as part of a *biosecurity plan* constructed in accordance with Chapter 4.1., or

2) compulsorily, on the instructions of the *Competent Authority*, following an outbreak of a *disease* which is subject to emergency management measures as described in Chapter 4.11.

In the case of the voluntary *fallowing*, the objectives are to prevent transmission of *pathogenic agents* between successive production cycles and suppress *pathogenic agent infection* pressure.

In the case of compulsory *fallowing*, the objective is to eradicate a *pathogenic agent* from an *aquaculture establishment* or in the case of synchronous *fallowing*, from a group of epidemiologically connected *aquaculture establishments*.

Article 4.7.2.

Considerations for fallowing

Fallowing is used to provide a temporal break in the transmission of a *pathogenic agent* between successive cohorts of *susceptible species* or where relevant, vector species, of *aquatic animals*. It should be implemented taking the following factors into account:

1) the possible sources of *infection* at the *aquaculture establishment* such as farmed or wild populations of *susceptible species*, *vectors*, fomites or *pathogenic agents* in the environment (e.g. water or sediment);

2) characteristics of the relevant *pathogenic agent*, including its survival and stability outside the host and its infective period;

3) the need for spatial coordination to synchronously fallow epidemiologically connected *aquaculture establishments*;

4) the type of *aquaculture* production system taking into account its design, extent and application of *biosecurity* measures;

5) *aquaculture establishment(s)* should be fallowed for a period of time, the length of which should be based on a *risk assessment*.

Article 4.7.3.

Voluntary fallowing

When assessing the potential benefits of recommending voluntary *fallowing*, the *Aquatic Animal Health Services* in a country should, in addition to the considerations outlined in Article 4.7.2., take the following factors into account:

1) the level of *risk* a particular *pathogenic agent* poses to local *aquaculture* operations, and to other aquatic resources in the area;

2) the relevant socioeconomic conditions and the likely beneficial effects of *fallowing* in proportion to the economic costs involved.

Article 4.7.4.

Compulsory fallowing

Compulsory *fallowing* may be mandated by the *Competent Authority* following an outbreak of an important *disease* which has been subject to the measures described in Chapters 4.10. and 4.11. The *Competent Authority* may require that an infected *aquaculture establishment*, and other epidemiologically linked *aquaculture establishments* in an officially declared *infected zone*, are subjected to a period of *fallowing*. The duration of the *fallowing* period will be prescribed by the *Competent Authority*, following *risk assessment*. *Risk assessment* will also be used to determine if a period of synchronous *fallowing* is required in epidemiologically linked *aquaculture establishments* in the *infected zone* as well as the duration of such *fallowing*.

The *Competent Authority* should ensure compulsory *fallowing* is underpinned by legal provisions that set out the following details;

1) conditions under which *fallowing* or synchronised *fallowing* is required including specific implementation steps for each;

2) specific point at which *fallowing* should commence;

3) duration of the *fallowing* period;

4) conditions under which the re-introduction of *aquaculture* species will be permitted, once the *fallowing* period has been completed.

Article 4.7.5.

Technical parameters for the implementation of a compulsory fallowing plan

Taking into account the categories of *aquaculture* production systems referred to in Article 4.1.5., as well as the measures described in paragraph 5 of Article 4.10.7., *fallowing* of an a*quaculture establishmen*t should start immediately after the following actions are taken:

1) removal and biosecure disposal of:

   a) all *susceptible species* of *aquatic animals* for the *disease* of concern; and

   b) all species of *aquaculture* animals which are capable of acting as *vectors* of the *disease* of concern, if indicated by *risk assessment*; and

   c) other species, if indicated by *risk assessment*;

2) removal of water in which infected stocks have been held, where feasible; and

3) appropriate *disinfection* measures have been completed on equipment and other contaminated materials in accordance with Article 4.7.4., under the oversight of the *Competent Authority.*

In addition to the considerations outlined in Article 4.7.2., the *Competent Authority* should consider that the duration of the compulsory *fallowing* period should be based on scientific evidence of the likelihood of a *pathogenic agent* remaining infective in the local environment, at a level likely to cause an unacceptable risk of re-*infection* of the *aquaculture establishment*. Factors to be considered include the extent of the *disease outbreak*, local distribution of *susceptible species* and possible *vectors,*the survival and infectivity characteristics of the *pathogenic agent,* and the relevant climatological, geographical and hydrographical conditions.

Article 4.7.6.

Disinfection prior to fallowing

Aquatic Animal Health Services establishing *fallowing* procedures should develop a detailed set of instructions for *disinfection* of *aquaculture establishments* prior to *fallowing* for approval by the *Competent Authority*. These instructions should be appropriate for the type of production system and circumstances. Disinfection should be completed in accordance with Chapter 4.4. and in the case of compulsory *fallowing*, in accordance with Chapters 4.10. and 4.11., taking into account current scientific knowledge on the efficacy of the disinfectants for the *pathogenic agent* of concern.

Article 4.7.7.

Restocking after fallowing

An *aquaculture establishment* that has been subject to 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 compromise the objectives of the *fallowing* procedure. All farms subjected to compulsory *fallowing* should have a period of official *surveillance* after *susceptible species* have been restocked. The duration and intensity of the *surveillance* should be appropriate for the *disease* in question and subject to the requirements set out in Chapter 1.4., and to the relevant disease-specific chapter in cases of *listed diseases*.

Annex 9. Item 6.4. – Proposed approach to revision of Section 5 'Trade measures, importation/exportation procedures and health certification'

SECTION 5

TRADE MEASURES, IMPORTATION/EXPORTATION PROCEDURES AND HEALTH CERTIFICATION

Objectives of Section 5 revision:

- Revise older standards and improve quality as necessary
- Address any gaps in standards for trade
- Improve useability for developing trade measures
- Address aquatic specific trade issues while also maintaining alignment with *Terrestrial Code*
- Improve alignment of chapters within Section 5 and between Section 5 and other sections of the *Aquatic Code*

Aquatic Code **Section 5 structure**	***Terrestrial Code*** **Section 5 structure** (for comparison only)	***Aquatic Code*** **Proposed approach**
N/A	N/A	**New chapter.** Development of a new introductory chapter to Section 5 in cooperation with the Code Commission (see item 7.1.2 in this report)
5.1. General obligations related to certification	5.1. General obligations related to certification	**Review**. Consider the need for revision in collaboration with the Code Commission. Proposed certification a*d hoc* Group to review chapter in both Codes and provide recommendations (see item 8.1.2. Feb 2025 report).
5.2. Certification procedures	5.2. Certification procedures	**Review**. Consider need for revision in collaboration with the Code Commission. Proposed certification a*d hoc* Group to review chapter in both Codes and provide recommendations (see item 8.1.2. Feb 2025 report).
5.3. WOAH procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization	5.3. WOAH procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization	**Revise**. Consider need for revision in collaboration with the Code Commission
5.4. Criteria to assess the safety of aquatic animal commodities	N/A	**Relocate.** Move to section 2, risk analysis (as for TC)
5.5. Control of aquatic animal health risks associated with transport of aquatic animals	N/A	**Revise.** Last adopted in 2010. Consider whether more appropriate in Section 4 or 5. If remains in Section 5 consider renumbering.

5.6. Aquatic animal health measures applicable before and at departure	5.4. Animal health measures applicable before and at departure	**Revise.** Consider revisions proposed to equivalent *Terrestrial Code* chapter.
5.7. Aquatic animal health measures applicable during transit from the place of departure in the exporting country to the place of arrival in the importing country	5.5. Animal health measures applicable during transit from the place of departure in the exporting country to the place of arrival in the importing country	**Revise.** Consider revisions proposed to equivalent *Terrestrial Code* chapter.
5.8. Frontier posts in the importing country	5.6. Border posts and quarantine stations in the importing country	**Revise.** Consider revisions proposed to equivalent *Terrestrial Code* chapter.
5.9. Aquatic animal health measures applicable on arrival	5.7. Animal health measures applicable on arrival	**Revise.** Consider revisions proposed to equivalent *Terrestrial Code* chapter.
5.10. Measures concerning international transport of aquatic animal pathogens and pathological material	5.8. International transfer and laboratory containment of animal pathogenic agents	**Revise.** Last adopted 2010.
N/A	5.9. Quarantine measures applicable to non-human primates	Not relevant to Aquatic Code
5.11. Model health certificates for international trade in live aquatic animals and products of aquatic animal origin	5.10. Model veterinary certificates for international trade in live animals, hatching eggs and products of animal origin	**Review.** Consider alignment between the three model certificates and with other provisions of the *Aquatic Code.* Proposed certification a*d hoc* Group to review chapter in both Codes and provide recommendations (see item 8.1.2. Feb 2025 report)
5.12. Movement of ornamental aquatic animals	N/A	**No action.** Adopted 2025.
N/A	5.11. Model veterinary certificate for international movement of dogs, cats and ferrets originating from countries considered infected with rabies	Not relevant to Aquatic Code
NA	5.12. Model passport for international movement of competition horses	Not relevant to Aquatic Code
N/A	5.13. Model veterinary certificate for international trade in laboratory animals	Consider need for a model certificate in *Aquatic Code* or whether Ch 5.11 of *Aquatic Code* is sufficient.

Other trade relevant considerations:

- Revision of trade articles in disease specific chapters (X.X.9 to X.X14; 10.4.13. to 10.4.20.); including reordering of articles and revision of commodity and pathway (end-use) combination; including addressing commodity gaps (e.g. ornamental aquatic animals)
- Consider diagrammatic guidance on appropriate application of provisions of disease-specific chapters, possibly in the User's Guide
- Consider general guidance on trade in live aquatic animal for aquaculture similar in approach to new ornamentals chapter
- Define "official control" considering approach in terrestrial code, and IPCC definition

Annex 10. Item 6.5. – Article 9.2.2. of Chapter 9.2. 'Infection with *Aphanomyces astaci* (crayfish plague)'

CHAPTER 9.2.

INFECTION WITH *APHANOMYCES ASTACI* (CRAYFISH PLAGUE)

[…]

Article 9.2.2.

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.: ~~all species of crayfish in all three crayfish families (Cambaridae, Astacidae and Parastacidae). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

Family	Scientific name	Common name
Astacidae	*Astacus astacus*	noble crayfish
	Austropotamobius pallipes	no common name
	Pacifastacus leniusculus	signal crayfish
	Pontastacus leptodactylus	Danube crayfish
Cambaridae	*Faxonius spp.* (all species)	N/A
	Procambarus spp. (all species)	N/A
Cambaroididae	*Cambaroides japonicus*	no common name
Parastacidae	*Cherax quadricarinatus*	red claw crayfish
Potamidae	*Potamon potamios*	no common name
Varunidae	*Eriocheir sinensis*	Chinese mitten crab

[…]

Annex 11. Item 6.6. – Articles 10.3.5. and 10.3.6. of Chapter 10.3. 'Infection with *Gyrodactylus salaris*'

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 months;

OR

2) ~~pathway 2 (historical freedom) is [under study]~~ there has been no occurrence of infection with *G. salaris* for at least the last 15 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 at least the last 15 years;

   Pathway 2 (historical freedom) is only applicable to make a *self-declaration of freedom from disease* for infection with *G. salaris* for Atlantic salmon (*Salmo salar*). If the study population comprises other *susceptible species* that do not exhibit clinical signs then pathway 2 is not suitable.

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three years without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least two 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 years in wild and farmed *susceptible species* without detection of *G. salaris*; or

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

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

Article 10.3.6.

Zone free from infection with *G. salaris*

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

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

1) none of the *susceptible species* referred to in Article 10.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six months;

OR

2) ~~pathway 2 (historical freedom) is [under study]~~ there has been no occurrence of infection with *G. salaris* for at least the last 15 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 at least the last 15 years;

Pathway 2 (historical freedom) is only applicable to make a *self-declaration of freedom from disease* for infection with *G. salaris* for Atlantic salmon (*Salmo salar*). If the study population comprises other *susceptible species* that do not exhibit clinical signs then pathway 2 is not suitable.

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three years without detection of *G. salaris* and *basic biosecurity conditions* have been continuously met and have been in place for at least two 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:

   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.

[...]

Annex 12. Item 6.7. – Article 10.4.9. of Chapter 10.4. 'Infection with infectious salmon anaemia virus'

CHAPTER 9.2.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

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 two ~~[under study]~~ years without detection of ISAV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.4.13. and 10.4.14. as appropriate; and

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

[…]

Annex 13. Item 6.8. – Update on viral taxonomy in Article X.X.1. of Chapters 9.3., 9.5., 9.6., 9.8., 9.10., 10.4., 10.5., 10.6., 10.7., 10.9., 10.10., 10.11. and 11.1.

SECTION 9

DISEASES OF CRUSTACEANS

CHAPTER 9.3.

INFECTION WITH DECAPOD IRIDESCENT VIRUS 1

Article 9.3.1.

For the purposes of the *Aquatic Code*, infection with decapod iridescent virus 1 (DIV1) means *infection* with the *pathogenic agent* *Decapodiridovirus litopenaeus1* ~~*Decapod iridescent virus 1*~~ (~~DIV1~~), of the ~~*Genus Decapodiridovirus*~~ and the Family *Iridoviridae*.

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

[…]

CHAPTER 9.5.

INFECTION WITH HYPODERMAL AND HAEMATOPOIETIC NECROSIS VIRUS

[...]

Article 9.5.1.

For the purposes of the *Aquatic Code*, infection with infectious hypodermal and haematopoietic necrosis virus (IHHNV) means *infection* with the *pathogenic agent* *Penstylhamaparvovirus decapod1* ~~*Decapod penstylhamaparvovirus 1*~~, of the ~~Genus *Penstylhamaparvovirus*~~ and Family *Parvoviridae*.

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

CHAPTER 9.6.

INFECTION WITH INFECTIOUS MYONECROSIS VIRUS

Article 9.6.1.

For the purposes of the *Aquatic Code*, infection with infectious myonecrosis virus (IMNV) means *infection* with the *pathogenic agent* infectious myonecrosis virus ~~(IMNV)~~ of the Genus *Artivirus* and of the Family Artiviridae ~~Totiviridae (tentative classification)~~.

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

[...]

CHAPTER 9.8.

INFECTION WITH TAURA SYNDROME VIRUS

Article 9.8.1.

For the purposes of the *Aquatic Code*, infection with Taura syndrome virus (TSV) means *infection* with the *pathogenic agent* *Aparavirus tauraense*~~Taura syndrome virus (TSV)~~, of the ~~Genus *Aparavirus*,~~ Family Dicistroviridae~~ and Order Picornavirales~~.

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

[...]

CHAPTER 9.10.

INFECTION WITH YELLOW HEAD VIRUS GENOTYPE 1

Article 9.10.1.

For the purposes of the *Aquatic Code*, infection with yellow head virus genotype 1 means *infection* with the *pathogenic agent* yellow head virus genotype 1 (YHV1), of the Genus *Okavirus*~~,~~ and Family Roniviridae, ~~Order Nidovirales~~.

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

[…]

SECTION 10

DISEASES OF FISH

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

Article 10.4.1.

For the purposes of the *Aquatic Code*, infection with infectious salmon anaemia virus (ISAV) means *infection* with the *pathogenic agent* *Isavirus salaris* of the Family *Orthomyxoviridae*. Infection with ISAV includes two genotypes; highly polymorphic region (HPR)-deleted ~~infectious salmon anaemia virus (~~ISAV~~)~~, or the non-pathogenic HPR0 ISAV(non-deleted highly polymorphic region ISAV) ~~ISAV, of the Genus *Isavirus* and Family *Orthomyxoviridae*~~. Both genotypes should be notified in accordance with Chapter 1.1.

There is a link between non-pathogenic HPR0 ISAV and pathogenic HPR-deleted ISAV, with some *outbreaks* potentially occurring as a result of the emergence of HPR-deleted from HPR0.

The provisions in this chapter are provided in recognition of three possible levels of disease status with respect to ISAV:

1) HPR0 ISAV and HPR-deleted ISAV free;

2) HPR0 ISAV endemic (but HPR-deleted ISAV free);

3) HPR0 ISAV and HPR-deleted ISAV endemic.

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

[…]

CHAPTER 10.5.

INFECTION WITH INFECTIOUS SALMONID ALPHAVIRUS

Article 10.5.1.

For the purposes of the *Aquatic Code*, infection with salmonid alphavirus (SAV) means *infection* with any genotype of the *pathogenic agent* *Alphavirus salmon*~~salmonid alphavirus (SAV)~~, of the ~~Genus *Alphavirus* and~~ Family *Togaviridae*.

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

[...]

CHAPTER 10.6.

INFECTION WITH INFECTIOUS HAEMATOPOIETIC NECROSIS VIRUS

Article 10.6.1.

For the purposes of the *Aquatic Code*, infection with infectious haematopoietic necrosis virus (IHNV) means *infection* with the *pathogenic agent* *Novirhabdovirus salmonid* ~~Salmonid novirhabdovirus (commonly known as infectious haematopoietic necrosis virus [IHNV])~~ of the ~~Genus *Novirhabdovirus* and~~ Family *Rhabdoviridae*.

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

[...]

CHAPTER 10.7.

INFECTION WITH KOI HERPESVIRUS

Article 10.7.1.

For the purposes of the *Aquatic Code*, infection with koi herpesvirus (KHV) means *infection* with the *pathogenic agent* *Cyvirus cyprinidallo 3*~~koi herpesvirus (KHV)~~ of the ~~Genus *Cyprinivirus* and~~ Family *Alloherpesviridae*.

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

[...]

CHAPTER 10.9.

INFECTION WITH SPRING VIRAEMIA OF CARP VIRUS

Article 10.9.1.

For the purposes of the *Aquatic Code*, infection with spring viraemia of carp virus (SVCV) means *infection* with the *pathogenic agent* *Sprivivirus cyprinus* ~~spring viraemia of carp virus (SVCV)~~ of the ~~Genus *Sprivivirus* and~~ Family *Rhabdoviridae*.

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

[...]

CHAPTER 10.10.

INFECTION WITH VIRAL HAEMORRHAGIC SEPTICAEMIA VIRUS

Article 10.10.1.

For the purposes of the *Aquatic Code*, infection with viral haemorrhagic septicaemia virus (VHSV) means *infection* with the *pathogenic agent* *Novirhabdovirus piscine* ~~viral haemorrhagic septicaemia virus (VHSV)~~, of the ~~Genus *Novirhabdovirus*~~ and Family *Rhabdoviridae*.

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

[...]

CHAPTER 10.11.

INFECTION WITH TILAPIA LAKE VIRUS

Article 10.11.1.

For the purposes of the *Aquatic Code*, infection with tilapia lake virus (TiLV) means *infection* with the *pathogenic agent* *Tilapinevirus tilapiae*~~*Tilapia tilapinevirus*~~, of the ~~Genus *Tilapinevirus* and the~~ Family *Amnoonviridae*.

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

[...]

SECTION 11

DISEASES OF MOLLUSCS

CHAPTER 11.1.

INFECTION WITH ABALONE HERPESVIRUS

Article 11.1.1.

For the purposes of the *Aquatic Code*, infection with abalone herpesvirus (AbHV) means *infection* with the *pathogenic agent* *Aurivirus haliotidmalaco 1*~~Haliotid herpesvirus 1 (HaHV-1)~~, of the ~~Genus *Aurivirus* and~~ Family *Malacoherpesviridae*.

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

[...]

Annex 14. Item 8.1.1. – Sections 2.2.1. and 2.2.2. of Chapter 2.2.2. 'Infection with *Aphanomyces astaci* (crayfish plague)'

CHAPTER 2.2.9.

INFECTION WITH *APHANOMYCES ASTACI* (CRAYFISH PLAGUE)

[…]

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Astacidae	*Astacus astacus*	noble crayfish
	Austropotamobius pallipes	no common name
	Pacifastacus leniusculus	signal crayfish
	Pontastacus leptodactylus	Danube crayfish
Cambaridae	*Faxonius spp.* (all species)	N/A
	Procambarus spp. (all species)	N/A
Cambaroididae	*Cambaroides japonicus*	no common name
Parastacidae	*Cherax quadricarinatus*	red claw crayfish
Potamidae	*Potamon potamios*	no common name
Varunidae	*Eriocheir sinensis*	Chinese mitten crab

~~The recommendations in this chapter apply to all species of crayfish in all three crayfish families (Cambaridae, Astacidae and Parastacidae).~~

~~[**Note**: an assessment of species that meet the criteria for listing as susceptible to infection with *A. astaci* 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 *A. astaci* according to Chapter 1.5. of the *Aquatic Code* are:

Family	Scientific name	Common name
Astacidae	*Austropotamobius torrentium*	no common name
Cambaridae	*Cambarellus (Cambarellus) montezumae*	no common name
	Cambarellus patzcuarensis	no common name
	Cambarellus shufeldtii	Cajun dwarf crayfish
	Cambarus bartonii	Appalachian brook crayfish

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
Cambaridae	*Cambarus latimanus*	no common name
	Cambarus striatus	Hay crayfish
	Creaserinus fodiens	no common name
	Creaserinus oryktes	no common name
Palaemonidae	*Palaemon kadiakensis*	no common name

~~[Under study]~~

[…]

Annex 15. Item 8.2.1. Chapter 2.4.5. 'Infection with *Bonamia exitiosa'* and Chapter 2.4.3. 'Infection with *Bonamia ostreae'*

CHAPTER 2.4.2.

INFECTION WITH *BONAMIA EXITIOSA*

. . .

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.

When two molecular methods are used for confirmation of a case, it is preferable to use two species-specific methods targeting non-overlapping regions of the pathogen genome.

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 is met:

i) Positive result by tissue imprints, histology or *in-situ* hybridisation and ~~real-time~~ positive result by PCR ~~and conventional PCR and~~ combined with sequencing

ii) Positive result~~s~~ by ~~real-time~~ two PCR~~s~~ ~~and *in-situ* hybridisation~~ targeting different parts of the genome combined with sequencing

~~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.

6.2 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. 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. ostreae* is considered to be confirmed if at least one of the following critera is met:

i) Positive result by tissue imprints, histology or in-situ hybridisation and positive result by ~~real-time~~ PCR ~~and conventional PCR and~~ combined with sequencing

ii) Positive results by ~~real-time~~ two PCRs ~~and *in-situ* hybridisation~~ targeting different parts of the genome combined with sequencing

~~iii) Positive result by tissue imprints, histology or *in-situ* hybridisation, and positive result by conventional PCR followed by sequence analysis~~

. . .

CHAPTER 2.4.3.

INFECTION WITH *BONAMIA OSTREAE*

. . .

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.

When two molecular methods are used for confirmation of a case, it is preferable to use two species-specific methods targeting non-overlapping regions of the pathogen genome.

6.1. Apparently healthy animals or animals of unknown health status[2]

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 at least one of the following criteria is met:

i) Positive result by tissue imprints, histology or *in-situ* hybridisation and ~~real-time~~ positive result by PCR ~~and conventional PCR and~~ combined with sequencing

ii) Positive results by ~~real-time~~ two PCRs ~~and *in-situ* hybridisation~~ targeting different parts of the genome combined with sequencing

~~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.

2 For example transboundary commodities.

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 at least one of the following critera is met:

i) Positive result by tissue imprints, histology or in-situ hybridisation and positive result by ~~real-time~~ PCR ~~and conventional PCR and~~ combined with sequencing

ii) Positive results by ~~real-time~~ two PCRs ~~and *in-situ* hybridisation~~ targeting different parts of the genome combined with sequencing

~~iii) Positive result by tissue imprints, histology or *in-situ* hybridisation, and positive result by conventional PCR followed by sequence analysis~~

. . .

Annex 16. Item 8.2.2. Chapter 2.4.5. 'Infection with *Marteilia refringens*'

CHAPTER 2.4.4.

INFECTION WITH *MARTEILIA REFRINGENS*

. . .

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.

When two molecular methods are used for confirmation of a case, it is preferable to use two species-specific methods targeting non-overlapping regions of the pathogen genome.

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 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 *M. refringens* shall be suspected if at least one of the following criteria is met:

i) Positive result by a recommended molecular detection test

ii) Visual observation of the pathogen by microscopy

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *M. refringens* is considered to be confirmed if at least one of the following ~~criterion~~ criteria is met:

i) Positive result by tissue imprints, histology or *in-situ* hybridisation and ~~real-time~~ positive result by PCR ~~and conventional PCR followed by sequence analysis~~ combined with sequencing

ii) Positive results by two PCRs targeting different parts of the genome combined with 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 *M. refringens* shall be suspected if at least one of the following criteria is met:

i) Positive result by wet mounts

1 For example transboundary commodities.

ii) Positive result by tissue imprints

iii) Positive result by histopathology

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 *M. refringens* is considered to be confirmed if at least one of the following criteria is met:

i) Positive result by tissue imprints, histology or *in-situ* hybridisation and ~~real-time~~ positive result by PCR ~~and conventional PCR followed by sequence analysis~~ combined with sequencing

ii) Positive results by ~~species-specific ISH and conventional~~ two PCRs ~~followed by sequence analysis~~ targeting different parts of the genome combined with sequencing

~~iii) Positive result of real-time PCR followed by species-specific ISH~~

. . .

Annex 17. Item 8.2.3. Chapter 2.4.5. 'Infection with *Perkinsus marinus*'

CHAPTER 2.4.5.

INFECTION WITH *PERKINSUS MARINUS*

1. Scope

Infection with *Perkinsus marinus* means infection with the pathogenic agent *Perkinsus marinus,* of the Family Perkinsidae.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

Perkinsus marinus is a Perkinsid parasite initially described infecting eastern oysters, *Crassostrea virginica* and causing disease and mortality (Mackin *et al.,* 1950).

Current phylogenomic studies place *P. marinus* within the class Perkinsea of the phylum Perkinsozoa, under the Kingdom Alveolata (Reece *et al.,* 1997).

The parasite occurs as motile zoospores, trophozoites, and schizonts. Following infection, trophozoites proliferate within oyster tissues, particularly in connective tissue and haemolymph. As trophozoites grow, they undergo schizogony: cleavage furrows form, leading to the production of multiple merozoites within a morula-like stage. Fully developed schizonts rupture to release large numbers of merozoites, which disseminate through host tissues or into the environment (Andrews, 1988; Villalba *et al.,* 2004).

As in *P. olseni*, the ribosomal RNA transcription units in *P. marinus* are highly duplicated and variable, complicating the use of rDNA as a reliable quantitative marker for infection intensity (Bogema *et al.,* 2021). Alternative genomic regions, including internal transcribed spacer (ITS) sequences and non-ribosomal single-copy genes, have been explored for molecular diagnostics (Audemard *et al.,* 2004; De Faveri *et al.,* 2009; Gauthier *et al.,* 2006; Reece *et al.,* 1997; Robledo *et al.,* 1999).

Cytogenetic and molecular studies suggest that *P. marinus* may also display variable ploidy. Early work using microsatellite loci and karyotyping suggested diploidy (Reece *et al.,* 1997; Robledo *et al.,* 1999), but subsequent genomic sequencing has raised the possibility of polyploidy or aneuploidy, with variation across life stages and isolates (Bogema *et al.,* 2021; Thompson *et al.,* 2011). Further investigation is needed to resolve the extent and biological implications of ploidy variation in this species.

2.1.2. Survival and stability in processed or stored samples

The survival and stability of *P. marinus* varies according to the conditions when processing and storing samples. Refrigeration (2–6°C) and low salinity (7 ppt) significantly decreases the viability and metabolic activity of *P. marinus* but could not eliminate *P. marinus* from oysters (La Peyre *et al.,* 2008b; 2010). It is likely that *P. marinus* can survive in dead or frozen oysters for an unknown, potentially long period (Andrews & Hewatt, 1957).

2.1.3. Survival and stability outside the host

Perkinsus marinus meront cells can survive for at least 14 days in the water column, with their infectivity potentially persisting beyond 7days (Chu & Lund, 2006).

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 *P. marinus* according to Chapter 1.5. of the *Aquatic Animal Health Code* (*Aquatic Code*) are:

Family	Scientific name	Common name
Ostreidae	*Crassostrea corteziensis*	Cortez oyster
	Crassostrea virginica	American cupped oyster
	Magallana [syn. *Crassostrea*] *ariakensis*	Ariake cupped oyster
	Saccostrea palmula	palmate oyster

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. marinus* according to Chapter 1.5. of the *Aquatic Code* are:

Family	Scientific name	Common name
Ostreidae	*Crassostrea tulipa*	Gasar cupped oyster
	Crassostrea rhizophorae	mangrove cupped oyster
	Magallana [syn. *Crassostrea*] *gigas*	Pacific cupped 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
Myidae	*Mya arenaria*	soft shell clam
Ostreidae	*Crassostrea columbiensis*	Columbia black oyster
	Striostrea prismatica	stone oyster

2.2.3. Likelihood of infection by species, host life stage, population or sub-populations

Perkinsus marinus usually infects and kills oysters between 1 and 3 years of age. Differences in clinical expression to the infection with *Perkinsus marinus* has been shown between *Crassostrea virginica* populations (e.g. Bushek & Allen, 1996; Green-Beach *et al.,* 2011).

Compared with *C. virginica, Crassostrea corteziensis, Saccostrea palmula* and triploid *M. ariakensis* were found to exhibit partial resistance to *P. marinus* infection and associated disease (Cáceres-Martínez *et al.,* 2012; 2016; Calvo *et al.* 2000; 2001).

2.2.4. Distribution of the pathogen in the host

While *P. marinus* can be found in various tissues and organs, it mostly infects intestine, vesicular connective tissue, haemocytes and digestive gland (Remacha-Triviño *et al.,* 2008). The proliferation of the parasite causes systemic disruption of connective tissue and epithelial cells.

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

Infection is often lethal for *C. virginica*. Death usually occurs 1 or 2 years after infection, during or shortly after the warmest annual water temperatures (Burreson & Ragone Calvo, 1996). Prevalence is expected to be higher in individuals with more than 1 year of exposure to the pathogen (Andrews, 1996; Burreson & Ragone Calvo, 1996).

Prevalence is highly variable depending on host populations, pathogen strain and environmental factors (Kim *et al.,* 2025; Proestou *et al.,* 2023). Along the US east coast, *C. virginica* populations consistently exhibit high *P. marinus* infection rates, typically exceeding 80% and sometimes reaching 100% prevalence (Smolowitz*,* 2013). While populations from the Mexico Gulf typically exhibit low to moderate prevalence, with infection intensities generally remaining light (Ammons *et al.,* 2023; Cáceres-Martínez *et al.,* 2016; Gullian-Klanian *et al.,* 2008).

Infection prevalence and intensity are consistently low in *M. ariakensis*, *C. corteziensis* and *S. palmula* populations (Cáceres-Martínez *et al.,* 2012; 2016; Calvo *et al.,* 2000; 2001). Notably, no significant *P. marinus*-associated mortality has been observed in natural populations of *C. corteziensis* and *S. palmula* (Cáceres-Martínez *et al.,* 2012; 2016). Furthermore, *M. ariakensis* demonstrates superior survival, faster growth, and reduced disease susceptibility compared to *C. virginica* across varying salinity regimes (low, medium, and high) (Calvo *et al.,* 2001).

2.3.2. Clinical signs, including behavioural changes

Perkinsus marinus causes a chronic wasting disease.

Infected oysters may have a pale appearance to the digestive gland, reductions in condition index, severe emaciation, gaping, shrinkage of the mantle away from the outer edge of the shell, reduced gonadal development and/or retardation of growth (Ford & Tripp, 1996). Occasionally, pus-like pockets may occur in the soft tissues. However, these signs are not pathognomonic of perkinsosis.

2.3.3 Gross pathology

Gross signs are thin, watery tissue, eventually presence of pus-like pockets, but these gross signs are not specific to infection with *P. marinus*.

2.3.4. Modes of transmission and life cycle

The life cycle is direct from host to host (Andrews, 1996; Villalba *et al.,* 2004). *Perkinsus marinus* is transmitted directly from host to host through the water column following release of parasites in faeces or the decay or scavenging of moribund tissues (Bushek *et al.,* 2002). The parasite enters the paleal cavity of the oyster during filter-feeding. Labial palps and particularly the pseudo-faeces discharge area of the mantle are important sites of infection (Allam *et al.,* 2013; Winnicki *et al.,* 2008). Parasites infect and multiply within haemocytes. The infected circulating haemocytes migrate throughout the host tissues.

Experimental infection in controlled conditions is possible by exposing animals to *in vitro* culture of *P. marinus* (Dungan *et al.,* 2007).

2.3.5. Environmental factors

The prevalence and intensity of *P. marinus* are primarily driven by salinity and temperature. On the east coast of US, infections are acquired during the warm months of the year, when the water temperatures reach above 18°C (Smolowitz, 2013). Proliferation of the parasite and associated lesions are correlated with temperature. Temperature controls the annual cycle of *P. marinus*, with maximum prevalence and intensity lagging 1–2 months behind maximum summer water temperatures and minimum prevalence and intensity lagging 1–2 months behind minimum winter temperatures. Thus, *P. marinus* infections are most intense in autumn and least intense in early spring (Burreson & Ragone Calvo, 1996). Parasite infection intensity peaked at about 35°C (Malek *et al*., 2018). In tropical regions such as the Gulf of Mexico, however, *P. marinus* proliferates at significantly higher temperatures, suggesting an adaptation of host-parasite dynamics to these conditions (Cáceres-Martínez *et al.,* 2016).

Perkinsus marinus cells were released on a diurnal cycle, with most cells released during the hottest and brightest period of the day (12:00–18:00). Temperature had a strong and immediate effect on the number of cells released, but salinity did not, only influencing the intensity of infection over the course of several months

(Gignoux-Wolfsohn *et al*., 2020). Prevalence and intensity of *P. marinus* infections are greatest at salinities greater than 12 practical salinity units (psu). Transmission can occur between 9 and 12 psu, but infections remain low in intensity. *Perkinsus marinus* can persist for long periods in hosts at salinities less than 9 psu, but replication is low and no host mortality occurs.

2.3.6. Geographical distribution

Infection with *P. marinus* has been reported from the Atlantic coast of North and South America (da Silva *et al.,* 2013). It was introduced to the Pacific coast of North America (Cáceres-Martínez *et al.,* 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

None.

2.4.2. Chemotherapy including blocking agents

N-Halamine disinfectant compounds killed cultured *P. marinus* cells without affecting oyster larvae (Delaney *et al.,* 2003). Bacitracin, cycloheximide and freshwater have been shown to reduce, but not eliminate *P. marinus* in infected oyster hosts (Calvo & Burreson, 1994; Faisal *et al.,* 1999; La Peyre *et al.,* 2003). Moreover, the antimicrobial drug triclosan (5-chloro-2-[2,4 dichlorophenoxy]) phenol, may be effective in treating *P. marinus*-infected oysters (Chu *et al.,* 2008; Lund *et al.,* 2005). Finally copper (as $CuCl_2$) was shown to greatly reduce infection levels of *P. marinus* in haemocytes *in vivo* (Foster *et al.,* 2011) These treatments may be relevant for aquaculture, but are not practical in the natural environment.

2.4.3. Immunostimulation

None.

2.4.4. Breeding resistant strains

Selective breeding of surviving oysters from epizootics has demonstrated effectiveness for reducing mortality caused by *P. marinus* (Ragone Calvo *et al.,* 2003).

2.4.5. Inactivation methods

Desiccation, chlorination (>0.3 mg ml^{-1} = 300 ppm [parts per million]), UV light (>28,000 µWs cm^{-2}) and freshwater have all been shown to inactivate *P. marinus* cells (Bushek *et al.,* 1997; Bushek & Howell 2000). UV irradiation from 4000 to 14,000 µWs cm^{-2} will inhibit proliferation of *P. marinus* (Bushek & Howell, 2000).

2.4.6. Disinfection of eggs and larvae

Perkinsus marinus is not known to infect eggs or larvae, but cells could occur extracellulary. Disinfection of eggs or larvae may be possible using N-halamine disinfectant compounds (Delaney *et al.,* 2003).

2.4.7. General husbandry

Farming in areas where salinity is less than 12 psu and use of fast-growing, disease-tolerant strains has shown some benefit (Andrews, 1996; Burreson & Ragone Calvo, 1996).

Water filtration to 1 µm followed by UV exposure should allow protecting hatchery produced seed against infection (Ford *et al.,* 2001). Inversely, treating water effluents should minimise the transmission of *P. marinus* to local oyster populations from infected oysters maintained in facilities such as processing plants, depuration facilities or hatcheries (Bushek & Howell, 2000).

Cultured off-bottom and air daily exposed oysters from infected area showed increased survival and higher condition indexes (La Peyre *et al.,* 2008).

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 finding infected animals. For histology, only live (including moribund) animals should be sampled.

Sampling of bivalves should be organised once a year when prevalence is known to be at a maximum. When such data is not available in a particular ecosystem, sampling should preferably be carried out during periods of oyster spawning which also corresponded with warmer temperatures (Burrell *et al.,* 1984).

3.2. Selection of organs or tissues

For Ray's fluid thioglycollate culture method (RFTM), pieces of gill, mantle and rectum are typically used. For histology, a 5-mm thick section through the visceral mass that includes digestive gland, gill and mantle is used. For PCR, a pool of organs including digestive gland, gill and mantle is best.

3.3. Samples or tissues not suitable for pathogen detection

Tissues other than digestive gland, mantle and gills are less suitable.

3.4. Non-lethal sampling

A real-time PCR assay targeting the multicopy internal transcribed spacer region of the genome was developed to detect *P. marinus* DNA in environmental waters allowing detecting equivalent of $3.3 \times 10^{(-2)}$ cell per 10-microl reaction mixture (Audemard *et al.,* 2004).

Perkinsus cells can be detected from haemolymph, faeces or water samples using RFTM methods (Bushek *et al.,* 2002; Ellin & Bushek, 2006; Gauthier & Fisher*,* 1990).

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 and time in storage). Fresh specimens should be kept on ice and preferably sent to the laboratory within 24 hours of collection. To avoid degradation of samples, use alternate storage methods only after consultation with the receiving laboratory.

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).

For diagnosis using RFTM, samples must be fresh.

3.5.2. Preservation of samples for molecular detection

For polymerase chain reaction (PCR) assays, samples must be preserved in 70–100% ethanol and not denatured alcohol.

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

For histology, the best preservative is Davidson's AFA, but 10% buffered formalin or other standard histology fixatives are also acceptable.

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		++	++	1		+++	+++	NA				
Cell culture												
Transmission electron microscopy									++	++	++	NA
Real-time PCR	+++	+++	+++	2	+++	+++	+++	2	+++	+++	+++	2
Conventional PCR	++	++	++	1	++	++	++	1				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	1
In-situ hybridisation										+	+	1
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
RFTM		++	+++	2		++	+++	NA				

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. RFTM = Ray's fluid thioglycollate culture method

[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 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).

A positive result is the occurrence of spherical, uninucleated cells, trophozoïtes, ranging from about 2 to 5 µm (sometimes to 10 µm) in diameter with a large vacuole and an eccentrically displaced nucleus. These are typically associated with host gut or sometimes epithelium in lighter infections, with colonisation of connective tissues characteristic of more advanced cases. Binucleated *P. marinus* schizonts (dividing forms) may be observed, though larger schizonts of greater nuclear count are not reliably presented. Many of the parasites may occur within oyster haemocytes. *Perkinsus marinus* cells stain basophilic. A change in *Perkinsus* marinus phenotype (large trophozoïtes at low infection intensity were replaced by abundant tinny cells) was reported since 1986 in oysters from Chesapeake Bay by Carnegie *et al.,* 2021).

4.3. Electron microscopy

Fixed sections reveal large multifocal lesions in gut epithelium or connective tissue of any organ containing *P. marinus* cells (Mackin, 1951). Haemocyte infiltration and phagocytosis of *P. marinus* cells occurs in most infections. In high intensity infections, the gut epithelium may be almost completely destroyed.

Perkinsus marinus zoospores, like zoospores of all species of *Perkinsus,* show an ornamented anterior flagellum with hair-like and spurs-like structures and a glabrous posterior flagellum. The zoospore contains an apical complex consisting of a conoid, subpellicular microtubules, rhoptries, rectilinear micronemes and conoid-associated micronemes. Large vacuoles also occur at the anterior end of the zoospore (Perkins 1976; 1996).

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.

Several PCR assays have been developed for the detection of *Perkinsus* sp. and *P. marinus*, most of them target portions of the rRNA gene complex. Primers that target the NTS region have demonstrated good species specificity for *P. marinus*, however, little is known of the variation within species for the NTS region and there is a risk of false negatives. The sequence variation in the ITS region is more broadly characterised (see the GenBank database) and primers targeting the ITS region are more thoroughly tested for specificity. For these reasons, primers that target the ITS region are recommended

Depending on the context of analysis, *Perkinsus* genus PCR assays be conducted first, and then samples with positive results should be tested with a *P. marinus* specific assay.

Extraction of nucleic acids

Samples to be taken consist of live or freshly dead molluscs. 2–3 mm^2 tissue pieces are excised aseptically from gill, mantle and digestive gland placed into 1.5 ml microcentrifuge. Dissecting utensils should be flamed between samples to prevent cross-contamination.

Different kits and procedures can be used for nucleic acid extraction. DNA is usually extracted by proteinase K digestion at 56°C (generally overnight), and the spin-column methodology using commercially available kits. Faster extraction protocols using Chelex resin has also been described (De Faveri *et al.,* 2009; Piesz *et al.,* 2022). 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

***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: TCC-GTG-AAC-CAG-TAG-AAA-TCT-CAA-C PERK-R: GGA-AGA-AGA-GCG-ACA-CTG-ATA-TGT-A PERK Probe: (FAM) CCC-TTT-GTG-CAG-TAT-GC-MGB	0.9 µM 0.9 µM 0.25 µM	40 cycles of: 95°C/15 sec and 60°C/1 min
Method 2: TaqMan PCR: Gauthier *et al.,* 2006; GenBank Accession No.: AF149876.1; amplicon size: 72 bp			
Perkinsus marinus/ITS	PMAR F: TTG-TTA-ACG-CAA-CTC-AAT-GCT-TTG-T PMAR R: AAG-CGC-ACA-TAA-CGA-ACC-ACC PMAR-MGB Probe: (FAM)-GCT-TGA-ACT-AAC-TCT-MGB-	0.9 µM 0.9 µM 0.25 µM	40 cycles of: 95°C/15 sec and 60°C/1 min
Method 3: Real-time PCR: De Faveri *et al.,* 2009; GenBank Accession No.: No data; amplicon size: 90 bp			
Perkinsus marinus/ITS	F: CGC-CTG-TGA-GTA-TCT-CTC-GA R: GTT-GAA-GAG-AAG-AAT-CGC-GTG-AT Probe: [FAM]CGC-AAA-CTC-GAC-TGT-GTT-GTG-GTG	0.2 µM 0.2 µM 0.04 µM	35 cycles at 95°C for 30 sec, and 60°C for 45 sec

[(a)]A denaturation step prior to cycling has not been included.

Interpretation of results:

A sample is considered positive when a PCR amplification curve is observed (with the expected Ct value when a cut-off Ct value has been established) with the appropriate melting temperature peak (Tm) in case of SYBR Green PCR assays, with all negative controls being negative and all positive controls being positive.

Depending on the context/objective of the analysis, a cut-off Ct value can be used to define if samples are positives or negatives. The cut-off Ct value may vary depending on the equipment, reagents and consumables used for the test.

If PCR inhibitors are detected in a sample producing a negative result, this sample should be considered as uninterpretable.

4.4.2. Conventional PCR

Pathogen/ target gene	Primer/probe (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Audemard *et al.*, 2004 (primers from Casas *et al.*, 2002); GenBank Accession No.: AF149876.1, amplicon size: 703 bp			
Perkinsus sp./ITS (detects all known *Perkinsus* species *except P. qugwadi*)	PerkITS-85: CCG-CTT-TGT-TTG-GAT-CCC PerkITS-750: ACA-TCA-GGC-CTT-CTA-ATG-ATG	0.5 µM 0.5 µM	40 cycles of: 95°C/1 min and 55°C/1min and 72°C/1min Final elongation 72°C/10 min
Method 2: Audemard *et al.*, 2004; GenBank Accession No.: AF149876.1, amplicon size: 509 bp			
Perkinsus marinus/ITS	PmarITS-70F: CTT-TTG-YTW-GAG-WGT-TGC-GAG-ATG PmarITS-600R: CGA-GTT-TGC-GAG-TAC-CTC-KAG-AG	0.5 µM 0.5 µM	40 cycles of: 95°C/1 min and 57°C/1min and 72°C/3min Final elongation 72°C/10 min

[(a)]A denaturation step prior to cycling has not been included.

4.4.3. Other nucleic acid amplification methods

None.

4.5. Amplicon sequencing

The size of the PCR amplicon should be verified, for example by agarose gel electrophoresis. Obtained sequences are analysed in comparison with reference sequences.

4.6. *In-situ* hybridisation

Samples to be taken consist of live or freshly dead molluscs.

A specific DNA probe that targets the small subunit rRNA gene has been developed for the genus *Perkinsus*: Perksp700DIG (Elston *et al.,* 2004) and a DNA probe that targets the LSU of the rRNA gene has been developed for the specific detection of *P. marinus:* PmarLSU-181 (Moss *et al.,* 2006). Additionally, two other *P. marinus* probes also targeting the LSU region has been developed: Pmar LSU-420 and LSU 560 (Reece *et al.,* 2008), and can be used in cocktails with the first one.The probe should be 5' end-labelled with digoxigenin. Alternatively, probes can be labelled with a fluorochrome (ex. Alexa Fluor 488®)

Pathogen/target	ISH probe type	ISH probe (5'-3')	Reference
Perkinsus sp./SSU (detects all known *Perkinsus* species *except P. qugwadi)*	Labelled oligonucleotide	PerkspSSU-700 CGC-ACA-GTT-AAG-TRC-GTG-RGC-ACG	Elston *et al.* (2004)
Perkinsus marinus/LSU	Labelled oligonucleotide(s) (PmarLSU-181 alone or cocktail of the 3)	PmarLSU-181 GAC-AAA-CGG-CGA-ACG-ACT-C PmarLSU-420 GAA-GAC-AGG-AGC-GAG-CAG-C PmarLSU-560 AAC-CAA-TTC-ACA-GAT-AGC-G	Moss *et al.* (2006); Reece *et al.* (2008)

4.7. Immunohistochemistry

Not available.

4.8. Bioassay

Not available.

4.9. Antibody- or antigen-based detection methods (ELISA, etc.)

Polyclonal antibody-based analyte-capture ELISAs are reported to detect *P. marinus* extracellular secretions (ECP) in tissue homogenates from oysters with infection intensities of one parasite cell/g oyster tissue (Ottinger *et al.,* 2001). The specificity of polyclonal antibodies against *P. marinus* ECP was not tested against other *Perkinsus* spp. or marine mollusc protistan associates.

4.10. Other methods

4.10.1. Ray's fluid thioglycollate culture method (RFTM)

Incubation in thioglycollate is routinely used for surveillance of *P. marinus.* The technique is simple, inexpensive and very sensitive, but not species specific. Trophozoites of *P. marinus* in oyster tissue will enlarge when cultured for at least 5 days in fluid thioglycollate medium containing dextrose that is fortified 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 become easily visible at low power because of their bluish–black colouration and 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 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. 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.

Interpretation of results:

Cultured parasites enlarge from 2–10 to 20–70 µm during incubation. *Perkinsus* spp. cells are spherical and the walls stain blue or bluish-black with Lugol's iodine solution (Bushek *et al.,* 1994; Ray 1966).

In susceptible host species, within the known range of *P. marinus*, a positive result is presumptive evidence of *P. marinus* infection, but should be confirmed in accordance with Section 6.

4.10.2. Cell culture/artificial media

Perkinsus marinus cells are easily cultured in a variety of media (e.g. La Peyre *et al.,* 1993). Culture medium is usually inoculated with heart, haemolymph, or gill tissue. Comparisons of commercially available media have been made (Dungan & Hamilton, 1995) and growth was supported in all media, but was at a maximum in 1/1 DME (Dulbecco's Modified Eagle's)/Ham's F-12 medium.

5. Test(s) recommended for surveillance to demonstrate freedom in apparently healthy populations

Real-time PCR and eventually RFTM tissue or whole-body burden assays should be used for targeted surveillance to declare freedom from infection with *P. marinus*.

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 marinus*.

When two molecular methods are used for confirmation of a case, it is preferable to use two species-specific methods targeting non-overlapping regions of the pathogen genome.

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. marinus* 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. marinus* 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 species specific 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 *P. marinus* 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. marinus* 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

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 *P. marinus* 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.

Some data on analytical performances (stage 1 validation) are available for most diagnostic tests described in this chapter, but are not always complete (for example for inclusivity and exclusivity). RFTM assays and histopathology allow a diagnostic at the genus level and do not allow species discrimination. RFTM assays are considered to be specific for all members of the genus *Perkinsus* except *P. qugwadi* (incertae sedis). However, the apparent exclusivity of RFTM assays for detection of only *Perkinsus* species lacks exhaustive confirmation through testing of all other protists (Dungan & Reece, 2020). Molecular tools have been evaluated for their analytical sensitivity and specificity to varying extents. Diagnostic sensitivity (DSe) and specificity (DSp) (stage 2 validation) have generally not been estimated, however data comparing sensitivity performances of the different diagnostic tests are available. Histopathology is considered as less sensitive than PCR and RFTM assays. Whole body burden (WBB) RFTM assay is considered very sensitive, with a theoretical sensitivity of one *Perkinsus* sp. cell per host. Tissue and haemoplymph RFTM assays have a limited sensitivity when infection intensity is below 1000 *perkinsus* cells per g wet tissue (Bushek *et al.,* 1994).

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

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* *

NB: Currently (2025) there is no WOAH Reference Laboratory for infection with *Perkinsus marinus* (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 2024 (SECTIONS 2.2.1 AND 2.2.2).

Annex 18. Item 8.2.4. 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 the pathogenic agent *Perkinsus. olseni* of the ~~(~~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 (Reece *et al.,* 1997). *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

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	no common name
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
	Leukoma jedoensis	Jedo venus
	Paratapes undulatus	undulate venus
	Protapes gallus	rooster venus
	Proteopitar patagonicus	no common name
	Ruditapes decussatus	grooved carpet shell
	Ruditapes philippinarum	Japanese carpet shell

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
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

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~~ shellfish 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; for example, in clam hosts 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 produce 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

Bivalves that are gaping, ~~clams~~ that are found at the sediment surface ~~instead of being~~ when they would normally be 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 Ray's fluid thioglycollate medium (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 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~~ 1	+++	+++	+++	NA				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	~~3~~ 1
In-situ hybridisation										~~++~~+	~~++~~+	~~3~~ 1
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
RFTM		+++	+++	3		+++	+++	~~3~~ NA				

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; RRTM = Ray's fluid thioglycollate medium

[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; amplicon size: 76 bp			
P. olseni / ITS 2	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.[b]: ~~???~~; amplicon size 346 bp			
P. olseni / ITS	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.: ~~???~~ AF369975; 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.~~???~~[b]			
P. olseni / ITS	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.: ~~???~~ AF473840, amplicon size: 97 bp			
P. olseni / 5.8S & ITS2	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.
[b]For GenBank Accession numbers see original publications

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.: ~~???~~ AF369975; 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.: ~~???~~ AF369975; amplicon size: 655 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

Samples to be taken consist of live or freshly dead molluscs.

A specific DNA probe that targets the small subunit rRNA gene has been developed for the genus *Perkinsus*: Perksp700DIG (Elston *et al.,* 2004) and a DNA probe that targets the LSU of the rRNA gene has been developed for the specific detection of *P. olseni:* PolsLSU-464DIG (Moss *et al.,* 2006). Muznebin *et al.* (2023) also used a DIG labelled probe using primers targeting the ITS gene region.

Pathogen/target	**ISH probe type**	**ISH probe (5'-3')**	**Reference**
Perkinsus sp./SSU (detects all known *Perkinsus* species *except P. qugwadi)*	Labelled oligonucleotide	PerkspSSU-700-CGC-ACA-GTT-AAG-TRC-GTG-RGC-ACG	Elston *et al.* (2004)
*Perkinsus olseni/*LSU	Labelled oligonucleotide	PolsLSU-464DIG-CTC-ACA-AGT-GCC-AAA-CAA-CTG	Moss *et al.* (2006);
Perkinsus olseni/ITS	Labelled primers	Pols140F-GAC-CGC-CTT-AAC-GGG-CCG-TGT-T and PolsITS-600R-GGR-CTT-GCG-AGC-ATC-CAA-AG-3	Muznebin *et al.,* (2023)

~~***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.

Interpretation of results:

Cultured parasites enlarge from 2–10 to 20–70 µm during incubation. *Perkinsus* spp. cells are spherical and the walls stain blue or bluish-black with Lugol's iodine solution (Bushek *et al.,* 1994; Ray 1966).

In susceptible host species, within the known range of *P. olseni,* a positive result is presumptive evidence of *P. olseni* infection, but should be confirmed in accordance with Section 6.

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*.

When two molecular methods are used for confirmation of a case, it is preferable to use two species-specific methods targeting non-overlapping regions of the pathogen genome.

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 at least one of the following ~~criterion~~ 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 species specific 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 *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

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 *P. olseni* are provided in Tables 6.3.1. (no data are currently available) 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
Real-time PCR	Targeted surveillance	Wild populations	Gill tissue Haemolymph	*Ruditapes philippinarum*	100 79	50 12.5	RFTM	Rios *et al.*, 2020

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction; RFTM = Ray's fluid thioglycollate medium.

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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 19. Item 8.2.5. 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

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

Family	Scientific name	Common name
	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

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* is:

Family	Scientific name	Common name
Haliotidae	*Haliotis gigantea*	giant abalone

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
Haliotidae	*Haliotis discus hannai*	Japanese disc abalone

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; 2007; Moore *et al*., 2000; 2001; Rosenblum *et al*., 2008). 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	+++	+++	+++	NA ~~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.

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 *Xenohaliotis californiensis* are provided in Tables 6.3.1. [no data currently available] 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 (no data are currently available)

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
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.

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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.

Annex 20. Item 8.3. – Update on viral taxonomy in Scope of Chapters 2.2.3., 2.2.5., 2.2.6., 2.2.7., 2.2.8., 2.2.10., 2.3.2., 2.3.4., 2.3.5., 2.3.6., 2.3.8., 2.3.9., 2.3.10., and 2.4.1.

CHAPTER 2.2.3.

INFECTION WITH DECAPOD IRIDESCENT VIRUS 1

1. Scope

Infection with decapod iridescent virus 1 (DIV1) means infection with the pathogenic agent *Decapodiridovirus litopenaeus1* ~~decapod iridescent virus 1 (DIV1), Genus *Decapodiridovirus*,~~ of the Subfamily *Betairidovirinae*, Family *Iridoviridae*.

[…]

CHAPTER 2.2.5.

INFECTION WITH HYPODERMAL AND HAEMATOPOIETIC NECROSIS VIRUS

1. Scope

Infection with infectious hypodermal and haematopoietic necrosis virus (IHHNV) means infection with the pathogenic agent *Penstylhamaparvovirus decapod 1* ~~Decapod penstylhamaparvovirus 1~~, of the ~~Genus *Penstylhamaparvovirus* and~~ Family *Parvoviridae*.

[…]

CHAPTER 2.2.6.

INFECTION WITH INFECTIOUS MYONECROSIS VIRUS

1. Scope

Infection with infectious myonecrosis virus (IMNV) means infection with the pathogenic agent infectious myonecrosis virus ~~(IMNV) that is tentatively assigned to the Family *Totiviridae*~~ of the genus Artivirus and Family Artiviridae.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

IMNV is tentatively assigned to the family Artiviridae (ICTV, 2025) ~~*Totiviridae* (Lightner, 2011; Nibert, 2007; Poulos *et al.,* 2006; Wickner *et al.,* 2011)~~.

IMNV particles are icosahedral in shape and 40 nm in diameter, with a buoyant density of 1.366 g ml^{-1} in caesium chloride. The genome consists of a single, double-stranded (ds) RNA molecule of 8226–8230 bp (Loy *et al*., 2015; Naim *et al.,* 2015). Sequencing of the viral genome reveals two non-overlapping open reading frames (ORFs). The first ORF (ORF1, 470–5596 nt) encodes a putative RNA-binding protein and a capsid protein. The coding region of the RNA-binding protein is located in the first half of ORF1 and contains a dsRNA-binding motif in the first 60 amino acids. The second half of ORF1 encodes a capsid protein, as determined by amino acid sequencing, with a molecular mass of 106 kDa. The second ORF (ORF2, 5884–8133 nt) encodes a putative RdRp (Poulos *et al.,* 2006). The most variable region of IMNV genome is located in the first half of ORF1, coinciding with a region which probably encodes the capsid protrusions (Dantas *et al*., 2015).

The complete genomes of IMNV types originating from Brazil and Indonesia have been sequenced and found to be 99.6% identical at the nucleotide level (Poulos *et al.,* 2006; Senapin *et al.,* 2007). The 99.6% full genome sequence identity (and anecdotal information on the introduction of *Penaeus vannamei* stocks from Brazil) indicate that the disease was introduced from Brazil to Indonesia in 2006. A new genotype was analysed in infected samples in 2018 in Indonesia, including an isolate that contains a deletion of 622 amino acids (Mai *et al.,* 2019).

[…]

CHAPTER 2.2.7.

INFECTION WITH MACROBRACHIUM ROSENBERGII NODAVIRUS (WHITE TAIL DISEASE)

1. Scope

Infection with Macrobrachium rosenbergii nodavirus means infection with the pathogenic agent Macrobrachium rosenbergii nodavirus (MrNV) in the Family *Nodaviridae*. The disease is commonly known as white tail disease (WTD).

Extra small virus (XSV) is associated with disease, but its role has not been determined.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

Two viruses are associated with WTD, namely MrNV (primary) and extra small virus (XSV) (associate) (Qian *et al.,* 2003; Romestand & Bonami, 2003). MrNV is a necessary cause of WTD in prawns, however, the role of XSV in pathogenicity remains unclear.

MrNV belongs in the family *Nodaviridae* (Bonami *et al.,* 2005). While the physico-chemical properties of MrNV are consistent with those of other members of the *Nodaviridae*, it differs structurally and genetically from other nodaviruses within the two recognised genera, *Alphanodavirus* and *Betanodavirus* (Ho *et al*., 2017, 2018; Naveenkumar *et al*., 2013). Consequently, a third genus, *Gammanodavirus*, has been proposed for nodaviruses that infect crustaceans, including MrNV and *Penaeus vannamei* nodavirus (*Pv*NV) (Naveenkumar *et al*., 2013).

XSV is the first sequenced satellite virus in aquatic animals and it is also the first record of a satellite-nodavirus association (Bonami *et al.,* 2005). XSV has been classified by the ICTV as *Macronovirus macrobrachii* ~~*Macrobrachium satellite virus 1*~~ of the family *Sarthroviridae.*

[…]

CHAPTER 2.2.8.

INFECTION WITH TAURA SYNDROME VIRUS

1. Scope

Infection with Taura syndrome virus (TSV) means infection with the pathogenic agent *Aparavirus tauraense* ~~Taura syndrome virus (TSV)~~, ~~Genus *Aparavirus*,~~ of the Family *Dicistroviridae*, Order *Picornavirales*.

[…]

CHAPTER 2.3.4.

INFECTION WITH HRP-DELETED OR HPR0 INFECTIOUS SALMON ANAEMIA VIRUS

1. Scope

Infection with infectious salmon anaemia virus (ISAV) means infection with the pathogenic agent *Isavirus salaris* of the ~~Genus *Isavirus* and~~ Family *Orthomyxoviridae*. Infection with ISAV includes two genotypes; highly polymorphic region (HPR)-deleted ISAV, or the non-pathogenic HPR0 ISAV (non-deleted HPR) ~~ISAV of the Genus Isavirus and Family Orthomyxoviridae~~.

HPR-deleted ISAV may cause disease in Atlantic salmon (Salmo salar), which may progress to a generalised and lethal condition characterised by severe anaemia, and variable haemorrhages and necrosis in several organs.

Detection of HPR0 ISAV has not been associated with clinical signs of disease in Atlantic salmon (Christiansen et al., 2011). A link between non-pathogenic HPR0 ISAV and pathogenic HPR-deleted ISAV has been suggested, with some disease outbreaks potentially occurring as a result of the emergence of HPR-deleted ISAV from HPR0 ISAV (Cardenas et al., 2014; Christiansen et al., 2017; Cunningham et al., 2002; Gagne & Leblanc, 2017; Mjaaland, et al., 2002).

[…]

CHAPTER 2.3.5.

INFECTION WITH INFECTIOUS HAEMATOPOIETIC NECROSIS VIRUS

1. Scope

Infection with infectious haematopoietic necrosis virus (IHNV) means infection with the pathogenic agent *Novirhabdovirus salmonid* ~~Salmonid novirhabdovirus (commonly known as infectious haematopoietic necrosis virus [IHNV]) Genus *Novirhabdovirus* and~~ of the Family *Rhabdoviridae*.

[…]

CHAPTER 2.3.6.

INFECTION WITH KOI HERPESVIRUS

1. Scope

Infection with koi herpesvirus (KHV) means infection with the pathogenic agent *Cyvirus cyprinidallo 3* (previously known as cyprinid herpesvirus-3 [CyHV-3]), of ~~the Genus *Cyprinivirus* in~~ the Family *Alloherpesviridae*.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

KHV, also known as carp interstitial nephritis and gill necrosis virus (CNGV) (Ilouze *et al.,* 2010), has been classified as *Cyvirus cyprinidallo 3* ~~cyprinid herpesvirus-3 (CyHV-3) following the nomenclature of other cyprinid herpesviruses: CyHV-1 (carp pox virus, fish papilloma virus) and CyHV-2 (goldfish haematopoietic necrosis virus)~~. Analysis of the complete genome has shown that CyHV-3 is closely related to CyHV-1, CyHV-2, anguillid herpesvirus-1 (AngHV-1) and distantly related to channel catfish virus (Ictalurid herpesvirus: IcHV-1) and Ranid (frog) herpesvirus (RaHV-1) (Waltzek *et al.,* 2005). CyHV-3 was designated the type species of the new *Cyprinivirus* genus within the *Alloherpesviridae* family, that also contains CyHV-1 and CyHV-2. However, the designation KHV has been retained in the *Aquatic Code* and *Aquatic Manual* for reasons of continuity and is used here synonymously with CyHV-3.

The size of the KHV genome is now confirmed as 295 kbp. Virus nucleocapsids have been measured at 100–110 nm in diameter and are surrounded by an envelope (Ilouze *et al.,* 2010). The enveloped virions range in size from 170 to 230 nm in the different infected cell types (Hedrick *et al.,* 2000; Miwa *et al.,* 2007; Miyazaki *et al,* 2008a). Aoki *et al.* (2007) initially described the complete genome sequence of three isolates of KHV and the genome includes 164 open reading frames (ORFs) of which 156 are unique protein-coding genes. They suggested that the finding that 15 KHV genes are homologous with genes in IcHV-1 confirms the proposed place of KHV in the family Herpesviridae. Forty viral proteins and 18 cellular proteins are incorporated into mature virions.

Engelsma *et al.* (2013) detected novel strains of cyprinid herpesvirus closely related to KHV. These strains may represent low or non-pathogenic variants of CyHV-3, but further investigation is required to establish the true genetic relationship between these strains, and KHV.

[…]

CHAPTER 2.3.8.

INFECTION WITH INFECTIOUS SALMONID ALPHAVIRUS

1. Scope

Infection with salmonid alphavirus (SAV) means infection with any genotype of the pathogenic agent Alphavirus salmon ~~SAV~~, ~~Genus *Alphavirus*~~ and Family *Togaviridae*.

[…]

CHAPTER 2.3.9.

INFECTION WITH SPRING VIRAEMIA OF CARP VIRUS

1. Scope

Infection with spring viraemia of carp virus (SVCV) means infection with the pathogenic agent *agent Sprivivirus cyprinus* ~~(commonly known as spring viraemia of carp virus [SVCV])~~, of ~~the Genus *Sprivivirus* and~~ the Family *Rhabdoviridae*.

[…]

CHAPTER 2.3.10.

INFECTION WITH VIRAL HAEMORRHAGIC SEPTICAEMIA VIRUS

1. Scope

Infection with viral haemorrhagic septicaemia virus (VHSV) means infection with the pathogenic agent ***Novirhabdovirus piscine*** ~~viral haemorrhagic septicaemia virus~~ of the ~~Genus *Novirhabdovirus* and~~ Family *Rhabdoviridae*.

[…]

CHAPTER 2.4.1.

INFECTION WITH ABALONE HERPESVIRUS

1. Scope

Infection with abalone herpesvirus (AbHV) means infection with the pathogenic agent *Aurivirus haliotidmalaco1* (previously known as *Haliotid herpesvirus 1*, and *abalone herpesvirus* [AbHV]) of ~~the genus *Aurivirus* and~~ the Family *Malacoherpesviridae*.

[…]