Report of the Meeting of the WOAH Aquatic Animal Health Standards Commission

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16 to 23 September 2026

Paris

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 16 to 23 September 2026.

The Aquatic Animals Commission wished to thank the following Members for providing written comments for the WOAH *Aquatic Animal Health Code* (hereinafter 'the *Aquatic Code*') and WOAH *Manual of Diagnostic Tests for Aquatic Animals* (hereinafter 'the *Aquatic Manual*'):Australia, Brazil, Canada, Chile, China (People's Rep. of), Chinese Taipei, Japan, Korea (Rep. of), Malaysia, Mexico, New Zealand, Norway, 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 Member States of the European Union (EU) and the International Coalition for Animal Welfare (ICFAW), the WOAH Working Group on Antimicrobial Resistance (AMRWG) and the WOAH Working Group on Wildlife. 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 topics and annexes 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 based on the latest scientific and technical data and take into consideration the different contexts among Members and stakeholders and are feasible to 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, including those that do not include a supporting rationale may be excluded from consideration 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 its report may reference work and discussions of the Terrestrial Animal Health Standards Commission, the Biological Standards Commission, a Working Group or an *ad hoc* Group when these groups have addressed specific topics, comments or questions by the Aquatic Animals Commission.

These reports are available on dedicated webpages on the WOAH website, e.g., for Specialist Commissions reports, for Working Group reports and for *ad hoc* Group reports.

Deadline for comments

Comments on relevant texts in this report must be received by 2 January 2027 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: 10 to 17 February 2027.

Table of Contents

1. Meeting with the WOAH Director General and Deputy Director General - Standard Setting and Implementation 6

1.1. WOAH Director General 6

1.2. Deputy Director General, Standard Setting and Implementation 6

2. Adoption of the agenda 6

3. Cooperation with Other Specialist Commissions 7

3.1. Aquatic Animals Commission and Terrestrial Animal Health Standards Commission Bureaus meeting to discuss alignment of Chapters 1.1. and Section 5, including 5.Y. and recommendations of the ad hoc Group on certification 7

3.2. Biological Standards Commission on 'Workshop to Identify Research Gaps Limiting the Validation and Effective Use of eDNA/eRNA Approaches' 7

4. Work programme and priorities 8

4.1. Comments received on the Work Programme 8

4.2. Overview of the Work Programme 8

The WOAH Aquatic Animal Health Code 8

5. *Aquatic Code* items for Member comment 8

5.1. Glossary 'self-declaration of freedom from disease' 8

5.2. Chapter 1.1. Notification of diseases and provision of epidemiological information 8

5.3. Articles 1.4.4., 1.4.10., 1.4.13. and 1.4.14. of Chapter 1.4. Aquatic animal disease surveillance 9

5.4. Chapter 4.3. 'Application of compartmentalisation' 10

5.5. Model Article X.X.7. 'Compartment free from [pathogen X]' of the disease-specific chapters and Articles 10.4.9. and 10.4.10. Of 'Infection with Infectious salmon anaemia' 11

5.6. Chapter 5.Y. 'Introduction to recommendations for international aquatic animal health certification and export and import procedures' 12

5.7. Chapter 6.2. Principles for responsible and prudent use of antimicrobial agents in aquatic animals' 13

6. *Aquatic Code* Items for Member Information 13

6.1. Chapter 4.2. 'Application of zoning' 13

6.2. Section 5. 'Trade measures, importation/exportation procedures and health certification' 14

6.3. Section 7. 'Welfare of farmed fish' 15

6.4. Assessments of susceptible species 15

6.5. Emerging diseases 16

6.5.1. Infection with covert mortality nodavirus (CMNV) 16

6.5.2. Work of the *Ad hoc* Group on Emerging Threats for Animal Health and Welfare 17

The WOAH *Manual* of Diagnostic Tests for Aquatic Animals 17

7. The WOAH *Manual* of Diagnostic Tests for Aquatic Animals 17

7.1. *Aquatic Manual* items for Member comment 17

7.1.1. Section 2.2. 'Diseases of crustaceans' 17

7.1.1.1. Chapter 2.2.3. 'Infection with infectious decapod iridescent virus 1' 17

7.1.2. Section 2.3. 'Diseases of fish' 18

7.1.2.1. New draft Chapter 2.3.7. Infection with *Megalocytivirus pagrus1* 18

7.1.2.2. Chapter 2.3.9. 'Infection with spring viraemia of carp virus' 18

7.1.2.3. Chapter 2.3.11. 'Infection with tilapia lake virus' 19

7.1.3. Section 2.4. 'Diseases of mollusc' 19
7.1.3.1. Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' 19
7.1.3.2. Chapter 2.4.3. 'Infection with *Bonamia ostreae*' 20
7.2. *Aquatic Manual* ongoing work items 20
7.2.1. Chapter 1.1.2. Validation of diagnostic assays for infectious diseases of aquatic animals 20
7.2.2. Section 2.1. 'Diseases of amphibians' 21
7.2.2.1. Chapter 2.1.0. 'General information (diseases of amphibians)' 21
7.2.3. Section 2.2. 'Diseases of crustaceans' 21
7.2.3.1. Expert consultation for Infection with infectious hypodermal and haematopoietic necrosis virus (IHHNV) 21
7.2.4. Section 2.4. 'Diseases of molluscs' – case definitions review 22
7.2.4.1. Chapter 2.4.4. 'Infection with *Marteilia refringens*' 23
7.2.5. Review of PCR-Related Content throughout the Aquatic Manual 23
8. Reference centres network 23
8.1. Evaluation of applications for Reference Centres for aquatic animal health issues or change of experts 23
8.1.1. RL: White Spot syndrome_INDIA 24
8.1.2. RL: Tilapia lake virus_INDIA 24
8.2. Update on the Aquatic Collaborating Centres Network 24
8.3. New article in 'Procedures of Designation: case of one member of a consortium needs to withdraw' 24
8.4. Inclusion in the ToRs: To network between Collaborating Centres and Reference Laboratories 24
8.5. Collaborating Centers: Update of specialties under the focus area on capacity building 25
9. Other issues 25
9.1. Aquatic Animal Health Strategy 25
9.2. Proposal to develop a new chapter on Aquatic Animal Health Legislation (both domestic and wild) 26
9.3. The Observatory: preliminary findings of the thematic study on self-declaration in the aquatic sector 26
9.4. Development and piloting of the Veterinary Medicines Regulatory Agency Self-assessment Tool (VMRA-SAT) 27
9.5. Discussion on inclusion of vaccine quality, safety and efficacy in the Aquatic Manual 27
9.6. Update on the *ad hoc* Group on prioritisation of diseases for which vaccines could reduce global antibiotic use in animals 27
9.7. Update on aquatic disease situation and reporting by Members 28
9.8. Work of the Governance Review Committee 28
9.9. Specialist Commission elections process and future meeting dates 29

List of Annexes

Annex 1. Adopted Agenda **30**

Annex 2. List of Participants **32**

Annex 3. Comments considered by the Aquatic Animals Commission and its responses (separate document)

Annex 4. Item 4. – Work Programme for the Aquatic Animal Health Standards Commission 2025–2027 ..... **33**

Annex 5. Item 5.1. – Glossary – Self-declaration of freedom from disease **39**

Annex 6. Item 5.2. – Chapter 1.1. 'Notification of diseases, and provision of epidemiological information' **40**

Annex 7. Item 5.3. Articles 1.4.4., 1.4.10., 1.4.13. and 1.4.14. of Chapter 1.4. Aquatic animal disease surveillance **43**

Annex 8. Item 5.4. Chapter 4.3. 'Application of compartmentalisation' **48**

Annex 8a. Item 5.4. – Draft new Chapter 4.3. 'Application of Compartmentalisation' **57**

Annex 8b. Item 5.4. – Draft new Chapter 4.3. 'Application of Compartmentalisation' **66**

Annex 9. Item 5.4. Glossary definition for 'compartment' **73**

Annex 10. Item 5.5. Model Article X.X.7. 'Compartment free from [pathogen X]' of the disease-specific chapters and Articles 10.4.9. and 10.4.10. Of 'Infection with Infectious salmon anaemia' **74**

Annex 11. Item 5.6. Chapter 5.Y. 'Introduction to recommendations for international aquatic animal health certification and export and import procedures' **78**

Annex 12. Item 5.7. Chapter 6.2. 'Responsible and prudent use of antimicrobial agents in aquatic animals' **80**

Annex 13. Item 7.1.1.1. Chapter 9.3. 'Infection with infectious decapod iridescent virus 1', the Chapter title and revised viral taxonomy in Article 9.3.1 ..... **94**

Chapter title and revised viral taxonomy in Article 9.3.1. ..... **94**

Annex 14. Item 7.1.1.1. Chapter 2.2.3. 'Infection with infectious decapod iridescent virus 1', the Chapter title and revised viral taxonomy in Section 1. ..... **95**

Annex 15. Item 7.1.2.1. New draft Chapter 2.3.7. Infection with *Megalocytivirus pagrus1* **96**

Annex 16. Item 7.1.2.2. Chapter 2.3.9. 'Infection with spring viraemia of carp virus' **117**

Annex 17. Item 7.1.2.3. Chapter 2.3.11. 'Infection with tilapia lake virus' **125**

Annex 18. Item 7.1.3.1. Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' **140**

Annex 19. Item 7.1.3.2. Chapter 2.4.3. 'Infection with *Bonamia ostreae*' **142**

1. Meeting with the WOAH Director General and Deputy Director General - Standard Setting and Implementation

1.1. WOAH Director General

Dr Emmanuelle Soubeyran, the WOAH Director General, met with the Aquatic Animals Commission on 16 September 2026. Dr Soubeyran thanked the Commission members for their support and commitment to achieving WOAH's objectives in standard-setting and extended these thanks to their employing institutions and national governments.

Dr Soubeyran provided an update on the ongoing Specialist Commission election process. She thanked current members for their valuable contributions and recognised those who may not seek re-election. She explained that applications would now be reviewed by the Nomination Evaluation Committee before submission to the Council.

Dr Soubeyran highlighted that the 8th Strategic Plan, adopted at the 93rd General Session, reaffirms international standard-setting as a core mandate of WOAH. She emphasised the key role of the Specialist Commissions in ensuring that WOAH standards remain science-based, globally relevant and fit for purpose for all Members.

She also updated the Commission on the work of the Governance Review Committee (GRC), which continued to advance governance and accountability reforms. While a range of options for strengthening technical governance have been considered, the GRC concluded that major restructuring of WOAH's technical bodies is not currently required. Instead, efforts are focused on targeted improvements, including clarifying roles and mandates, strengthening scientific advisory functions, and addressing workload and resource challenges. She thanked the Commission for its valuable engagement in these initiatives and noted that consultations with Members, experts and Specialist Commissions would continue as part of the governance reform process.

Finally, Dr Soubeyran updated the Commission on staffing developments within the Standards Department and efforts to strengthen Secretariat support and collaboration among Specialist Commissions. She noted ongoing work aimed at improving the consistency and efficiency of standards development activities and thanked the Commission for its continued engagement during this period of organisational transition.

The Commission thanked Dr Soubeyran for her address. The Commission emphasised the importance of aligned work programmes and collaborative work with other WOAH Specialist Commissions when relevant. The Commission raised the need to ensure collaborative work between Commissions occurred in the most efficient way possible including addressing Member comments such as cross-Commission task forces to address cross-cutting topics. The Commission also highlighted the importance of engaging a wider network of partner organisations to advance aquatic animal health and to pursue collaboration on relevant activities.

1.2. Deputy Director General, Standard Setting and Implementation

Dr Montserrat Arroyo, WOAH Deputy Director General for International Standards and Science (DDG-SSI) met with the Aquatic Animals Commission on 16 September 2026. Dr Arroyo thanked the Commission for their commitment and acknowledged the wide span of work of the Aquatic Animals Commission which covered both *Aquatic Code* and *Aquatic Manual*.

Dr Arroyo congratulated the Commission on its work on susceptible species and noted that its timely update to these lists was well appreciated by Members. Dr Arroyo also highlighted current and planned horizontal work with the Terrestrial Animal Health Standards 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.

Dr. Arroyo noted the importance of the Reference Laboratories and Collaborating Centres, and potential for their inclusion in considerations on future aquatic strategies. She noted that the networks can provide valuable insight, and there needs to be clear guidance on objectives and roles.

The Aquatic Animals Commission thanked Dr Arroyo for her updates.

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 Other Specialist Commissions

3.1. Aquatic Animals Commission and Terrestrial Animal Health Standards Commission Bureaus meeting to discuss alignment of Chapters 1.1. and Section 5, including 5.Y. and recommendations of the *ad hoc* Group on certification

The Bureaux of the Terrestrial Animal Health Standards Commission (Code Commission) and the Aquatic Animals Commission held a side meeting chaired by the DDG SSI to discuss texts addressing common topics and planned for circulation by both Commissions. Both Bureaux discussed proposed changes to Chapter 1.1. 'Notification of diseases and provision of epidemiological information' of the *Aquatic Code* (see Item 5.2.) and *Terrestrial Code* to ensure alignment and agreed to circulate the draft chapter in their respective reports.

The Bureaux also discussed Chapter 5.X. (*Terrestrial Code*) and Chapter 5.Y. (*Aquatic Code*) 'Introduction to recommendations for international veterinary certification and export and import procedures' which was circulated for comments in their February 2026 meeting report. Both Bureaux agreed to circulate the draft chapters in their respective reports for Member comments. The Bureau of the Code Commission will propose Chapter 5.X. for adoption at the May 2027 General Session (see Item 6.3.).

Furthermore, the Bureaux discussed progress of the revision of Chapter 5.1. 'General Obligations Related to Certification' and 5.2. 'Certification Procedures'. Both Bureaux acknowledged that the work is progressing although further work by the *ad hoc* Group was necessary. Both Commissions agreed to provide their combined guidance to the *ad hoc* Group and requested the Secretariat to report back at their February 2027 meeting

The Aquatic Animals Commission thanked the Bureaux and encouraged Members to consider the Code Commission's report for the details of relevant horizontal items. The Aquatic Animals Commission encouraged Members to read the Code Commission's report for the details of relevant items.

3.2. Biological Standards Commission on 'Workshop to Identify Research Gaps Limiting the Validation and Effective Use of eDNA/eRNA Approaches'

The Aquatic Animals Commission was informed of the forthcoming STAR IDAZ IRC diagnostics workshop, scheduled for early 2027, which would include a dedicated session on environmental DNA/RNA (eDNA/eRNA) approaches. The Aquatic Animals Commission noted that the Biological Standards Commission was similarly informed of this workshop and had provided its opinion on the potential of these approaches for surveillance, early warning, disease monitoring, risk assessment, and demonstrating freedom from disease. The Aquatic Animals Commission likewise acknowledged the importance of these tools for aquatic animal health surveillance and diagnosis, but also emphasised the need for further validation, standardisation and evidence to support interpretation of these approaches.

In this regard, validation should address both laboratory and field performance, considering factors such as pathogen load and prevalence, water conditions and PCR inhibitors, evaluation of recovery performance for enrichment methods, and pathogen viability testing. Requirements for official use should reflect the intended purpose, including early warning, targeted surveillance, outbreak investigation, demonstration of freedom from disease and post-eradication monitoring. The Commission also highlighted the need for minimum requirements across the full workflow to improve comparability and reproducibility between laboratories.

Regarding interpretation, the Aquatic Animals Commission cautioned that positive results did not necessarily represent that an animal population is infected, owing to nucleic acid persistence or residual contamination. Conversely, negative results would not preclude infection such as when shedding is minimal, becomes diluted, nucleic acids are degraded or inhibitors are present. This might necessitate comparison with animal testing or other validated methods, where appropriate.

The Commission wished to remind members that it had previously prepared a discussion paper to explore the potential use of eDNA/eRNA methods with respect to the WOAH aquatic standards and to outline benefits and limitations.

Finally, the Commission acknowledged that the evidence base was still developing and that further review of relevant scientific literature and emerging research, particularly field studies and inter-laboratory comparisons addressing interpretation and reproducibility, are desirable.

4. Work programme and priorities

4.1. Comments received on the Work Programme

Comments were received from from Canada, Chile, Norway, the UK, the AU-IBAR, and the EU.

The Aquatic Animals Commission noted comments expressing support for the Commission's work programme. 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.

4.2. Overview of the Work Programme

The Aquatic Animals Commission reviewed the status of existing work and proposed work, and prioritised work programme items after considering factors including the expected improvement of the standards, benefit to Members, Member comments, capacity constraints, WOAH 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 on the work programme 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

5. *Aquatic Code* items for Member comment

5.1. Glossary 'self-declaration of freedom from disease'

September 2026 meeting

The Aquatic Animals Commission received a Member comment on the usage of Competent Authority in the glossary definition for 'self-declaration of freedom from disease' and noted that the more appropriate term would be Veterinary Authority. Under the glossary definition of Veterinary Authority, it 'means the Governmental Authority of a Member Country having the primary responsibility in the whole territory for coordinating the implementation of the standards of the *Aquatic Code* by the Competent Authorities'. The Veterinary Authority holds responsibility for notifications to WOAH and is the appropriate term to use in the definition for 'self-declaration of freedom from disease'. The Commission also agreed to remove the note at the end of the definition on WOAH's role in the publication of the self-declaration as it considered this to be administrative guidance and not needed for the definition.

Texts for comment

The revised glossary definition for 'self-declaration of freedom from disease' is presented as Annex 5 for comment.

5.2. Chapter 1.1. Notification of diseases and provision of epidemiological information

Background

At its September 2025 meeting, the Aquatic Animals Commission considered comments from WOAH Headquarters on Chapter 1.1. 'Notification of diseases, and provision of epidemiological information' and was informed the corresponding chapter of the *Terrestrial Code* was being revised to consider these comments. At the September 2025 Bureaux meeting of the Aquatic Animals Commission and the Code Commission, the Bureaux agreed to propose revisions to Chapter 1.1. 'Notification of diseases and provision of epidemiological information' of the *Aquatic Code* and *Terrestrial Code* in parallel to ensure consistency between respective chapters. The Bureaux agreed to review each other's draft revised Chapters 1.1. in February 2026.

At its February 2026 meeting, the Aquatic Animals Commission reviewed Chapter 1.1. and proposed revisions, which were discussed with the Code Commission at a side meeting involving the Bureaux.

The revised Chapter 1.1. 'Notification of diseases and provision of epidemiological information' has been circulated once for comment.

Previous Commission reports where this item was discussed

September 2025 report (Item 7.1.2., page 21), February 2026 report (Item 3.1., page 7).

September 2026 meeting

Comments were received from Australia, Canada, Chile, People's Republic of China, Chinese Taipei, Japan, Korea (Rep. of), Mexico, New Zealand, Thailand, the UK, the USA, the EU and the ICFAW.

The Aquatic Animals Commission considered comments received and noted that Members were supportive of the proposed changes while providing revisions for clarity.

The Aquatic Animals Commission made revisions of Chapter 1.1. with consideration of the revisions of the Code Commission made at its September 2026 meeting, for consistency between the two chapters were feasible. The Commission noted that some Members questioned the use of only 'variant' in the *Aquatic Code* version of Chapter 1.1. The Commission directed Members to item 3.1. in its February 2026 report where the rationale for this difference from the *Terrestrial Code* chapter was explained.

The Commission noted that in its February 2026 report that the term 'susceptible species' would be used in the context of the *Aquatic Code* rather than 'animal host' as used in the *Terrestrial Code*. However, the Commission highlighted this was an error and that in some articles of Chapter 1.1. the term 'aquatic animal host' was more appropriate rather than susceptible species. 'Susceptible species' is defined as meeting the criteria of Chapter 1.5. 'Criteria for listing a species as susceptible infection with a specific pathogen'. For the *Aquatic Code*, it is intended that detection of a disease be notified either if it has been detected in an aquatic animal species that has been assessed by WOAH to meet the criteria of Chapter 1.5, or in another aquatic animal species. This is necessary due to the evolving knowledge on susceptibility of aquatic animal species to WOAH listed diseases. The Commission clarified that the term 'aquatic animal host' is the appropriate term to use in Article 1.1.2. because it covers both circumstances.

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

Texts for comment

The revised Chapter 1.1. 'Notification of diseases and provision of epidemiological information' is presented as Annex 6 for comment.

5.3. Articles 1.4.4., 1.4.10., 1.4.13. and 1.4.14. of Chapter 1.4. Aquatic animal disease surveillance

Background

At its February 2025 meeting the Aquatic Animals Commission noted that the revision of Chapter 4.3. 'Application of compartmentalisation' with the inclusion of the concepts of dependent and independent compartments would require a review of Chapter 1.4. 'Aquatic animal disease surveillance'.

At its February 2026 meeting, the Aquatic Animals Commission reviewed Chapter 1.4. 'Aquatic animal disease surveillance' taking into consideration the revisions to Chapter 4.3. 'Application of compartmentalisation'. Considerations for independent and dependent compartments as well as internal and external surveillance were added to this chapter for consistency with the revised Chapter 4.3. The Commission noted that it was necessary to ensure conceptual distinction between the purposes of internal surveillance which is required to demonstrate freedom in accordance with Chapter 1.4., and external surveillance which informs assessment of risk. The Commission also reviewed the model article X.X.7. in the disease-specific chapters to include considerations for dependent and independent compartments into the article on 'compartment free from [pathogen X]'

The revised Chapter 1.4. 'Aquatic animal disease surveillance' has been circulated once for comment.

Previous Commission report where this item was discussed

September 2025 report (Item 6.2., page 10), February 2026 meeting report (Item 6.4. page 15)

September 2026 meeting

Comments were received from Australia, Brazil, Canada, Chile, People's Republic of China, Chinese Taipei, Japan, Mexico, New Zealand, Thailand, United Kingdom, United States of America, The EU, ICFAW, and Working Group on Wildlife.

The Aquatic Animals Commission considered comments received and noted that Members were generally supportive of the revised articles of Chapter 1.4. 'Aquatic animal disease surveillance'. The Commission noted that proposal modifications on Chapter 1.4. were to focus on the implications of revised Chapter 4.3., particularly in relation to dependent and independent compartments. These revisions were not intended to open discussion on all aspects of Chapter 1.4.; however, the Commission noted that several comments were received on text not related to compartmentalisation. The Commission responded to comments related to revisions on compartmentalisation, and in this report only those articles with revisions will be circulated for comment. Although comments not related to compartmentalisation were not considered at this meeting, the Commission invites Members to submit these comments upon the next full revision of Chapter 1.4.

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

Texts for comment

The revised Articles 1.4.4., 1.4.10., 1.4.13. and 1.4.14. Chapter 1.4. 'Aquatic animal disease surveillance' is presented as Annex 7 for comment.

5.4. 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.

At its February 2024 meeting, the Aquatic Animals Commission considered comments received on the discussion paper and 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 and revised the Glossary definition for 'compartment' for consistent usage in the draft text. The revised Chapter 4.3 was provided to members for comment.

At its September 2025 meeting the Commission noted that to account for the many comments received, extensive revisions and the re-ordering of articles were made. These revisions included providing clarity to the categories of independent and dependent compartments as well as to highlight the use of risk analysis. The Commission agreed to review Chapter 1.4. 'Aquatic animal disease surveillance' at its February meeting to communicate what revisions would be required with the update to Chapter 4.3.

At its February 2026 meeting, the Commission emphasised that revised Chapter 4.3. provides a framework for Members to apply compartmentalisation and negotiate requirements with trading partners. The intention was not to provide prescriptive requirements, rather it utilises risk analysis to provide a flexible approach that can be applied to mitigate risks across a range of circumstances. At this meeting, the Commission considered proposals from some Members to include semi-open production systems within the scope of dependent compartments and requested Members to provide a rationale on whether such systems should be included. The Commission also highlighted that the intention of external surveillance is to inform risk analysis for the compartment, rather than to provide evidence for declaration of freedom in the surrounding water body.

The Commission reviewed comments received on the Glossary definition of 'compartment' and noted that Members were supportive with minor suggestions for edits.

The revised Chapter 4.3. and Glossary definition ‘compartment’ has been circulated three times 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 report (Item 6.2., page 9); February 2026 (Item 6.3, page 15).

September 2026 meeting

Comments were received on the glossary definition of ‘compartment’ from People's Republic of China, the USA, the EU, and ICFAW for the glossary definition of compartment.

Comments received on Chapter 4.3. ‘Application of compartmentalisation’ from Australia, Canada, Chile, People’s Republic of China, Japan, Republic of Korea, Mexico, New Zealand, Norway, Thailand, the United Kingdom, the United States of America and the EU.

The Aquatic Animals Commission considered comments received on the glossary definition of 'compartment' and noted that Members were generally supportive while providing some edits for clarity.

The Commission also considered comments received on Chapter 4.3. ‘Application of compartmentalisation’ and noted that Members continued to welcome the integration of risk analysis through the chapter while continuing to want clarification of dependent compartments.

The Commission thanked the Members who responded and considered the rationales submitted on the inclusion of semi-open production systems within the scope of dependent compartments. It noted that most responding Members supported the inclusion of semi-open production systems within the scope of dependent compartments. The supporting rationales indicated that some countries already have the conditions necessary to establish biosecurity compartments comprising semi-open establishments, with successful practical examples available. They also indicated that the degree of dependence of these establishments on the external environment can be comparable to that of semi-closed establishments, and that risk analysis can support the development of effective biosecurity measures, including measures for early detection and disease control. Furthermore, their inclusion could support the application of compartmentalisation across diverse production systems, including mixed-system and multi-species aquaculture, and facilitate safe international trade.

Following its review of these rationales and further discussion, the Commission agreed to include semi-open production systems within the scope of dependent compartments in Chapter 4.3. and revised the chapter accordingly.

The Commission noted comments on the status of the surrounding water body around a dependent compartment. The Commission highlighted that the intention of external surveillance is to inform risk analysis for the compartment to determine appropriate risk management measures. External surveillance is not intended to provide evidence for declaration of freedom in the surrounding water body, and it is not necessary that the surrounding water body of a dependent compartment be a free zone. It was noted that external surveillance may be passive and/or targeted depending on suitability and requirements to evaluate risk. It proposed revisions to the text to clarify this.

The Commission’s responses to comments received regarding revised Chapter 4.3. and Glossary definition of ‘compartment’ are presented in Annex 3.

Texts for comment

The revised Chapter 4.3. ‘Application of compartmentalisation’ is presented as Annex 8 for comment. The marked-up changes are those made on the first revision provided to Members in the Commission’s Feb 2025 meeting report (rather than against the currently adopted text). A clean version of the revised chapter is provided as Annex 8B.

The revised glossary definition for ‘compartment’ is presented as Annex 9 for comment.

5.5. Model Article X.X.7. ‘Compartment free from [pathogen X]’ of the disease-specific chapters and Articles 10.4.9. and 10.4.10. Of ‘Infection with Infectious salmon anaemia’

Background

At its February 2026 meeting, the Aquatic Animals Commission revised model Article X.X.7. in the disease specific chapters to incorporate considerations for both dependent and independent compartments in the article

‘Compartment free from [pathogen X]’. This revision aligned with the Commission’s revision of Chapter 1.4. ‘Aquatic animal disease surveillance’ and considered revision to Chapter 4.3. ‘Application of compartmentalisation’.

The revised model article has been circulated once for comment.

Previous Commission reports where this item was discussed

February 2026 report (Item 6.3., page 17).

September 2026

Comments were received from Canada, People’s Republic of China, Republic of Korea, New Zealand, Thailand, the United States of America and the EU.

The Aquatic Animals Commission considered comments received and noted that most Members were supportive while providing comments for clarification. The Commission noted the comment that after the adoption of changes to Chapter 10.4. at the 93rd General Session that the compartment articles in that chapter vary from the model article. To provide clarity in the annex of this report model article X.X.7. is provided together with Articles 10.4.9. and 10.4.10. of 'Infection with infectious salmon anaemia'.

The revised model article X.X.7. ‘Compartment free from infection with [Pathogen X]’ and Articles 10.4.9. and 10.4.10. of 'Infection with infectious salmon anaemia' are presented as Annex 10 for comments.

5.6. Chapter 5.Y. ‘Introduction to recommendations for international aquatic animal health certification and export and import procedures’

Background

At the 2024 Bureaux meeting the Aquatic Animals Commission and Code Commission discussed the need to collaboratively develop a new introductory chapter for Section 5 of the *Aquatic Code* and *Terrestrial Code* to provide clarity on its objectives and how the Section 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.

At its September 2025 meeting, the Aquatic Animals Commission reviewed the new draft Chapter 5.Y. ‘Introduction to trade measures, importation/exportation procedures and health certification’ prepared by the task force and requested the task force to 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.

At its February 2026 meeting, the Aquatic Animals Commission reviewed a revised draft of the introductory chapter to Section 5. The Commission considered that the updated scope of the chapter was fit for purpose and edited the chapter for clarity and consistency. During the Bureaux meeting a final version of Chapter 5.Y. was approved, and the Bureaux agreed to circulate the Chapter 5.Y. for comments.

The new chapter has been circulated once for comment.

Previous Commission report where this item was last discussed

September 2025 report (Item 7.1.2., page 18); February 2026 report (Item 3.1., page 8, and Item 6.5., page 17)

September 2026 meeting

Comments were received from Australia, Canada, Chile, People’s Republic of China, Japan, Malaysia, Norway, USA, the EU and ICFAW.

The Aquatic Animals Commission considered comments received and noted that Members were supportive of the new chapter. The Commission met with the Bureau of the Code Commission to review this chapter as described in item 3.1.

The Commission’s responses to comments received regarding new Chapter 5.Y. ‘Introduction to recommendations for international aquatic animal health certification and export and import procedures’ are presented in Annex 3.

Texts for comment

The draft Chapter 5.Y. 'Introduction to recommendations for international aquatic animal health certification and export and import procedures' is presented as Annex 11 for comments.

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

Background

At its February 2024 meeting, the WOAH Working Group on Antimicrobial Resistance (Working Group) recommended that Section 6 'Antimicrobial use in aquatic animals' of the *Aquatic Code* be revised. The revision was requested to incorporate current scientific information and alignment with Chapter 6.10. 'Responsible and prudent use of antimicrobial agents in veterinary medicine' of the *Terrestrial Code*. This chapter had been recently revised, to reflect the One Health approach, and adopted at the 91st General Session in May 2024.

At its September 2024 meeting, the Aquatic Animal Commission agreed that Chapter 6.2. 'Principles for responsible and prudent use of antimicrobial agents in aquatic animals' of the *Aquatic Code* is no longer aligned with the newly adopted Chapter 6.10. of the *Terrestrial Code*. The Commission agreed that revision of this and other chapters on Section 6 of the *Aquatic Code* should be added to the Commission's work programme and requested a gap analysis of the section. In its February 2025 meeting, the Commission, based on gap analysis, requested to convene an *ad hoc* Group to revise Chapter 6.2.

In April 2025, an *ad hoc* Group, composed of six experts including a member of the Working Group and a member of the Commission, was convened to update Chapter 6.2. of the *Aquatic Code*. After two meetings (July and August 2025), a draft was prepared and submitted to the Commission for consideration at their meeting in September 2025. After a third *ad hoc* Group meeting (November 2025), a revised draft of Chapter 6.2 was presented to the Commission for their meeting in February 2026.

During their February 2026 meeting, the Commission shared the updated draft of Chapter 6.2 with Members for their comment.

September 2026 meeting

Comments were received from Australia, Canada, Chile, China, Chinese Taipei, EU, Mexico, Norway, Singapore, Thailand, USA, the International Coalition for Animal Welfare (ICFAW) and the WOAH Working Group on AMR (AMRWG).

The Aquatic Animals Commission considered comments received and acknowledged comments expressing support for the revised chapter and largely incorporated the proposals related with the alignment with Chapter 6.10 of the *Terrestrial Code* and congruence with the other chapters of section 6 in the *Aquatic Code*.

Texts for comment

The revised Chapter 6.2. 'Principles for responsible and prudent use of antimicrobial agents in aquatic animals' is presented as Annex 12 for comments.

6. *Aquatic Code* Items for Member Information

6.1. Chapter 4.2. 'Application of zoning'

Background

At its February 2025 meeting, 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'.

At its September 2025 meeting, the Commission completed a gap analysis on Chapter 4.2. considering 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.

Previous Commission reports where this item was discussed

September 2025 report (Item 7.1.1., page 18); February 2026 meeting (Item 7.1., page 19)

September 2026 meeting

Due to time constraints, the Aquatic Animals Commission agreed to review a draft revision for Chapter 4.2. 'Application of zoning' at its February 2027 meeting.

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

Background

At its September 2024 meeting, the Aquatic Animals Commission agreed that the usability of the *Aquatic Code* for developing and implementing sanitary measures should be reviewed. This should include relevant chapters 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, relevant chapters from other sections, including any relevant new texts.

At its February 2025 meeting, the Aquatic Animals Commission agreed that the work on Section 5 'Trade measures, importation/exportation procedures and health certification' should focus on providing a clear understanding of how implementation of sanitary measures should occur and identifying barriers to the implementation of these standards. The Commission agreed to finalise its work plan for Section 5 at its September 2025 meeting following the Bureaux meeting with the Terrestrial Code Commission.

At its September 2025 meeting the Commission discussed Section 5 and agreed that the objectives of the proposed approach to the revision of Section 5 would include: revision and improved quality of older standards as necessary; addressing any gaps in the standards for trade; improving usability for developing sanitary measures; addressing aquatic specific issues while maintaining alignment with the *Terrestrial Code*; and 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 revision of Section 5.

At its February 2026 report, the Commission reviewed Member comments on the circulated plan for Section 5 and noted that specific comments would be addressed when chapters were revised.

The Commission agreed, at its September 2026 meeting, to review Section 5 in association with Member comments to determine if updates are required to other aspects of the *Aquatic Code* in line with the planned work on Section 5.

Previous Commission reports where this item was discussed

September 2025 report (Item 6.4., page 11); February 2026 report (Item 6.4., page 11)

September 2026 meeting

The Aquatic Animals Commission reviewed the proposed plan for Section 5. The Commission noted that the following considerations would guide the approach:

- Revision of trade articles in disease specific chapters (X-X.9 to X.X.14; 10.4.13. to 10.4.20.); including reordering of articles and revision of commodity and pathway (end-use) combinations; 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;
- Develop a new chapter in Section 5, with general guidance on trade for aquaculture with similar approach with Chapter: 5.12. (Movement of ornamental aquatic animals) (this item was added to its work programme);
- Develop a new chapter on Section 4 for Official Control Programme of aquatic animal diseases considering the approach in the *Terrestrial Code* (this item was added to its work programme);
- Re-organisation of Section 5 for logical flow while considering the movement of some applicable chapters to Section 2 including Chapter 5.3. 'WOAH procedures relevant to the Agreement on the Application of Sanitary Measures of the World Trade Organization', and Chapter 5.4. 'Criteria to assess the safety of aquatic animal commodities'.

The Commission noted that the approach should be discussed in conjunction with the Code Commission for alignment.

6.3. 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 Section 7. 'Welfare of farmed fish' in the *Aquatic Code* are scientifically sound and meet the needs of Members. This work aligns with the WOAH Aquatic Strategy, specifically Activity 1.3, Review the scientific basis of existing animal welfare standards.

At its September 2025 meeting, the Commission considered the review of scientific justification and recommendations for revision to Section 7.'Welfare of farmed fish' completed by an external expert. 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. and requested that the expert prepare revised draft chapters.

At its February 2026 meeting, the Commission shared the expert reports and asked the Members on their preference for the approach to revision of these chapters and planned to consider Member response to create a plan for revision at its next meeting.

Previous Commission reports where this item was discussed

September 2025 report (Item 7.1.4., page 20); February 2026 report (Item 7.1.4., page 20)

September 2026 meeting

Comments were received from: Canada, Chile, the European Union, Republic of Korea, Norway, Switzerland, and the International Coalition for Animal Welfare (ICFAW).

The Aquatic Animals Commission reviewed Members' responses to the questions presented in its February 2026 report. Regarding the first question, which sought Members' views on whether the *Aquatic Code* should provide a high-level approach to animal welfare or more detailed standards where supported by scientific evidence, most respondents favoured a high-level approach aimed at achieving positive welfare outcomes. Only one respondent expressed a preference for more detailed technical requirements. Nevertheless, several Members noted that additional guidance for specific species or production systems could be developed where sufficient scientific evidence is available or becomes available in the future

The Aquatic Animals Commission agreed to consider all suggestions submitted in response to the second question, concerning alternative approaches, as part of the revision of the chapters in Section 7.

In response to the third question, the majority of Members expressed a preference for the four chapters in Section 7 to be revised and circulated for comment sequentially rather than simultaneously. Some Members also emphasised the importance of maintaining an overarching perspective to ensure coherence across the four chapters and suggested that closely related chapters, such as Chapters 7.3. and 7.4., could be circulated together.

The Commission accordingly requested the Secretariat to use the reports completed by the expert to update the Section 7 chapters, taking into account the responses by Members to the three questions, and report back at its February 2027 meeting. As requested, the revision will be done sequentially with relevant chapters released for comments together.

6.4. Assessments of susceptible species

Background

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.

Previous Commission report where this item was last discussed

September 2025 report (Item 7.1.5., page 20)

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* was organised in August 2026 the report of its meeting is being finalised. This *ad hoc* Group will continue to meet in 2027 to continue the work on assessing 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 a proposed process and agreed to propose possible expert members.

6.5. Emerging diseases

As a standing agenda item at each meeting, the Aquatic Animals Commission reviews scientific information, together with information provided by Members, experts and WOAH Reference Centres, to assess whether diseases meet the definition of an 'emerging disease' in the *Aquatic Code* (in accordance with Article 1.1.4. of the *Aquatic Code*.)

The Aquatic Animals Commission encourages 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.

6.5.1. 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.

At its September 2025 meeting, the Commission noted that there had been no notifications of infection with covert mortality nodavirus (CMNV) in WAHIS since the previous Commission meeting. The Commission had requested feedback from Members on importance of this disease, and no feedback had been received. With the absence of information and lack of reporting the Commission agreed that infection with CMNV would no longer be considered an emerging 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 (Item 6.9.1., page 16).

September 2026 meeting

The Aquatic Animal Commission met with Dr Zhang Qingli, WOAH Reference Laboratory expert for white spot syndrome virus from the Chinese Academy of Fishery Sciences, who provided scientific information on CMNV and its current implications on aquatic animal health and human health. The Commission thanked the expert for their presentation. Following its assessment of the available evidence against the definition of an 'emerging disease' in the *Aquatic Code*, the Commission agreed to keep CMNV under review, particularly regarding its potential public health implications. The Commission agreed to update the technical disease card in collaboration with the expert to incorporate the latest scientific information. The Commission will keep track of the latest scientific advances regarding CMNV as a zoonotic disease affecting humans and aquatic animals. The Commission also encouraged Members to provide to WOAH other important aquatic animal health information on CMNV in accordance with Article 1.1.5. of the *Aquatic Code*.

6.5.2. Work of the *Ad hoc* Group on Emerging Threats for Animal Health and Welfare

The Aquatic Animals Commission was informed of the second Threats Watch Report, a horizon-scanning initiative designed to inform WOAH Members' decision-makers about current and emerging challenges to animal health and welfare that was developed by the *ad hoc* Group on Emerging Threats for Animal Health and Welfare (ETG). The report was well received by the Commission, and it welcomed the inclusion of aquatic animal health in the work of the ETG but encouraged the Group to consider how its work could remain impactful. The Commission noted the importance of clear communication when disseminating the report among WOAH Members to ensure that its purpose is well understood.

The Commission acknowledged that the ETG could provide support to its work on emerging diseases by analysing specific threats as triaged by the Commission. To this end, the Commission requested the ETG to review 3 diseases in advance of its February 2027 meeting: CMNV (covert mortality nodavirus), TPD (Translucent Post-larvae Disease) and OsHV-1 (Ostreid herpesvirus disease). The Commission also requested to be an Observer at the next ETG meeting.

The WOAH *Manual* of Diagnostic Tests for Aquatic Animals

7. The WOAH *Manual* of Diagnostic Tests for Aquatic Animals

7.1. *Aquatic Manual* items for Member comment

7.1.1. Section 2.2. 'Diseases of crustaceans'

7.1.1.1. Chapter 2.2.3. 'Infection with infectious decapod iridescent virus 1'

Background

At the 93rd General Session, in response to a Member comment on consistency in the expression of the scientific name in both scope and title of Chapter 2.2.3. 'Infection with infectious decapod iridescent virus 1', the word 'infectious' was added before 'decapod iridescent virus 1' in the scope and adopted as such.

Previous Commission reports where this item was discussed

N.A.

September 2026 meeting

The Commission noted that the scientific name of the pathogenic agent is 'decapod iridescent virus 1'. It also noted that the word 'infectious' had been included in the disease name in error and to maintain consistency and accuracy, the word 'infectious' should be removed. It proposed to apply this correction to the *Aquatic Code* Chapter 9.3. 'Infection with infectious decapod iridescent virus 1' as well.

Texts for comment

The title and revised viral taxonomy in Article 9.3.1. 'Infection with decapod iridescent virus 1' is presented as Annex 13 for comment.

The title and revised viral taxonomy in scope of the Chapter 2.2.3. 'Infection with decapod iridescent virus 1' is presented as Annex 14 for comment.

7.1.2. Section 2.3. 'Diseases of fish'

7.1.2.1. New draft Chapter 2.3.7. Infection with *Megalocytivirus pagrus1*

Background

Following the listing of 'infection with Megalocytivirus pagrus1' at the 91st General Session in May 2024, a new disease-specific chapter for the Aquatic Manual needed to be developed 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.

At its February 2025 meeting, the Commission was informed that the Group had reviewed the available literature, shortlisted diagnostic methods covering the three genogroups and developed a technical disease card to provide preliminary guidance to Members.

The disease card was subsequently made available in the three official languages at: Technical disease card: Megalocytivirus pagrus1.

At its September 2025 meeting, the Commission was informed of progress in establishing an interlaboratory comparability exercise covering the three genogroups of M. pagrus1. The inter-laboratory comparability (ILC) study would be undertaken to determine the performance of the shortlisted assays and support their inclusion in the revised chapter.

Previous Commission reports where this item was discussed

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

September 2025 (Item 9.1.3., page 27), February 2026 (Item 10.2, page 30),

September 2026 meeting

The Aquatic Animals Commission reviewed draft Chapter 2.3.7. and congratulated the authors on their hard work and the high quality of the draft. The Commission acknowledged the considerable efforts of the expert group and recognised the scientific rigor underpinning the chapter.

Texts for comment

The revised Chapter 2.3.7. 'Infection with Megalocytivirus pagrus1 is presented as Annex 15 for Member comment.

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

Background

At its September 2025 meeting, the Aquatic Animals Commission was updated on ongoing work to finalise a research publication on the validation of real-time PCR assays for infection with spring viraemia of carp virus. The Commission noted that the outcomes of this study were expected to provide updated scientific evidence to support revisions to Tables 4.1 and 4.2, as well as Sections 5 and 6 of the chapter, ensuring alignment with the latest validated methodologies.

At its February 2026 meeting, the Commission reviewed proposed revisions to Section 4 based on the publication of the validation study and agreed to circulate the revised text for Member comment.

Previous Commission reports where this item was discussed

September 2025 report (Item 9.1.4., page 28), February 2026 report (Item 9.2.2., page 28).

September 2026 meeting

Comments were received from Canada, Chinese Taipei, Mexico, Thailand, the United States of America, and the European Union.

The Aquatic Animals Commission addressed Member comments and made amendments to the chapter as it considered appropriate. The Commission's responses to Member comments are presented in Annex 3.

Texts for comment

The revised Chapter 2.3.9. 'Infection with spring viraemia of carp virus' is presented as Annex 16 for comment.

7.1.2.3. Chapter 2.3.11. 'Infection with tilapia lake virus'

Background

At its September 2025 meeting, the Aquatic Animals Commission identified a subject-matter expert to complete the draft chapter on infection with tilapia lake virus. Subsequently, an expert from the WOAH Collaborating Centre for Emerging Aquatic Animal Diseases, in collaboration with the designated subject-matter expert, prepared a new Chapter 2.3.X. *Infection with tilapia lake virus* using the disease-specific chapter template. The draft chapter was presented to the Aquatic Animals Commission at its February 2026 meeting, where it was reviewed and approved for circulation for Member comment.

Previous Commission reports where this item was discussed

September 2025 report (Item 9.2.3., page 29), February 2026 report (Item 9.2.1., page 28).

September 2026 meeting

Comments were received from Australia, Canada, China (People's Rep. of), Malaysia, Mexico, Thailand, the United States of America, and the European Union.

The Aquatic Animals Commission addressed Member comments and made amendments to the chapter as it considered appropriate. The Commission's responses to Member comments are presented in Annex 3.

Texts for comment

The revised Chapter 2.3.11. 'Infection with tilapia lake virus' is presented as Annex 17 for comment.

7.1.3. Section 2.4. 'Diseases of mollusc'

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

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 Members on the understanding that the Commission would review the case definitions set out 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 report (Item 8.2.1, page 23),
February 2026 report (Item 9.1.1., page 27).

September 2026

Comments were received from Chinese Taipei, Thailand, and the European Union.

The Aquatic Animals Commission addressed Member comments and made amendments to the chapter as considered appropriate. A new sentence has been added at the end of Section 6.1 and 6.2 concerning the use of visualisation techniques. This statement on case definition was initially introduced in the *Bonamia* chapters (Chapters 2.4.2 and 2.4.3) and presented for Member comments as a pilot approach. Subject to a positive response and support from Members, the same approach would be extended to all mollusc-related chapters (Section 2.4) to ensure consistency across the *Aquatic Manual*. This would apply to Items 7.1.3.2., 7.2.4. and 7.2.4.1. of this report. The Commission will consider these items together and align its approach at its meeting in February 2027 before proposing any broader implementation.

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

Texts for comment

The revised Section 6 of the Chapter 2.4.2. 'Infection with *Bonamia exitiosa*' is presented as Annex 18 for comment.

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

Background

See Item 7.2.2.1 above.

Previous Commission reports where this item was discussed

See Item 7.2.2.1 above.

September 2026 meeting

Comments were received from Chinese Taipei, Thailand, and the European Union.

The Aquatic Animals Commission addressed Member comments and made amendments to the chapter as considered appropriate. A new sentence has been added at the end of Section 6.1 and 6.2 concerning the use of visualisation techniques.

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

Texts for comment

The revised Section 6 of the Chapter 2.4.3. 'Infection with *Bonamia ostreae*' is presented as Annex 19 for comment.

7.2. *Aquatic Manual* ongoing work items

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

Background

In September 2025, the Aquatic Animals Commission was updated on the progress to revise Chapter 1.1.2. 'Validation of diagnostic assays for infectious diseases of aquatic animals'. The chapter was undergoing a comprehensive review to better address the validation of diagnostic assays for aquatic animal diseases,

including their application in surveillance of apparently healthy animals, presumptive diagnosis of clinically affected animals, and confirmatory diagnosis of suspect results arising from surveillance or presumptive testing.

Previous Commission reports where this item was discussed

September 2025 report (Item 9.2.1, page 29).

September 2026 meeting

The Aquatic Animals Commission thanked the expert for their work in revising the chapter and proposed revisions for clarity and consistency. The Commission discussed the need for consultation with the Biological Standards Commission for alignment with the equivalent chapter in the *Terrestrial Manual* and with aquatic Reference Centres experts for their opinion. The Commission agreed to consult with experts on the revised chapter ahead of its February 2027 meeting.

7.2.2. Section 2.1. 'Diseases of amphibians'

7.2.2.1. Chapter 2.1.0. 'General information (diseases of amphibians)'

Background

At its September 2025 meeting, the Aquatic Animals Commission identified amphibian disease experts to assist with the revision of the amphibian disease chapters and the development of a new Chapter 2.1.0. 'General Information on Diseases of Amphibians'.

Previous Commission reports where this item was discussed

September 2025 report (Item 8.2.1, page 23),

September 2026 meeting

The Commission considered the work of the WOAH *ad hoc* Group on Susceptibility of Amphibian Species to Infection with WOAH Listed Diseases, which held its first in-person meeting in Paris, France, from 4 to 6 August 2026.

While the primary mandate of the *ad hoc* Group is to address issues related to the susceptibility of amphibian species to WOAH-listed diseases, the Commission considered that its expertise could also contribute to the revision of the amphibian disease chapters and the development of Chapter 2.1.0. The Commission requested the Secretariat to explore this with the *ad hoc* Group for its meetings in 2027.

7.2.3. Section 2.2. 'Diseases of crustaceans'

7.2.3.1. Expert consultation for Infection with infectious hypodermal and haematopoietic necrosis virus (IHHNV)

Background

A Member requested the Aquatic Animals Commission to 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 could 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.

In February 2025, the Aquatic Animals Commission reviewed the replies received from the Reference Laboratory experts, which highlighted the complexity of the issue. An expert consultation was convened comprising the two WOAH Reference Laboratory experts and other internationally recognised experts to review the current scientific knowledge on EVEs to provide an informed opinion on approaches to confirmatory diagnosis in relevant aquatic species.

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). The experts had 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 considered that there was still a lack of clarity in the information provided and extended an invitation to a Reference Laboratory expert for IHHNV to attend the Aquatic Animal Commission February 2026 meeting to support the development of a revised proposal.

In February 2026 the Commission noted that the matter remained under revision and acknowledged the scientific and diagnostic complexity associated with differentiating IHHNV from endogenous viral elements. It was further noted that the WOAH Reference Laboratories continued to actively contribute to the process, with one laboratory submitting a revised proposal and the other participating in the discussion during the meeting, including through a presentation on the current state of research in this area.

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 (Item 9.1.2., page 27), February 2026 (Item 10.1., page 29)

September 2026 meeting

The Commission thanked the experts from both WOAH Reference Laboratories for IHHNV for their updates on diagnostic tests to support the application of the case definition in apparently healthy animals. The Commission acknowledged the ongoing efforts to refine diagnostic methods that distinguish infectious IHHNV from non-infectious endogenous viral elements (EVEs) and welcomed the progress achieved by both laboratories.

The Commission requested that the experts submit validation data and complete the validation template for the PCR assay for review at its February 2027 meeting. The Commission acknowledged the limitations of the currently recommended diagnostic methods in distinguishing IHHNV from endogenous viral elements (EVEs) and noted the ongoing progress in developing and validating improved diagnostic approaches.

The Commission expressed its appreciation to the experts for their continued support and valuable contributions to this longstanding work. The revised information and supporting validation data will be considered by the Commission at its February 2027 meeting.

7.2.4. Section 2.4. 'Diseases of molluscs' – case definitions review

Background

Following receipt of a large number of Member comments on the case definitions, the Commission had decided to place '[Under study]' the definitions of a suspect case in apparently healthy and in clinically affected animals and the definitions of a confirmed case in apparently healthy and in clinically affected animals outlined in Section 6.1. 'Apparently healthy animals or animals of unknown health status' and Section 6.2. 'Clinically affected animals' for all three mollusc disease chapters proposed for adoption (Chapter 2.4.5; Chapter 2.4.6 and Chapter 2.4.7). The Commission decided to undertake an in-depth review of the case definitions of all seven of the mollusc disease chapters at the next meeting of the Commission, in September 2026.

September 2026 meeting

Following the request made by Members at the General Session to review the case definitions in the molluscan disease chapters, the Commission discussed the need to clearly distinguish between suspect and confirmed cases. It also supported the inclusion of explanatory text in the *Aquatic Manual* on the principles underlying case definitions.

At the September meeting, the Commission reviewed the case definitions in the two *Bonamia* chapters, focusing on the roles of histopathology, visualisation techniques and molecular methods in detecting and confirming infection, and amended the relevant sections accordingly (see Item 7.1.3).

The Commission agreed that a broader review of case definitions across the disease-specific chapters should be undertaken as part of future revisions and that this outstanding work should be brought to the attention of the incoming Commission for further consideration. The Commission will consider these items together and align its approach at its meeting in February 2027 before proposing any broader implementation.

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

Background

In September 2025, following discussion of the two *Bonamia* chapters, the Aquatic Animals Commission reviewed Section 6, 'Corroborative diagnostic criteria', of Chapter 2.4.4. *Infection with Marteilia refringens*. At its February 2026 meeting, the Aquatic Animals Commission considered Member comments and amended the chapter, as appropriate. The revised section was subsequently presented for Member comment.

Previous Commission reports where this item was discussed

September 2025 report (Item 8.2.2, page 24), February 2026 report (Item 9.1.2., page 28).

September 2026 meeting

Comments were received from Chinese Taipei, and the European Union.

The Aquatic Animals Commission appreciated the comments submitted by Members and noted that they will be considered when the case definition is discussed at its February 2027 meeting.

The Commission highlighted the value of Member input in supporting the review process and informing future decisions regarding the chapter and welcomed feedback on how case definitions should be approached.

The Commission considered a recent publication (Hooper et al, 2025) that concluded that M and O type *Marteilia refringens* are distinct species. The Commission agreed to consult with the Reference Laboratory expert and consider this issue further at its February 2027 meeting.

The Commission reminded that this item is linked to Item 7.1.3. of this report; the approach to case definitions will be aligned at its February 2027 meeting before broader implementation is proposed.

7.2.5. Review of PCR-Related Content throughout the Aquatic Manual

The Aquatic Animals Commission noted the need to improve consistency across the *Aquatic Manual* chapters (including Chapter 2.3.5. 'Infection with infectious haematopoietic necrosis virus' and Chapter 2.3.9 'Infection with spring viraemia of carp virus') and supported harmonising approaches on PCR assay presentation and validation.

The Commission discussed outcomes of a review of PCR tables for multiple chapters. The Commission requested the Secretariat to share the revised tables with the appropriate Reference Laboratories for their review and will discuss their feedback at its February 2027 meeting.

8. Reference centres network

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

The Commission thanked the applicants for their interest to be part of WOAH Reference Centre Network. The Commission acknowledged the increasing engagement among Reference Centres, their respective Delegates and Regional Commissions, and encouraged the continued strengthening of these relationships.

Following the meeting and in accordance with the standard operational procedure, the applications were supported by the Commission and would be presented for validation:

Directly to the WOAH Council regarding Reference Laboratories.

8.1.1. RL: White Spot syndrome_INDIA

WOAH Reference Laboratory for White spot syndrome
Address: National Referral Laboratory for Brackishwater Aquatic Animal Diseases (CIBA), India
Tel.: +91 44 2461 88 17; +91 44 2461 6948
E-mail: subhendu.otta@icar.org.in
Website: www.ciba.res.in
Designated Expert: Dr Subhendu Kumar Otta

8.1.2. RL: Tilapia lake virus_INDIA

WOAH Reference Laboratory for Tilapia Lake Virus
Address: Aquatic Animal Health Laboratory, Lucknow, India
Tel.: (0522) 2441735, 2440145
E-mail: directornbfgr2025@gmail.com
Designated Expert: Dr Neeraj Sood

8.2. Update on the Aquatic Collaborating Centres Network

The Commission received an update on the Aquatic Collaborating Centres Network and discussed opportunities to strengthen its contribution to WOAH's aquatic animal health priorities.

The Commission recognised the efforts made to facilitate collaboration, while noting challenges in coordinating meetings across time zones and identifying shared activities with clearly defined outputs. It highlighted the importance of establishing common objectives that draw on the Centres' complementary expertise, including opportunities for collaboration with aquatic Reference Laboratories.

The Commission considered that the Network's future arrangements should be guided by the added value and tangible outputs it could deliver. Options discussed included maintaining the current format with a more focused work programme or adopting a needs-based approach, whereby collaboration would be mobilised in response to specific technical priorities identified by the Commission.

The Commission recommended an open discussion with Network members to review their experience, interest and capacity for continuing this collaboration, and to explore the most appropriate arrangements for the future.

8.3. New article in 'Procedures of Designation: case of one member of a consortium needs to withdraw'

Following a request from a partner institution, the Commission noted current Procedures for Designation address the withdrawal of a WOAH Collaborating Centre but do not establish a process for changes to the composition of a consortium. The Commission was presented with an applicable administrative process, including notification requirements, the involvement of the remaining partners and whether the consortium could retain its designation following a change in the composition of the consortium.

The Commission agreed on the proposal to amend Section 2, 'Submission of an application', to specify that a consortium constitutes a single Collaborating Centre composed of two or more independent partner institutions working under one five-year work plan, submitting one annual report and appointing one administrative contact point. It also agreed to replace the term 'associates' with 'partners' and to include a diagram illustrating the consortium structure.

In addition, the Commission also agreed with the amendments to Section 10, 'De-listing of WOAH Collaborating Centres', establishing that the withdrawal of a partner should be formally notified to WOAH and followed by a reassessment, based on a revised five-year work plan and updated distribution of responsibilities, to determine whether the remaining consortium retains sufficient capacity to fulfil its mandate and maintain its designation.

8.4. Inclusion in the ToRs: To network between Collaborating Centres and Reference Laboratories

The ToR for WOAH Reference Laboratories and Collaborating Centres currently encourage networking within their respective categories. A network of Collaborating Centres recently enquired whether it could also establish formal links with Reference Laboratories. Although such collaboration is permitted and encouraged, it is not explicitly reflected in their current ToR. The Commission considered amendments to explicitly enable networking between the WOAH Reference Centre and strengthen collaboration and complementarity across the network.

The Commission requested the Secretariat to implement the changes in the ToR of both Collaborating Centres and Reference Laboratories.

8.5. Collaborating Centers: Update of specialties under the focus area on capacity building

In collaboration with the WOAH Capacity Building Department, the Secretariat presented a proposal to revise the description and specialties under the focus area currently entitled '4. Training and education' in the list of main focus areas and specialties for WOAH Collaborating Centres.

The proposed changes aimed to align the terminology with WOAH's current approach to capacity building, which extends beyond education and training to encompass institutional and workforce development, and performance strengthening. It targets Veterinary and Aquatic Animal Health Services, and involves the veterinary workforce, i.e. veterinarians, veterinary paraprofessionals and community animal health workers.

The following revised focus area and specialties was agreed by the Commission:

'Capacity building, education and continuing education'

In line with WOAH's mandate to strengthen the quality, governance, competency, and sustainability of Veterinary Services and Aquatic Animal Health Services, this area focuses on methodologies and services aiming at strengthening their institutional and workforce capacities according but not limited to the provisions of Section 3 of the *Terrestrial* and *Aquatic Codes*. It covers capacity building from performance assessment to performance improvement, overarching the continuous development of the veterinary workforce, including veterinarians, terrestrial/ aquatic animal health professionals, veterinary paraprofessionals, community animal health workers and other relevant professions contributing to the implementation of WOAH Standards.

- Capacity building of Veterinary Services and Aquatic Animal Health Services

- Competencies of graduating veterinarians

- Continuing education and competency-based training

- Technology-supported learning

- Competency-based development of veterinary paraprofessionals

The Commission emphasised the importance of establishing common expectations regarding the contribution of Collaborating Centres to WOAH activities.

9. Other issues

9.1. Aquatic Animal Health Strategy

The Aquatic Animals Commission received an update on the implementation of WOAH's Aquatic Animal Health Strategy 2021–2025 and plans to build on its achievements in alignment with WOAH's 8th Strategic Plan. Key achievements included improved and more accessible standards, a better understanding of barriers to implementation, and strengthened capacities through e-learning, the PVS Pathway, public-private partnerships and guidance on antimicrobial resistance.

The Commission was also informed that implementation had varied across regions. Progress in the Asia-Pacific region was supported by dedicated staff, funding and established networks, while other regions faced resource constraints. Regional workshops, including one in Tokyo, and planned training in Africa were also reported. Gaps remain, particularly in emergency preparedness and response, as well as in strengthening international partnerships and regional networks. WOAH is currently identifying emerging areas requiring support and assessing needs from a regional perspective.

In this context, the development of a follow-up Aquatic Animal Health Strategy for 2027–2031 is being proposed. Its development and subsequent implementation will require investment and support from WOAH partners. The Commission welcomed the progress achieved and expressed its support for the development of the next strategy. It emphasised the importance of a participatory process involving Members, regional networks and relevant partners to ensure that the strategy reflects shared priorities and regional needs. The Commission looked forward to receiving an update at its next meeting.

9.2. Proposal to develop a new chapter on Aquatic Animal Health Legislation (both domestic and wild)

The Aquatic Animals Commission received a proposal from WOAH Headquarters for the development of specific standards on Aquatic Animal (both domestic and wild) legislation, based on the results and recommendations from two studies conducted in 2025, namely 'WOAH/Legal Atlas report Uncharted Waters' and 'Lessons Learned from Review of WOAH PVS Aquatic Reports' (internal, not published). Both reports identified numerous legislative gaps in the jurisdictions and recommend developing a comprehensive legislation chapter on aquatic animal (both wild and domestic) that would support WOAH Members to improve their national legislation to better regulate aquaculture production and take into account ecosystems surrounding aquatic industries. The proposal included a checklist of contents of aquatic animal health legislation for validation and eventually to serve as a basis for the Commission for the development of such proposed chapter. The Commission noted the proposal and added this item to its work programme.

9.3. The Observatory: preliminary findings of the thematic study on self-declaration in the aquatic sector

The Commission was informed of the preliminary findings of the Observatory's analysis of aquatic self-declarations published in 2024 and 2025, including their number, disease coverage, geographical distribution and status. Of 136 self-declarations, 112 concern terrestrial diseases (82%) and 24 concern aquatic diseases (18%). Terrestrial self-declarations were concentrated on a few diseases, while aquatic ones are spread across 14 diseases and come from only five Members. Aquatic zoning involved only two Members, and compartmentalisation was not used in the aquatic sector. All 24 aquatic self-declarations were active at the time of the study. The analysis was strictly descriptive and did not go into why Members use, or do not use, this tool.

The Commission discussed the ongoing revision of the compartmentalisation chapter and noted that the planned Thematic Study on compartmentalisation would be highly relevant to the aquatic sector. It highlighted the importance of public-private partnerships, particularly incentives for the private sector and training for the public sector.

The Commission pointed out that zones and compartments often exist in practice but are not formally notified to WOAH through self-declarations. A key question raised was what incentives would encourage Members to submit self-declarations, as some countries may already have confidence in their own systems and see limited added value in external recognition. In considering differences between the aquatic and terrestrial sectors, participants also noted that significant aquatic animal production is concentrated in fewer countries, which may partly explain the lower number of aquatic disease self-declarations.

The discussion highlighted that prior experience with self-declarations may help build confidence and facilitate future aquatic disease self-declarations. However, differences in national validation processes and governance structures can create barriers, particularly for Aquatic Animal Health Focal Points. Participants suggested examining countries that have terrestrial disease self-declarations but none for aquatic diseases to better understand sector-specific obstacles. These may include differences in institutional leadership and legislative frameworks between the two sectors within the same country.

The Commission sought clarification on the treatment of inactive self-declarations and expressed interest in exploring officially endorsed aquatic disease control programmes in the future. Existing WOAH recognition mechanisms for disease control programmes were noted as potentially relevant examples.

A Commission member suggested incorporating findings from the PVS Pathway, particularly legislative and regulatory capacities related to aquatic animal health, zoning, and compartmentalisation, as baseline information for the Thematic Study. The Observatory agreed to consider these competencies when developing its questionnaire.

The Commission also discussed possible incentives for self-declaration, including greater visibility and recognition by WOAH and other stakeholders. Participants suggested highlighting successful implementation of self-declarations through WOAH's communication channels**.** While concerns were raised about highlighting declarations that may later become inactive, the Observatory noted that recommendations on incentives could be developed based on the study findings.

The Commission and the Observatory agreed to proceed with a Thematic Study examining the benefits of, and incentives for, aquatic disease self-declarations at zonal and compartment levels. Preliminary findings and draft recommendations will be presented to the Commission for consultation before final recommendations are issued to WOAH and Members.

9.4. Development and piloting of the Veterinary Medicines Regulatory Agency Self-assessment Tool (VMRA-SAT)

The Commission received an update on the development and evaluation of the Veterinary Medicines Regulatory Agency Self-Assessment Tool (VMRA-SAT) by the UK Veterinary Medicines Directorate in collaboration with WOAH and its partners. The VMRA-SAT was a self-assessment tool designed to support National Regulatory Agencies (NRAs) in assessing veterinary medicinal products regulatory systems and identifying regulatory gaps and has been piloted in 11 countries across different WOAH regions.

The Commission was informed that the VMRA-SAT would complement existing WOAH standards and exiting capacity building tools, including Article 6.2.4 of Chapter 6.2 and Article 6.3.3 of Chapter 6.3 of the *Aquatic Code*, and would support the strengthening of regulatory systems for veterinary medicinal products used in the prevention and control of aquatic animal diseases. The Commission was invited to provide comments on the complementarities between the VMRA-SAT and the relevant chapters of the *Aquatic Code,* which may inform consideration of its potential adoption by WOAH World Assembly of Delegates at the 94th General Session.

The Commission took note of the information presented and requested an update on the results of the further pilot studies in February 2027, particularly regarding recommendations for aquatic animal medicines. The Commission noted that Chapter 6.2 of the *Aquatic Code* was being amended to align with Chapter 6.10. of the *Terrestrial Code* and has been circulated to Members for consultation The Commission would provide feedback on the relevance of the VMRA-SAT to Chapter 6.2. of the *Aquatic Code*, particularly regarding the role of Competent Authorities in regulating veterinary medicinal products for aquatic animals.

9.5. Discussion on inclusion of vaccine quality, safety and efficacy in the Aquatic Manual

The Technical Item of the 92nd General Session, entitled 'Veterinary vaccines and vaccination: from science to action – reflections for change', highlighted the challenges currently hindering the development, availability and effective use of vaccines as part of disease prevention and control strategies.

Given the evolving socio-economic and epidemiological context, there is a broader reflection on disease control approaches, including the need, in certain circumstances, to move beyond strategies focused exclusively on disease elimination towards sustainable disease management. In this context, there is a need to explore how vaccination can be more effectively integrated into aquatic disease prevention and control strategies, while ensuring that such approaches remain science-based, economically viable and environmentally sustainable and do not create unnecessary barriers to safe trade.

The Technical item highlighted the critical role of vaccines in sustainable disease prevention and control, the containment of antimicrobial resistance, and the protection of public health.

The Commission recognised the potential value of internationally agreed requirements for vaccine quality, safety and efficacy in supporting Members' use of vaccination for aquatic animal disease prevention and control. It noted that any provisions would require a coordinated approach across the *Aquatic Code* and *Aquatic Manual*, combining general principles with disease-specific requirements, as appropriate.

The Commission emphasised the need to clarify Members' priorities and the practical benefits of this work before initiating the development of standards. It highlighted the importance of considering vaccine availability, regulatory approaches, economic feasibility and the diversity of aquatic production systems. Consultation with WOAH Reference Laboratories and relevant stakeholders would help identify needs and inform the scope and most appropriate form of guidance.

The Commission agreed to continue exploring this work through a discussion paper setting out the needs, potential scope and options for supporting Members. It requested that the Secretariat prepare the paper for consideration at its February 2027 meeting.

9.6. Update on the *ad hoc* Group on prioritisation of diseases for which vaccines could reduce global antibiotic use in animals

The Commission was informed of the progress of the deliverables under the *ad hoc* Group established to deliver an updated, evidence-based list of priority animal diseases for which vaccines could achieve the greatest global reduction in AMU in pigs, chickens, and fish. The ad hoc group met in person in February 2026 and also participated in three virtual meetings. To date the fifteen experts have:

- updated the 2015 priority disease lists for pigs, chickens and fish;

- scored each disease against four criteria to rank the lists;
- identified a ‘Top 6’ (two priority diseases per sector) on which advocacy and investment should concentrate over the next five years;
- published their first report.The next phase of work will focus on developing draft vaccine target product profiles (TPPs) for these Top 6 diseases, and a Communication, Dissemination and Exploitation (CDE) plan.

The Commission highlighted that, for some fish pathogens on the list, rapidly evolving subtypes could jeopardise vaccine efficacy and complicate vaccine coverage. It therefore emphasised that vaccination should be supported by strong surveillance systems. Drawing on the substantial reduction in AMU achieved through vaccination in Norway’s salmon industry, the Commission highlighted the potential to achieve similar benefits in other aquaculture settings. However, technological advances in vaccine delivery are needed for high-volume, low-cost farmed fish species, for which injectable vaccines remain a major constraint to wider uptake.

In related discussions on aquatic vaccines, the Commission considered the need for guidance on minimum quality, safety and efficacy requirements before marketing authorisation. It also discussed the integration of vaccination into official disease control programmes, including cost–benefit considerations and the feasibility of commercial vaccine production.

9.7. Update on aquatic disease situation and reporting by Members

The Commission received an update from the World Animal Health Information Department (WAHID) on aquatic animal disease reporting through WAHIS. The presentation covered notification trends from 2013 to 31 August 2026, the most frequently reported aquatic diseases, the updating of ongoing events and the submission of six-monthly reports for 2025 and 2026.

The Commission was informed that 12 aquatic disease events involving 10 diseases remained ongoing in 10 countries or territories, and that only half had been updated within the preceding nine weeks. The presentation highlighted the need for weekly updates to ongoing events until they are finalised. One notification concerning occurrence in a new host had been submitted since 18 February 2026: infection with spring viraemia of carp virus in wild Prussian carp in Greece, confirmed by RT-PCR.

The Commission also took note of the issues raised by a Member on the aquatic standards regarding the recognition and assessment of susceptible host species for infection with koi herpesvirus and viral haemorrhagic septicaemia virus.

The Commission was also informed of the findings of a workshop on reporting barriers held with Aquatic Animal Health Focal Points in Asia and the Pacific in July 2026. The main challenges identified were capacity and resource constraints, gaps in WAHIS knowledge, and communication and collaboration barriers. Participants also raised concerns about the perceived consequences of reporting, including trade implications, and insufficient clarity regarding Focal Point roles and responsibilities.

Proposed solutions included stronger diagnostic and surveillance capacity, targeted training and individual support, improved coordination among national Focal Points, and greater awareness of the benefits of reporting. Clarifying and formalising Focal Point responsibilities received particular support. The Commission was informed that challenges and solutions had been ranked using different voting arrangements; consequently, vote counts were not directly comparable and low scores should not be interpreted as indicating low relevance.

In related discussions, the Commission requested WOAH to provide clarity on the linkage between WildEpi and WAHIS reporting processes and to ensure that significant reports are brought to their attention.

9.8. Work of the Governance Review Committee

The Commission was briefed on the Governance Review Committee’s (GRC) ongoing technical governance reform programme. The Commission was informed of the GRC’s recommendation that the Secretariat undertake a phased programme of diagnostic assessments, development of policy options and consultation with WOAH Members, Specialist Commissions and other relevant stakeholders, with the objective of strengthening technical governance, scientific advisory functions, expert selection processes, standards development procedures and institutional memory.

The Commission highlighted the importance of aquatic animal health expertise, diversity of representation and stronger institutional memory and record-keeping to support continuity of its work. These points complemented its earlier discussions with WOAH, in which it had highlighted the need to maintain adequate attention to aquatic animal

health within WOAH's technical governance arrangements, clarify Commission roles to improve efficiency and ensure aquatic animal health representation in WOAH's One Health and global strategy work

The Commission received an update on the development of the WOAH Technical Procedural Manual (TPM), which is intended to consolidate and explain WOAH's principal technical processes, improve transparency and facilitate Member and stakeholder engagement.

The Commission was further advised of planned consultations with the Specialist Commissions on analytical work regarding the strategic direction and drafting of WOAH standards, including future consideration of how mandatory requirements, recommendations and guidance should be reflected across WOAH's technical instruments.

9.9. Specialist Commission elections process and future meeting dates

The Commission was informed of the selection and election process for Specialist Commission members for the 2027–2030 term.

Following the closure of the call for applications on 11 September 2026, applications would be assessed by the Nomination Evaluation Committee. The shortlist would then be submitted to the Council for approval in March 2027, taking geographical and gender balance into account, and communicated to Delegates at least 60 days before the General Session. Elections would take place during the General Session in May 2027.

The Commission thanked the Secretariat for the update and took note of the process and timeline for the forthcoming elections of Specialist Commission members for the 2027–2030 term.

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…/Annexes

Annex 1. Adopted Agenda

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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1. Meeting with the WOAH Director General and Deputy Director General - Standard Setting and Implementation

1.1. WOAH Director General

1.2. Deputy Director General, Standard Setting and Implementation

2. Adoption of the agenda

3. Cooperation with Other Specialist Commissions

3.1. Aquatic Animals Commission and Terrestrial Animal Health Standards Commission Bureaus meeting to discuss alignment of Chapters 1.1. and Section 5, including 5.Y. and recommendations of the ad hoc Group on certification

3.2. Biological Standards Commission on 'Workshop to Identify Research Gaps Limiting the Validation and Effective Use of eDNA/eRNA Approaches'

4. Work programme and priorities

4.1. Comments received on the Work Programme

4.2. Overview of the Work Programme

5. *Aquatic Code* items for Member comment

5.1. Glossary 'self-declaration of freedom from disease'

5.2. Chapter 1.1. Notification of diseases and provision of epidemiological information

5.3. Articles 1.4.4., 1.4.10., 1.4.13. and 1.4.14. of Chapter 1.4. Aquatic animal disease surveillance

5.4. Chapter 4.3. 'Application of compartmentalisation'

5.5. Model Article X.X.7. 'Compartment free from [pathogen X]' of the disease-specific chapters and Articles 10.4.9. and 10.4.10. Of 'Infection with Infectious salmon anaemia'

5.6. Chapter 5.Y. 'Introduction to recommendations for international aquatic animal health certification and export and import procedures'

5.7. Chapter 6.2. 'Responsible and prudent use of antimicrobial agents in aquatic animals'

6. *Aquatic Code* Items for Member Information

6.1. Chapter 4.2. 'Application of zoning'

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

6.3. Section 7. 'Welfare of farmed fish'

6.4. Assessments of susceptible species

6.5. Emerging diseases

6.5.1. Infection with covert mortality nodavirus (CMNV)

6.5.2. Work of the *Ad hoc* Group on Emerging Threats for Animal Health and Welfare

7. The WOAH *Manual* of Diagnostic Tests for Aquatic Animals

7.1. *Aquatic Manual* items for Member comment

7.1.1. Section 2.2. 'Diseases of crustaceans'

7.1.2. Section 2.3. ‘Diseases of fish’

7.1.3. Section 2.4. ‘Diseases of mollusc’

7.2. *Aquatic Manual* ongoing work items

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

7.2.2. Section 2.1. ‘Diseases of amphibians’

7.2.3. Section 2.2. ‘Diseases of crustaceans’

7.2.4. Section 2.4. ‘Diseases of molluscs’ – case definitions review

7.2.5. Review of PCR-Related Content throughout the Aquatic Manual

8. Reference centres network

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

8.1.1. RL: White Spot syndrome_INDIA

8.1.2. RL: Tilapia lake virus_INDIA

8.2. Update on the Aquatic Collaborating Centres Network

8.3. New article in ‘Procedures of Designation: case of one member of a consortium needs to withdraw’

8.4. Inclusion in the ToRs: To network between Collaborating Centres and Reference Laboratories

8.5. Collaborating Centers: Update of specialties under the focus area on capacity building

9. Other issues

9.1. Aquatic Animal Health Strategy

9.2. Proposal to develop a new chapter on Aquatic Animal Health Legislation (both domestic and wild)

9.3. The Observatory: preliminary findings of the thematic study on self-declaration in the aquatic sector

9.4. Development and piloting of the Veterinary Medicines Regulatory Agency Self-assessment Tool (VMRA-SAT)

9.5. Discussion on inclusion of vaccine quality, safety and efficacy in the Aquatic Manual

9.6. Update on the *ad hoc* Group on prioritisation of diseases for which vaccines could reduce global antibiotic use in animals

9.7. Update on aquatic disease situation and reporting by Members

9.8. Work of the Governance Review Committee

9.9. Specialist Commission elections process and future meeting dates

Annex 2. List of Participants

MEETING OF THE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

16 to 23 September 2026

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MEMBERS OF THE COMMISSION

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Head
Standards Department

Dr Valentyna Yatsyshyn
Scientific Secretariat Officer
Standards Department

Dr Mariana Delgado
Scientific Secretariat Officer
Science Department

Dr Farah Gonul Aydin
Scientific Coordinator - Aquatic
Standards Department

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

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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Chapter	Subject	Summary of the work	Status – February 2026		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Aquatic Code and Manual					
	Vaccines and vaccination	Exploratory work on incorporation of vaccines in aquatic standards	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
	Emerging diseases	Review emerging diseases	Standing agenda item	Refer to Sep 2026 AAHSC report	**1**
Aquatic Code					
Ch. 1.1.	Notification of diseases, and provision of epidemiological information	Discussed with Code Commission to ensure consistency and clarity on revisions.	Second circulation for comments	Refer to Sept 2026 AAHSC report (Sept 2026/2)	**1**
UG	User's Guide	Update User's Guide to update description of different sections, alignment with the *Terrestrial Code*	Preparatory work	Refer to Sept 2026 AAHSC report	**3**
Ch. 1.4.	Aquatic animal disease surveillance	Reviewed Ch. 1.4. to consider if revision required following the update of Ch. 4.3.	Second circulation for comments	Refer to Sept 2026 AAHSC report (Sept 2026/2)	**1**
Ch. 3.X.	Aquatic animal health legislation	New proposal to develop chapter on aquatic animal health legislation	Preparatory work	Refer to Sept 2026 AAHSC report	**3**
Ch 3.1.	Quality of aquatic animal health Services	Revise Ch. 3.1. to incorporate above	Not started	Refer to Sept 2026 AAHSC report	**4**
Ch. 4.X.	Official control programme	New proposal to develop chapter on official control programme	Not started	Refer to Sept 2026 AAHSC report	**3**
Ch. 4.2.	Application of zoning	Draft revision of the chapter taking into account work in *Terrestrial Code*.	Preparatory work – revision of chapter ongoing	Refer to Feb 2026 AAHSC report	**1**

Chapter	Subject	Summary of the work	Status – February 2026		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
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 2026 AAHSC report (Feb 2025/4)	**1**
Section 5	Trade measures, importation/exportation procedures and health certification	Revision of chapters in Section 5 to ensure useability for trade purposes	To discuss priority of chapters to revise at February 2027 meeting.	Refer to Sept 2026 AAHSC report (Sept 2025/1)	**1**
Ch. 5.X.	Movement of aquaculture	New proposal to develop chapter on movement of aquaculture, modelled after Ch. 5.12.	Not started	Refer to Sept 2026 AAHSC report	**3**
Ch. 5.Y.	New introductory chapter to Section 5	Taskforce between AAC and TCC convened and drafted chapter. Proposed amendments coordinated with TCC.	Circulated for comments.	Refer to Sept 2026 AAHSC report (Feb 2026/2)	**1**
Ch. 5.1.	General obligations related to certification	Update certification procedures to align with Codex (e-certification). *Ad hoc* Group provided Commission with draft chapter.	Second *ad hoc* Group meeting to continue work in 2027.	Refer to Sept 2026 AAHSC report	**2**
Ch. 5.2.	Certification procedures	Update certification procedures to align with Codex (e-certification). *Ad hoc* Group provided Commission with draft chapter.	Second *ad hoc* Group meeting to continue work in 2027.	Refer to Sept 2026 AAHSC report	**2**
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). *Ad hoc* Group to provide Commission with draft chapter.	Second *ad hoc* Group meeting to continue work in 2027.	Refer to Sept 2026 AAHSC report	**2**
Ch. 6.2.	Principles for responsible and prudent use of antimicrobial agents in aquatic animals	*Ad hoc* Group provided Commission with draft chapter.	Circulated for comments.	Refer to Sept 2026 AAHSC report (Feb 2026/2)	**1**
Section 7	Welfare of farmed fish	Commission reviewed report on current science for welfare of farmed fish and Member feedback on papers.	Considered Member feedback on papers prepared by an expert consultant	Refer to Feb 2026 AAHSC report	**1**
Ch. 8.1.	Infection with *Batrachochytrium dendrobatidis*	Update the susceptible species list in each chapter following an assessment against the criteria outlined in Ch. 1.5. 'Criteria for listing species as susceptible to infection with a specific pathogen'.	First *ad hoc* Group meeting convened in August 2026, will continue work in 2027.	Refer to Sept 2026 AAHSC report	**2**

Chapter	Subject	Summary of the work	Status – February 2026		
			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'.	First *ad hoc* Group meeting convened in August 2026, will continue work in 2027.	Refer to Sept 2026 AAHSC report	**3**
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'.	First *ad hoc* Group meeting convened in August 2026, will continue work in 2027.	Refer to Sept 2026 AAHSC report	**3**
Disease-specific chapters	Model Article X.X.7.	Revise article on freedom of compartments to reflect revisions on Chapter 4.3.	Circulated for comments	Refer to Sept 2026 AAHSC report (Feb 2026/2)	**1**
Aquatic Manual					
Disease-specific chapters	Case definition	Develop principles and framework for development and application of case definition across listed diseases	Ongoing work	Refer to Sept 2026 AAHSC report	**1**
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, experts to be consulted on draft revised chapter.	Refer to Sept 2026 AAHSC report	**1**
Ch. 2.1.0.	General Information	To create an introductory chapter on amphibians.	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. No reference laboratory expert so consider if *ad hoc* Group on susceptibility (amphibians) could update chapter.	Refer to Sept 2026 AAHSC report	**3**
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'.	First *ad hoc* Group meeting convened in August 2026, will continue work in 2027.	Refer to Sept 2026 AAHSC report	**2**

Chapter	Subject	Summary of the work	Status – February 2026		
			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'.	First *ad hoc* Group meeting convened in August 2026, will continue work in 2027.	Refer to Sept 2026 AAHSC report	**3**
Ch. 2.1.3.	Infection with *Ranavirus* species	Update the chapter to the new template for disease-specific chapter.	Not started. Consider if *ad hoc* Group on susceptibility (amphibians) could update chapter.	Refer to Sept 2026 AAHSC report	**3**
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'.	First *ad hoc* Group meeting convened in August 2026, will continue work in 2027.	Refer to Sept 2026 AAHSC report	**3**
Ch. 2.1.3.	Infection with *Ranavirus* species	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
Ch. 2.2.1	Acute hepatopancreatic necrosis disease	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
Ch. 2.2.3	Infection with Decapod iridescent virus 1	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
Ch. 2.2.5.	Infection with infectious hypodermal and haematopoietic necrosis virus	Expert consultation to update EVE in chapter.	Expert consultation	Refer to Sept 2026 AAHSC report	**1**
Ch. 2.2.9	Infection with white spot syndrome virus	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
Ch. 2.3.1	Infection with Aphanomyces invadans	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
Ch. 2.3.2	Infection with epizootic haematopoietic necrosis virus	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
Ch. 2.3.3	Infection with Gyrodactylus salaris	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**

Chapter	Subject	Summary of the work	Status – February 2026		
			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 presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 AAHSC report	**2**
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. *Ad hoc* Group provided Commission with draft chapter.	First circulation for comments	Refer to Sept 2026 AAHSC report (Sept 2026/1)	**1**
Ch. 2.3.8	Infection with salmonid alphavirus	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sept 2026 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	Circulation for comments	Refer to Sept 2026 AAHSC report (Feb 2026/2)	**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	Circulation for comments	Refer to Sept 2026 AAHSC report (Feb 2026/2)	**1**
Ch. 2.4.1	Infection with abalone herpesvirus	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sep 2026 AAHSC report	**2**
Ch. 2.4.2.	Infection with *Bonamia exitiosa*	Update the case definition	Circulation for comments	Refer to Sept 2026 AAHSC report (Sep 2025/3)	**1**
Ch. 2.4.3.	Infection with *Bonamia ostreae*	Update the case definition	Circulation for comments	Refer to Sept 2026 AAHSC report (Sep 2025/3)	**1**
Ch. 2.4.3.	Infection with *Bonamia ostreae*	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sep 2026 AAHSC report	**2**
Ch. 2.4.4.	Infection with *Merteilia refringens*	Update the case definition	Circulated for comments	Refer to Sept 2026 AAHSC report (Sep 2025/2)	**1**
Ch. 2.4.4.	Infection with *Merteilia refringens*	Update presentation of PCR methods to align with recently adopted chapters	Preparatory work	Refer to Sep 2026 AAHSC report	**2**
Ch. 2.4.5.	Infection with *Perkinsus marinus*	Update the case definition	Preparatory work	Refer to Sept 2026 AAHSC report	**1**
Ch. 2.4.6.	Infection with *Perkinsus olseni*	Update the case definition; Update PCR standards	Preparatory work	Refer to Sept 2026 AAHSC report	**1**

Chapter	Subject	Summary of the work	Status – February 2026		
			Stage of consideration	Remarks (Month when draft text first circulated for comment /# of rounds for comment)	Priority order *
Ch. 2.4.7.	Infection with *Xenohaliotis californiensis*	Update the case definition	Preparatory work	Refer to Sept 2026 AAHSC report	**1**
Disease specific	Update of tables 2.2.1. and 2.2.2. of susceptible species	Review susceptible species tables. Establish standing expert groups/ *ad hoc* Groups to review susceptibility	Ongoing (amphibians) Preparatory work (crustaceans, fish, molluscs)	Refer to Sept 2026 AAHSC report.	**2**

* 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
UG	User's Guide
Ch	Chapter
HQ	WOAH Headquarters
EVE	Endogenous Viral Element
AAHSC	Aquatic Animal Health Standard Commission
TCC	Terrestrial Animal Health Standards Commission

Annex 5. Item 5.1. – Glossary – Self-declaration of freedom from disease

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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GLOSSARY

[…]

SELF-DECLARATION OF FREEDOM FROM DISEASE

means declaration by the *Veterinary Authority* ~~*Competent Authority*~~ of the Member Country concerned that the country, *zone* or c*ompartment* is free from a listed disease based on implementation of the provisions of the *Aquatic Code* and the *Aquatic Manual*. ~~[NOTE: The Member Country is encouraged to inform WOAH of its claimed status and WOAH may publish the claim but publication does not imply WOAH endorsement of the claim.]~~

[…]

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Annex 6. Item 5.2. – Chapter 1.1. 'Notification of diseases, and provision of epidemiological information'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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CHAPTER 1.1.

NOTIFICATION OF DISEASES, AND PROVISION OF EPIDEMIOLOGICAL INFORMATION

Article 1.1.1.

Purpose

For the purposes of the *Aquatic Code* and in terms of Articles 5, 9 and 10 of the Organic Statutes of the Office international des Epizooties, Member Countries shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its *territory* or *territories*.

All *notifications* and all information sent by WOAH to the *Veterinary Authority* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to WOAH by the *Veterinary Authority* shall be regarded as having been sent by the country concerned.

Article 1.1.2.

General requirements

1) Member Countries shall make available to other Member Countries, through WOAH, whatever information is necessary to minimise the spread and to assist in achieving better worldwide prevention and control ~~impact~~ of important *diseases* of *aquatic animals* ~~and their *pathogenic agents* and to assist in achieving better worldwide control of these *diseases*~~.

2) To achieve this, Member Countries shall comply with the *notification* requirements specified in Articles 1.1.3. and 1.1.4.

3) For the purposes of this chapter an 'event' means a single *outbreak* or a group of epidemiologically related *outbreaks* of a given *disease* that is the subject of a *notification*. An event is specific to a *pathogenic agent*~~pathogen~~ and variant thereof ~~strain~~, as~~when~~ appropriate, and includes all related *outbreaks* reported from the time of the immediate *notification* through to the final report. *Notification* ~~R~~reports of an event include the taxonomic name of the *aquatic animal* host ~~*susceptible species*~~, approximate number and geographical distribution of affected *aquatic animals* and the relevant *epidemiological units*.

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

4~~5~~) The detection of the *pathogenic agent* of a *listed disease* in an *aquatic animal* shall~~should~~ be notified~~reported~~, even in the absence of clinical signs. ~~Recognising that scientific knowledge concerning the relationship between *pathogenic agents* and clinical *disease* is constantly developing and that the presence of an infectious agent does not necessarily imply the presence of clinical *disease*, Member Countries shall ensure through their *notification* reports that they comply with the spirit and intention of point 1 above~~.

5~~6~~) In addition to notifying events~~findings~~ in accordance with Article 1.1.3. and 1.1.4., Member Countries shall also provide information on the measures taken to prevent the spread of *listed diseases* and *emerging diseases*. Such information shall include whether the event pertains to a specific *zone or compartment*. Information shall include *biosecurity* and *sanitary* ~~*quarantine*~~ *measures*, including vaccinations and restrictions applied to the movement of *commodities*~~*aquatic animals*, *aquatic animal products*, *biological products*~~ and fomites ~~other miscellaneous objects~~ which could ~~by their nature~~ be responsible for

transmission of *disease*. In the case of *diseases* transmitted by *vectors*, the measures taken against such *vectors* shall also be described ~~specified~~.

6~~7~~) The *Headquarters* shall communicate to *Veterinary Authorities* all notifications received as provided in this article and Articles 1.1.3. and 1.1.4. and other relevant information.

Article 1.1.3.

Notification of listed diseases

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

1) in accordance with Chapter 1.3., Article 1.1.2. and the definition of the *listed disease* ~~relevant provisions~~ in the disease-specific chapters, *notification*, through the World Animal Health Information System (WAHIS) or other electronic correspondence under the responsibility ~~authority~~ of the Delegate ~~by fax or e-mail~~ within 24 hours of the confirmation of any of the following events:

   a) first occurrence of a *listed disease* in a country, ~~a~~ *zone* or ~~a~~ *compartment*;

   b) recurrence of a *listed disease* in a country, ~~a~~ *zone* or ~~a~~ *compartment* ~~following the final report that declared the last event~~*outbreak* ~~ended~~;

   c) first occurrence of a *listed disease* caused by ~~due to~~ a new variant~~strain~~ of a *pathogenic agent* ~~of a *listed disease*~~ in a country, ~~a~~ *zone* or ~~a~~ *compartment*;

   d) recurrence of a *listed disease* due to an eradicated variant of a *pathogenic agent* in a country, *zone* or *compartment* ~~following the final report that declared the last event ended~~;

   e) a sudden and unexpected change in the geographical distribution or increase in ~~*incidence* or virulence of, or~~ morbidity or mortality ~~caused by the *pathogenic agent*~~ of a *listed disease*, present within a country, a *zone* or a *compartment*;

   f) occurrence of a *listed disease* in a ~~new~~ host species not listed as a *susceptible species* in the relevant disease-specific chapter;

2) weekly reports subsequent to a *notification* under point 1 above, to provide further information on the evolution of the event which justified the *notification*. These reports shall~~should~~ continue until either the *disease* has been eradicated or the event is considered by the relevant *Competent Authority* as being stable which means its incidence, morbidity, mortality ~~and~~ or geographic spread have stabilised. In the latter situation, ~~the situation has become sufficiently stable so that six-monthly reporting under~~ point 3 shall apply. ~~will satisfy the obligation of the Member Country.~~ A final report shall be submitted for~~For~~ each event notified, once the *disease* has been eradicated, or is considered stable ~~and for both situations (eradication and stabilization), a final report shall~~~~should be submitted~~;

3) six-monthly reports on the absence or presence and evolution of *listed diseases* and epidemiological information relevant to minmise the spread and to assist in achieving better worldwide prevention and control of important *aquatic animal diseases* ~~of epidemiological significance to other Member Countries~~;

4) annual reports concerning any other information of significance to other Member Countries.

Article 1.1.4.

Notification of emerging diseases

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

1) a *notification* through WAHIS or by electronic correspondence ~~under the authority of the Delegate~~ ~~fax or email~~, when an *emerging disease* event has occurred in a country~~, a *zone* or a *compartment*~~;

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

   ~~a)~~ for the time necessary for the *Veterinary Authority* to ~~have reasonable~~ ~~reasonably~~ demonstrate ~~certainty~~ that:

a)~~i)~~ the *disease* has been eradicated; or

b)~~ii)~~ its incidence, morbidity, mortality and geographic spread have stabilised; in which case ~~this situation~~ information shall continue to be sent every ~~through the~~ six months~~ly reports~~;~~the situation has become stable~~;

~~OR~~

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

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

~~The requirements for notification of an *emerging disease* will continue until sufficient scientific information is available to determine whether it meets the criteria for inclusion in the WOAH list as described in Chapter 1.2.~~

Article 1.1.5.

Other important animal health information

~~1)~~ Although Member Countries are only required to notify *listed diseases* and *emerging diseases*, they are encouraged to provide WOAH with other important *aquatic animal* health information such as findings of variants of *pathogenic agents* of *listed diseases* that are not included in the definition of the *disease*, or findings of non-listed diseases of interest to Member Countries.

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

Annex 7. Item 5.3. Articles 1.4.4., 1.4.10., 1.4.13. and 1.4.14. of Chapter 1.4. Aquatic animal disease surveillance

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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CHAPTER 1.4.

AQUATIC ANIMAL DISEASE SURVEILLANCE

[...]

Article 1.4.4.

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

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

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

1) the scope of the declaration, i.e. the specific *disease*, the level of freedom (country, *zone* or *compartment*) and the pathway utilised to claim or return to *disease* freedom;

2) information to verify that *basic biosecurity conditions* and the requirements of *surveillance* systems have been met;

3) details of the *surveillance* design and assumptions;

4) the *surveillance* analysis and results;

5) the measures implemented to maintain freedom.

6) for a dependent *compartment*, the *risk analysis* referred to in Chapter 4.3., and the relevant *biosecurity* conditions which must be applied to ensure the integrity of that dependent *compartment*.

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

An *outbreak* in a Member Country, a *zone* or a *compartment* having a self-declared free status results in the loss of the self-declared free status. An outbreak in an *aquaculture establishment* or in a wild population, which is epidemiologically connected to a dependent *compartment* may ~~as described in Chapter 4.3., will~~ result in the loss of the compartment's self-declared free status as described in Chapter 4.3. The notification of an *outbreak* in a country, *zone* or *compartment* for which a *self-declaration of freedom* has been made, will result in an update of the WOAH website concerning the original declaration. A Member Country wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this chapter.

[...]

Article 1.4.10.

Required periods for targeted surveillance

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

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

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

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

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

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

For a country or *zone* to regain freedom in accordance with pathway 4, the required period of *targeted surveillance* specified in the disease-specific chapter of the *Aquatic Code* will be consistent with ~~the original self-declaration of freedom~~ the period required to establish freedom through pathway 3.

For *compartments*, the minimum default period that *targeted surveillance* should occur prior to a *self-declaration of freedom from disease* is one year; *targeted surveillance* constitutes the internal *surveillance* of both independent and dependent *compartments* as described in Article 4.3.6. This shorter period for a *compartment* reflects the more clearly defined populations, the *biosecurity* required to maintain its population's health status and a likely narrower variation in environmental variables. However, a different period (more than one year) may be stipulated in the disease-specific chapter of the *Aquatic Code* if warranted by the epidemiology of the *disease* and the criteria proposed above. For example, different requirements may be appropriate where *susceptible species* have a three-year production cycle, versus one that has a six-month production cycle; particularly if the *disease* is likely to occur at a very low *prevalence* until near the end of the production cycle.

For independent *compartments* as described in Chapter 4.3. to regain freedom in accordance with pathway 4, the required period of *targeted surveillance* specified in the disease-specific chapter of the *Aquatic Code* may be less than the period required to establish freedom through pathway 3 ~~the original declaration of freedom (~~dependingent on the nature of the specific *disease* ~~and as specified in the relevant disease-specific chapter)~~. However, at least one survey in the *compartment* is required to demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective.

For dependent *compartments* as described in Chapter 4.3. to ~~return to disease~~ regain freedom in accordance with Ppathway 4, the required period of *targeted surveillance* specified in the disease-specific chapter of the *Aquatic Code*, will be consistent with ~~the original *self-declaration of freedom from disease*~~ the period required to establish freedom through pathway 3 (i.e. a shorter period of time is not permitted).

[...]

Article 1.4.13.

Pathway 3 – Targeted surveillance

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

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

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

Requirements for targeted surveillance

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

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

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

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

Other sources of data

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

For dependent *compartments* ~~whose *disease* free status is dependent on the *disease* status of the surrounding environment,~~ as described in Chapter 4.3., external surveillance is required. External *surveillance* informs *risk analysis* and supports decisions on the adequacy of *biosecurity* ~~and internal *surveillance* measures for the *compartment*~~, but does not itself constitute evidence of disease freedom for the *compartment*, which is determined by internal *surveillance*. In accordance with the outcome of the *risk*~~*assessment analysis*~~, *surveillance* in other *aquaculture establishments* in the shared water body may constitute or contribute to the required external *surveillance*.

Article 1.4.14.

Pathway 4 – Returning to freedom

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

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

For a country, *zone* or *compartment*, a self-declaration utilising this pathway should provide information on the process employed to review and update *basic biosecurity conditions*. This information should also address the outcomes of the review and any relevant *sanitary measures* implemented to strengthen *basic biosecurity conditions*. *Targeted surveillance* to regain freedom should commence only after the extent of the outbreak has been determined, the boundaries of the *infected zones* and *protection zones* have been established, where applicable, and the relevant *disease* control and *sanitary measures* have been implemented.

Independent *compartments*~~*Compartments*~~ are able to return to freedom relatively rapidly; however, a minimum period of time is required as specified in each disease-specific chapter of the *Aquatic Code* to demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective. Dependent *compartments* may only return to freedom under ~~the~~ *surveillance* requirements ~~will be~~ consistent with the period required to establish freedom through pathway 3 ~~the original *self-declaration of freedom from disease*~~ (i.e. a shorter period of time is not permitted).

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

1. Infected zone and protection zone

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

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

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

2. Requirements for targeted surveillance in a country or zone

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

   a) establishments which have been restocked following depopulation;

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

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

   It is recommended that at least two negative surveys are conducted prior to reclaiming freedom. The second survey should start at least three months after completion of the first survey. Surveys should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. If there are

breaks in production, the surveys should also ideally span two production cycles. The number of *aquaculture establishments* and the samples taken per establishment in each survey should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected if present above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence). If *disease* is detected in wild populations of *susceptible species* and eradication is not possible, the country or *zone* remains infected.

3. Requirements for targeted surveillance in a compartment

Once the affected *aquaculture establishment*(s) ~~infected populations~~ have been depopulated and ~~affected *aquaculture establishments*~~ relevant *biosecurity* measures have been applied including disinfection ~~disinfected~~, as described in Chapter 4.4. and fallowed as described in Chapter 4.7.~~,~~ for a period determined by the biophysical properties of the *pathogenic agent* (i.e. survival in the environment), the *compartment* can be restocked.

In the case of an independent *compartment*, a~~A~~ single survey is required following restocking to demonstrate that eradication has been successful. The survey should be undertaken at least six~~th~~ months~~,~~ (or at the maximum length of time allowed by the production cycle ~~of species~~ if it is less than six months), after the *aquaculture establishment* has been restocked to ensure that the reviewed *basic biosecurity conditions* are effective. The survey should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. The number of holding *units* (e.g. ponds, tanks) and the animals per holding *unit* sampled should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

In the case of a dependent *compartment*, it is recommended that at least two negative surveys are conducted within one year in each *aquaculture establishment* which comprises the *compartment*, prior to reclaiming freedom. The second survey should start at least three months after completion of the first survey. Surveys should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. If there are breaks in production, the surveys should also ideally span two production cycles. If external *surveillance* detects infection in wild populations of *susceptible species* and eradication is not possible, the disease-free status of the *compartment* cannot be reinstated.

[...]

Annex 8. Item 5.4. Chapter 4.3. 'Application of compartmentalisation'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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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. It provides a framework for the development of requirements for *compartments* based on *risk analysis* and to support bilateral negotiation between Member Countries ~~that is based on *risk analysis*~~.

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 under the control of a single operator 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.

The *Veterinary Authority* ~~A *Competent Authority*~~ can make a *self-declaration of freedom from disease* for a *compartment* from specified *listed disease(s)* ~~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 and maintaining 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 have ~~ensure there are~~ effective measures (established through *risk analysis*) to prevent the entry ~~or spread~~ of *pathogenic agents* ~~from the external environments~~ into the *compartment* (i.e. to provide functional epidemiological separation between the *compartment* and infected populations);

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 independent from dependent on the *disease* status of the surrounding water body environment or those with disease-free status that is dependent on independent from the *disease* status of the surrounding water body environment, as described in Article 4.3.4.) and *biosecurity* and *surveillance* measures should be appropriate for the category of *compartment*~~ *Compartments* are categorised as independent or dependent based on their hydrological connection with the surrounding water body, with *biosecurity* and *surveillance* measures appropriate for the category, in accordance with 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 disease-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 the *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) *Competent Authority* ~~Official oversight~~ responsibilities must be clearly documented, including approval by the *Competent Authority*, an auditing schedule, underpinning regulatory instruments and approving~~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 a~~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 and *aquaculture establishments* that comprise the *compartment* 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 water body ~~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 water body ~~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 identified through *risk analysis* and ~~complete~~ epidemiological separation from the surrounding water body~~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* have a hydrological connection to ~~do not have complete epidemiological separation from~~ the surrounding water body ~~environment~~ but *risk management* measures or conditions exist which create a functional ~~an effective~~ disease-specific separation between the *compartment* and infected~~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:

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

2~~b~~) are dependent on the health status of the surrounding water~~s~~ body;

3~~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~~;

4~~d~~) meet the additional *biosecurity* and *surveillance* requirements to mitigate transmission *risk* from the surrounding water body ~~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. including the requirements for *risk analysis* as described in Article 4.1.8.

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*~~, declared free from *diseases* for which the *compartment* has been established, and any of international origin should be~~and in the case of international movements are~~ certified in accordance with Chapter 5.1.

For all categories of *compartments*, the required *risk analysis* should consider the likelihood and severity of extreme weather events (e.g. high rainfall, flood, storm surge, high wind) and other extreme environmental events (e.g. bush fires, earthquake) on the integrity of the *compartment*.

For dependent *compartments*, the *risk analysis* described below ~~in Article 4.3.4.~~4.1.8. should assess ~~include the assessment of~~ *risks* within the water body~~environment~~ surrounding the *compartment*. The geographic scope of the *risk analysis* and development of appropriate *risk management* and *surveillance* should be informed by the factors below. ~~to inform and the development of appropriate *risk management* and *surveillance* measures to mitigate *disease* transmission from the environment. The *risk*~~*Risk management* ~~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)* including the stability or viability of the *pathogenic agent* outside of the host;

2) presence~~absence~~ of *susceptible species* ~~and pathways of exposure~~*infection* in the surrounding ~~environment~~ water body and the probability of exposure to the *pathogenic agent(s),* due to ~~geographical location, environmental conditions or the application of *biosecurity* measures. Specific consideration should be given to~~:

   a) the hydrological conditions ~~in~~of the surrounding water body;

   b) the geographical location of each *aquaculture establishment* comprising the dependent *compartment* ~~and the nature of their the water supply~~;

   c) the nature of the water supply of the *aquaculture establishments* referred to in point b);

   d~~c~~) the health status of other *aquaculture establishments* containing *susceptible species* within the surrounding ~~shared~~ water body ~~system~~ and their source of *aquatic animals*, location and method of production;

   e~~d~~) proximity of~~the location of the *aquaculture establishments* referred to in point (c) or~~ processing facilities, their *biosecurity* measures including effluent management ~~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~~e~~f) the presence and abundance of wild *susceptible species* in the surrounding water body ~~and their health status~~;

   g~~f~~g) ~~the details of~~ whether the *susceptible species* referred to in point (e~~f~~) are sedentary or migratory and their natural distribution and migratory movement patterns;

hgh) the ability to excludethe exclusion of the wild *aquatic animals* referred to in point (ef) from entering the *compartment*;

ihi) the general *biosecurity* measures applied in *aquaculture establishments* and processing facilities in the surrounding shared water body;

j) environmental conditions conducive to *infection* (e.g. temperature and salinity)

k) presence of wild non-aquatic animals, such as birds, that may act as *vectors* for *disease* transmission

3) presenceabsence of *infection* in any nearby populations of *susceptible species* demonstrated by appropriate external *surveillance*;

4) additional internal *targeted surveillance* (i.e. in the *aquaculture establishment(s)* that comprise the *compartment*).

WhereFor some semi-closed *aquaculture establishments*, it ismay not be possible to mitigate identified *risks* from the water body surrounding the a semi-closed *aquaculture establishment* 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*, and 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 *pathogenic agent* of 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. offor populations of *susceptible species* within a *compartment*) is required to make a *self-declaration of freedom from disease* for both independent and dependent *compartments* as described in the relevant disease-specific chapters and Article 1.4.4. 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. offor populations of *susceptible species* in the environment outside a *compartment*) is used to evaluate *risk* presented to the *compartment* by the surrounding water body. It 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 and/or targeted based on the specific requirements to evaluate *risk* 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 water bodyenvironment surrounding the *compartment*. The *surveillance* should be developed taking into account the factors described in Article 4.3.5., and should be used at a level sufficient to inform the *risk analysis* as described in Article 4.3.4. 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 located 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*.

~~If the *pathogenic agent* is detected in the surrounding water body of the dependent *compartment* the *Competent Authority* should notify the operator of the compartment and assess the risk of *disease* exposure to the *compartment* and the surrounding water body. If *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease free status of the *compartment*.~~

~~Where the disease free status of a dependent *compartment* is conditional on its location within a *free zone* or *free country*, and the disease free status of the *free zone* or *free country* is lost, the *Competent Authority* should assess the risk of disease exposure to the *compartment* and the surrounding water body. If *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease free status of 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 *infection*~~*disease*~~ as described in Article 1.4.18.;

4) is independent from management and ownership structures of the *compartment*;

5) has a legal obligation to report positive test results to the *Competent Authority* in accordance with the requirements of *basic biosecurity conditions* specified in Article 1.4.6.

Article 4.3.8.

Traceability

Traceability systems ~~should apply throughout the supply chain and~~ are required to reliably differentiate *commodities* that originate from a *free compartment* from those that originate from outside a *free compartment* when a *commodity* is destined for disease-free country, *zone* or *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, production and mortality records, veterinary treatments and health investigations;

5) maintain records for a 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 for which records should be maintained should ~~be~~ meet the 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.

Competent Authority responsibilities ~~Official oversight~~

A *Competent Authority* must have the authority to approve the ~~operation of the~~ *aquaculture establishment(s)* that comprise~~compromise~~ the *compartment* to operate as a *compartment*, as well as grant, suspend and revoke the status of a *compartment*. The~~A~~ *Veterinary~~Competent~~ Authority* has ~~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*~~.

A Competent Authority~~It~~ must~~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 verifiable and readily accessible to *importing countries*. The *Competent Authority* must~~should~~ ensure ~~appropriate~~ auditing of the *compartment* is completed by trained officials or ~~accredited~~ third party auditors which are independent from the management and ownership structures of the *compartment and* approved by the *Competent Authority~~ies~~*.

The *risk analysis* shall be reviewed and updated at a frequency determined by the *Competent Authority* or immediately following any significant change in the surrounding environment that may affect the risk of *pathogenic agen*t introduction into the *compartment*.

The *Competent Authority* must reassess ~~report~~ any significant modification of the *biosecurity* and *risk management* measures identified after the final approval of ~~in~~ the *compartment* ~~that supported its initial approval~~. The *Competent ~~Veterinary~~ Authority* should ensure that any changes to the health status including suspension or revocation of the *compartment* should be notified to the *Competent ~~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. 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.

If the *disease* for which the *compartment* ~~was defined~~ is confirmed within the *compartment*, the *Competent Authority* should immediately revoke its disease-free status, notify ~~*importing countries*~~ trading partners in accordance with Article 5.1.4 and make an immediate *notification* in accordance with ~~following~~ the provisions of Chapter 1.1. ~~In the event of confirmation of the *disease* for which the *compartment* was defined, the disease-free status should immediately be suspended.~~

If the pathogenic agent is detected in the surrounding water body of a dependent *compartment*, the *Competent Authority* should notify the operator of the *compartment*, suspend the disease-free status of the *compartment* and assess the risk of *disease* exposure to the *compartment*. If effective *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease-free status of the *compartment*.

Where a disease-free dependent *compartment* is located within a *free zone* or *free country*, and the disease-free status of the *free zone* or *free country* is lost, the *Competent Authority* should suspend the disease-free status of the *compartment* and assess the risk of *disease* exposure to the *compartment*. If effective *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease-free status of the *compartment*.

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 disease-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~~ The *Competent Authority* may only re-approve the compartment and the *Veterinary Authority* may make a *self-declaration of freedom from disease* 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.

Disease freedom must be maintained in accordance with Article 1.4.15. and the relevant disease-specific chapter. ~~*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*~~

Annex 8a. Item 5.4. – Draft new Chapter 4.3. 'Application of Compartmentalisation'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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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. It provides a framework for the development of requirements for *compartments* based on *risk analysis* and to support bilateral negotiation between Member Countries ~~that is based on *risk analysis*~~.

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 under the control of a single operator 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.

The *Veterinary Authority* ~~A *Competent Authority*~~ can make a *self-declaration of freedom from disease* for a *compartment* from specified *listed disease(s)* ~~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 and maintaining 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 have ~~ensure there are~~ effective measures (established through *risk analysis*) to prevent the entry ~~or spread~~ of *pathogenic agents* ~~from the external environments~~ into the *compartment* (i.e. to provide functional epidemiological separation between the *compartment* and infected populations);

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 independent from dependent on the *disease* status of the surrounding water body environment or those with disease free status that is dependent on independent from the *disease* status of the surrounding water body environment, as described in Article 4.3.4.) and *biosecurity* and *surveillance* measures should be appropriate for the category of *compartment* *Compartments* are categorised as independent or dependent based on their hydrological connection with the surrounding water body, with *biosecurity* and *surveillance* measures appropriate for the category, in accordance with 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 disease-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 the *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) *Competent Authority* ~~Official oversight~~ responsibilities must be clearly documented, including approval by the *Competent Authority*, an auditing schedule, underpinning regulatory instruments and approving~~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 a~~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 and *aquaculture establishments* that comprise the *compartment* 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 water body ~~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 water body ~~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:~~

~~2)~~ 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 identified through *risk analysis* and ~~complete~~ epidemiological separation from the surrounding water body~~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* have a hydrological connection to ~~do not have complete epidemiological separation from~~ the surrounding water body ~~environment~~ but *risk management* measures or conditions exist which create a functional ~~an effective~~ disease-specific separation between the *compartment* and infected~~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:

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

2~~b~~) are dependent on the health status of the surrounding water~~s~~ body;

3~~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~~;

4~~d~~) meet the additional *biosecurity* and *surveillance* requirements to mitigate transmission *risk* from the surrounding water body ~~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. including the requirements for *risk analysis* as described in Article 4.1.8.

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*~~, declared free from *diseases* for which the *compartment* has been established, and any of international origin should be~~and in the case of international movements are~~ certified in accordance with Chapter 5.1.

For all categories of *compartments*, the required *risk analysis* should consider the likelihood and severity of extreme weather events (e.g. high rainfall, flood, storm surge, high wind) and other extreme environmental events (e.g. bush fires, earthquake) on the integrity of the *compartment*.

For dependent *compartments*, the *risk analysis* described below ~~in Article 4.3.4.~~4.1.8. should assess ~~include the assessment of~~ *risks* within the water body~~environment~~ surrounding the *compartment*. The geographic scope of the *risk analysis* and development of appropriate *risk management* and *surveillance* should be informed by the factors below. ~~to inform and the development of appropriate *risk management* and *surveillance* measures to mitigate *disease* transmission from the environment. The *risk*~~*Risk management* ~~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)* including the stability or viability of the *pathogenic agent* outside of the host;

2) presence~~absence~~ of *susceptible species* ~~and pathways of exposure~~*infection* in the surrounding ~~environment~~ water body and the probability of exposure to the *pathogenic agent(s),* due to ~~geographical location, environmental conditions or the application of *biosecurity* measures. Specific consideration should be given to~~:

    a) the hydrological conditions ~~in~~of the surrounding water body;

    b) the geographical location of each *aquaculture establishment* comprising the dependent *compartment* ~~and the nature of their the water supply~~;

    c) the nature of the water supply of the *aquaculture establishments* referred to in point b);

    d~~c~~) the health status of other *aquaculture establishments* containing *susceptible species* within the surrounding ~~shared~~ water body ~~system~~ and their source of *aquatic animals*, location and method of production;

    e~~d~~) proximity of~~the location of the *aquaculture establishments* referred to in point (c) or~~ processing facilities, their *biosecurity* measures including effluent management ~~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~~e~~~~f~~) the presence and abundance of wild *susceptible species* in the surrounding water body ~~and their health status~~;

    g~~f~~~~g~~) ~~the details of~~ whether the *susceptible species* referred to in point (e~~f~~) are sedentary or migratory and their natural distribution and migratory movement patterns;

hgh) the ability to excludethe exclusion of the wild *aquatic animals* referred to in point (ef) from entering the *compartment*;

ihi) the general *biosecurity* measures applied in *aquaculture establishments* and processing facilities in the surrounding shared water body;

j) environmental conditions conducive to *infection* (e.g. temperature and salinity)

k) presence of wild non-aquatic animals, such as birds, that may act as *vectors* for *disease* transmission

3) presenceabsence of *infection* in any nearby populations of *susceptible species* demonstrated by appropriate external *surveillance*;

4) additional internal *targeted surveillance* (i.e. in the *aquaculture establishment(s)* that comprise the *compartment*).

WhereFor some semi-closed *aquaculture establishments*, it ismay not be possible to mitigate identified *risks* from the water body surrounding the a semi-closed *aquaculture establishment* 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*, and 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 *pathogenic agent* of 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. offor populations of *susceptible species* within a *compartment*) is required to make a *self-declaration of freedom from disease* for both independent and dependent *compartments* as described in the relevant disease-specific chapters and Article 1.4.4. 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. offor populations of *susceptible species* in the environment outside a *compartment*) is used to evaluate *risk* presented to the *compartment* by the surrounding water body. It 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 and/or targeted based on the specific requirements to evaluate *risk* 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 water bodyenvironment surrounding the *compartment*. The *surveillance* should be developed taking into account the factors described in Article 4.3.5., and should be used at a level sufficient to inform the *risk analysis* as described in Article 4.3.4. 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 located 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*.

~~If the *pathogenic agent* is detected in the surrounding water body of the dependent *compartment* the *Competent Authority* should notify the operator of the compartment and assess the risk of *disease* exposure to the *compartment* and the surrounding water body. If *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease free status of the *compartment.*~~

~~Where the disease free status of a dependent *compartment* is conditional on its location within a *free zone* or *free country*, and the disease free status of the *free zone* or *free country* is lost, the *Competent Authority* should assess the risk of disease exposure to the *compartment* and the surrounding water body. If *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease free status of 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 *infection*~~*disease*~~ as described in Article 1.4.18.;

4) is independent from management and ownership structures of the *compartment*;

5) has a legal obligation to report positive test results to the *Competent Authority* in accordance with the requirements of *basic biosecurity conditions* specified in Article 1.4.6.

Article 4.3.8.

Traceability

Traceability systems ~~should apply throughout the supply chain and~~ are required to reliably differentiate *commodities* that originate from a *free compartment* from those that originate from outside a *free compartment* when a *commodity* is destined for disease-free country, *zone* or *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, production and mortality records, veterinary treatments and health investigations;

5) maintain records for a 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 for which records should be maintained should ~~be~~ meet the 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.

Competent Authority responsibilities ~~Official oversight~~

A *Competent Authority* must have the authority to approve the ~~operation of the~~ *aquaculture establishment(s)* that comprise~~compromise~~ the *compartment* to operate as a *compartment*, as well as grant, suspend and revoke the status of a *compartment*. The~~A~~ *Veterinary~~Competent~~ Authority* has ~~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*~~.

A Competent Authority~~It~~ must~~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 verifiable and readily accessible to *importing countries*. The *Competent Authority* must~~should~~ ensure ~~appropriate~~ auditing of the *compartment* is completed by trained officials or ~~accredited~~ third party auditors which are independent from the management and ownership structures of the *compartment and* approved by the *Competent Authority~~ies~~*.

The *risk analysis* shall be reviewed and updated at a frequency determined by the *Competent Authority* or immediately following any significant change in the surrounding environment that may affect the risk of *pathogenic agen*t introduction into the *compartment*.

The *Competent Authority* must reassess ~~report~~ any significant modification of the *biosecurity* and *risk management* measures identified after the final approval of ~~in~~ the *compartment* ~~that supported its initial approval.~~ The *Competent ~~Veterinary~~ Authority* should ensure that any changes to the health status including suspension or revocation of the *compartment* should be notified to the *Competent ~~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. 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.

If the *disease* for which the *compartment* ~~was defined~~ is confirmed within the *compartment*, the *Competent Authority* should immediately revoke its disease-free status, notify ~~*importing countries*~~ trading partners in accordance with Article 5.1.4 and make an immediate *notification* in accordance with ~~following~~ the provisions of Chapter 1.1.~~In the event of confirmation of the *disease* for which the *compartment* was defined, the disease-free status should immediately be suspended.~~

If the pathogenic agent is detected in the surrounding water body of a dependent *compartment*, the *Competent Authority* should notify the operator of the *compartment*, suspend the disease-free status of the *compartment* and assess the risk of *disease* exposure to the *compartment*. If effective *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease-free status of the *compartment*.

Where a disease-free dependent *compartment* is located within a *free zone* or *free country*, and the disease-free status of the *free zone* or *free country* is lost, the *Competent Authority* should suspend the disease-free status of the *compartment* and assess the risk of *disease* exposure to the *compartment*. If effective *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease-free status of the *compartment*.

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 disease-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~~ The *Competent Authority* may only re-approve the compartment and the *Veterinary Authority* may make a *self-declaration of freedom from disease* 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.

Disease freedom must be maintained in accordance with Article 1.4.15. and the relevant disease-specific chapter. ~~*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.~~

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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 for *disease* prevention and control. It provides a framework for the development of requirements for *compartments* based on *risk analysis* and to support bilateral negotiation between Member Countries.

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 - *aquaculture establishments* that operate under a common set of *risk management* measures under the control of a single operator in accordance with this chapter.

Compartmentalisation provides an opportunity for the operator to demonstrate *disease* freedom – including in circumstances where alternatives such as *country* or *zone* freedom may not be feasible or cost-effective. Investment by the operator and oversight by the relevant *Competent Authorities* are- essential.

The *Veterinary Authority* can make a *self-declaration of freedom from disease* for a *compartment* from specified *listed disease(s)* 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 and maintaining 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 have effective measures (established through *risk analysis*) to prevent the entry of *pathogenic agents* into the *compartment* (i.e. to provide functional epidemiological separation between the *compartment* and infected populations);

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) *Compartments* are categorised as independent or dependent based on their hydrological connection with the surrounding water body, with *biosecurity* and *surveillance* measures appropriate for the category, in accordance with 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 disease-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* must be supported by reliable laboratory testing services which have independence from the *compartment* operator and which are approved by the *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) *Competent Authority* responsibilities must be clearly documented, including approval by the *Competent Authority*, an auditing schedule, underpinning regulatory instruments and approving 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 a *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.

Purpose 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, the species produced and *aquaculture establishments* that comprise the *compartment* should be clearly defined.

Article 4.3.4.

Independent and dependent compartments

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

Independent compartments

Independent *compartments* have epidemiological separation from the surrounding water body and are characterised by appropriate levels of physical and management measures to maintain effective *biosecurity*.

Independent *compartments* have the following characteristics:

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

2) have control over all transmission pathways identified through *risk analysis* and epidemiological separation from the surrounding water body;

3) 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.

Dependent compartments

Dependent *compartments* have a hydrological connection to the surrounding water body but *risk management* measures or conditions exist which create a functional disease-specific separation between the *compartment* and infected *aquatic animal* populations. 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:

1) are semi-open or semi-closed production system types (as described in Chapter 4.1.);

2) are dependent on the health status of the surrounding water body;

3) have appropriate levels of *biosecurity* and *surveillance* to mitigate the *risk* of introduction of the *pathogenic agent(s)* (for which the *compartment* has been established) in accordance with Article 4.3.5.;

4) meet the additional *biosecurity* and *surveillance* requirements to mitigate transmission *risk* from the surrounding water body as informed by a *risk analysis* in accordance with Article 4.3.5.

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 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.

Article 4.3.5.

Biosecurity and risk management 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. including the requirements for *risk analysis* as described in Article 4.1.8.

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* across all elements of the *compartment*.

The *Competent Authority* should require that all movements of *aquatic animals* into a *free compartment* originate from a *country, zone* or *compartment,* declared free from *diseases* for which the *compartment* has been established, and any of international origin should be certified in accordance with Chapter 5.1.

For all categories of *compartments*, the required *risk analysis* should consider the likelihood and severity of extreme weather events (e.g. high rainfall, flood, storm surge, high wind) and other extreme environmental events (e.g. bush fires, earthquake) on the integrity of the *compartment*.

For dependent *compartments*, the *risk analysis* described below should assess *risks* within the water body surrounding the *compartment*. The geographic scope of the *risk analysis* and development of appropriate *risk management* and *surveillance* should be informed by the factors below. *Risk management* 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*.

At a minimum, the following factors should be addressed within the *risk analysis:*

1) characteristics of the *pathogenic agent(s)* including the stability or viability of the *pathogenic agent* outside of the host;

2) presence of *susceptible species* in the surrounding water body and the probability of exposure to the *pathogenic agent(s),* due to:

    a) the hydrological conditions of the surrounding water body;

    b) the geographical location of each *aquaculture establishment* comprising the dependent *compartment*;

    c) the nature of the water supply of the *aquaculture establishments* referred to in point b);

    d) the health status of other *aquaculture establishments* containing *susceptible species* within the surrounding water body and their source of *aquatic animals*, location and method of production;

e) proximity of processing facilities, their *biosecurity* measures including effluent management*;*

f) the presence and abundance of wild *susceptible species* in the surrounding water body;

g) whether the *susceptible species* referred to in point (f) are sedentary or migratory and their natural distribution and migratory movement patterns;

h) the ability to exclude the wild *aquatic animals* referred to in point (f) from entering the *compartment*;

i) the general *biosecurity* measures applied in *aquaculture establishments* in the surrounding water body;

j) environmental conditions conducive to *infection* (e.g. temperature and salinity);

k) presence of wild non-aquatic animals, such as birds, that may act as *vectors* for *disease* transmission;

3) presence of *infection* in any nearby populations of *susceptible species* demonstrated by appropriate external *surveillance*.

Where it is not possible to mitigate *risks* from the water body surrounding the *aquaculture establishment* (e.g. presence of *disease* in adjacent wild populations of *susceptible species*), 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*, the period that *targeted surveillance* should be conducted prior to making a *self-declaration of freedom from disease,* and the requirements to maintain freedom.

If there is an increased *risk* of exposure to the *pathogenic agent* of 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. 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* as described in the relevant disease-specific chapters and Article 1.4.4. 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. of populations of *susceptible species* in the environment outside a *compartment*) is used to evaluate *risk* presented to the *compartment* by the surrounding water body. It 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 and/or targeted based on the specific requirements to evaluate *risk* in accordance with Chapter 1.4.

For dependent *compartments*, external *surveillance* is required if populations of *susceptible species* are present in the water body surrounding the *compartment*. The *surveillance* should be developed taking into account the factors described in Article 4.3.5., and should be used to inform the *risk analysis* as described in Article 4.3.4. 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* located 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) conducts testing in accordance with the recommendations of the *Aquatic Manual*;

3) can confirm or exclude cases of *infection* 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 are required to reliably differentiate *commodities* that originate from a *free compartment* from those that originate from outside a *free compartment* when a *commodity* is destined for disease-free country, *zone* or *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;

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, production and mortality records, veterinary treatments and health investigations;

5) maintain records for a sufficient period of time to inform tracing, recall or emergency response if a *disease* were detected within the *compartment* or in *commodities* originating from the *compartment*. The period for which records should be maintained should meet the 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.

Competent Authority responsibilities

A *Competent Authority* must have the authority to approve the *aquaculture establishment(s)* that comprise the *compartment* to operate as a *compartment*, as well as grant, suspend and revoke the status of a *compartment*. The *Veterinary Authority* has the authority to make a *self-declaration of freedom from disease* as described in Chapter 1.4.

A Competent Authority must 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 verifiable and readily accessible to *importing countries*. The *Competent Authority* must ensure auditing of the *compartment* is completed by trained officials or third party auditors which are independent from the management and ownership structures of the *compartment and* approved by the *Competent Authority*.

The *risk analysis* shall be reviewed and updated at a frequency determined by the *Competent Authority* or immediately following any significant change in the surrounding environment that may affect the risk of *pathogenic agen*t introduction into the *compartment*.

The *Competent Authority* must reassess any significant modification of the *biosecurity* and *risk management* measures identified after the final approval of the *compartment*. The *Competent Authority* should ensure that any changes to the health status including suspension or revocation of the *compartment* should be notified to the *Competent 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 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 while the occurrence of the disease is confirmed or ruled-out. 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.

If the *disease* for which the *compartment* is confirmed within the *compartment*, the *Competent Authority* should immediately revoke its disease-free status, notify trading partners in accordance with Article 5.1.4 and make an immediate *notification* in accordance with the provisions of Chapter 1.1.

If the pathogenic agent is detected in the surrounding water body of a dependent *compartment*, the *Competent Authority* should notify the operator of the *compartment*, suspend the disease-free status of the *compartment* and assess the risk of *disease* exposure to the *compartment*. If effective *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease-free status of the *compartment*.

Where a disease-free dependent *compartment* is located within a *free zone* or *free country*, and the disease-free status of the *free zone* or *free country* is lost, the *Competent Authority* should suspend the disease-free status of the *compartment* and assess the risk of *disease* exposure to the *compartment*. If effective *risk management* cannot be implemented in accordance with this chapter, the *Competent Authority* should revoke the disease-free status of the *compartment*.

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.

The *Competent Authority* may only re-approve the compartment and the *Veterinary Authority* may make a *self-declaration of freedom from disease* 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.

Disease freedom must be maintained in accordance with Article 1.4.15. and the relevant disease-specific chapter.

Annex 9. Item 5.4. Glossary definition for 'compartment'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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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 as approved by the *Competent Authority*.

~~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)*.~~

[…]

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Annex 10. Item 5.5. Model Article X.X.7. 'Compartment free from [pathogen X]' of the disease-specific chapters and Articles 10.4.9. and 10.4.10. Of 'Infection with Infectious salmon anaemia'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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CHAPTER X.X.

INFECTION WITH [PATHOGEN X]

[…]

Article X.X.7.

Compartment free from infection with [Pathogen X]

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with [Pathogen X] for a *compartment* within its *territory* if it can demonstrate that the requirements ~~of for~~ Chapter 4.3. have been met, and:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one year without detection of [Pathogen X], 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 [pathogen X] and subsequently lost its free status due to the detection of [Pathogen X] in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been ~~killed~~ depopulated and disposed of by means that minimise the likelihood of further transmission of [Pathogen X], 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 X.X.9. and X.X.10. as appropriate; and

   c) in the case of an independent *compartment* as described in Article 4.3.4., one survey for infection with [Pathogen X] has been completed at least six months after restocking (or at the maximum length of time allowed by the production cycle if it is less than six months as described in Article 1.4.14.) without detection of the *pathogenic agent*. In the case of a dependent *compartment* (also described in Article 4.3.4), the requirements of point 1 have been met without detection of the *pathogenic agent*;

OR

3) it is a dependent *compartment* which previously made a self-declaration of freedom from infection with pathogen [X] and subsequently lost its disease-free status due to the detection of pathogen [X] in the surrounding water body ~~or surrounding disease-free *zone* or *country*~~, but the following conditions have been met:

   a) *a risk analysis* has been completed which indicated that the risks relating to the detection of pathogen [X] in the surrounding waters have been managed and that the *compartment* may be effectively re-established following successful completion of points b) and c);

~~a~~b) the *compartment* has been depopulated of all *aquatic animals*, 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~~c) 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 X.X.9. and X.X.10. as appropriate; and

~~c~~d) the *targeted surveillance* and *basic biosecurity conditions* described in point 1 have been applied without detection of the *pathogenic agent.*

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA

[…]

Article 10.4.9.

Compartment free from infection with 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 the requirements of Chapter 4.3. have been met, and:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last two years without detection of 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~~ depopulated 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) in the case of an independent *compartment* as described in Article 4.3.4., 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*. In the case of a dependent *compartment* (also described in Article 4.3.4), the requirements of point 1 have been met without detection of the *pathogenic agent*;

OR

3) it is a dependent *compartment* which previously made a self-declaration of freedom from infection with ISAV and subsequently lost its disease-free status due to the detection of ISAV in the surrounding water body, but the following conditions have been met:

a) a *risk analysis* has been completed which indicated that the risks relating to the detection of ISAV in the surrounding waters have been managed and that the *compartment* may be effectively re-established following successful completion of points b) and c);

~~a~~b) the *compartment* has been depopulated of all *aquatic animals*, 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~~c) 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~~d) the *targeted surveillance* and *basic biosecurity conditions* described in point 1 have been applied without detection of the *pathogenic agent*.

Article 10.4.10.

Compartment free from infection with from infection with HPR-deleted ISAV

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

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with HPR-deleted ISAV for a *compartment* within its *territory* if it can demonstrate that the requirements of Chapter 4.3. have been met, and:

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

OR

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

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

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

   c) in the case of an independent *compartment* as described in Article 4.3.4., 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*. In the case of a dependent *compartment* (also described in Article 4.3.4), the requirements of point 1 have been met without detection of the *pathogenic agent*;

OR

3) it is a dependent *compartment* which previously made a self-declaration of freedom from infection with ISAV and subsequently lost its disease-free status due to the detection of HPR-deleted ISAV in the surrounding water body, but the following conditions have been met:

a) a *risk analysis* has been completed which indicated that the risks relating to the detection of HPR-deleted ISAV in the surrounding waters have been managed and that the *compartment* may be effectively re-established following successful completion of points b) and c);

~~a~~b) the *compartment* has been depopulated of all *aquatic animals*, 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~~c) 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~~d) the *targeted surveillance* and *basic biosecurity conditions* described in point 1 have been applied without detection of the *pathogenic agent*.

Annex 11. Item 5.6. Chapter 5.Y. 'Introduction to recommendations for international aquatic animal health certification and export and import procedures'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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SECTION 5

RECOMMENDATIONS FOR INTERNATIONAL AQUATIC ANIMAL HEALTH CERTIFICATION AND EXPORT AND IMPORT PROCEDURES

~~TRADE MEASURES, IMPORTATION/EXPORTATION PROCEDURES AND HEALTH CERTIFICATES~~

CHAPTER 5.Y.

INTRODUCTION TO RECOMMENDATIONS FOR INTERNATIONAL AQUATIC ANIMAL HEALTH CERTIFICATION AND EXPORT AND IMPORT PROCEDURES

Article 5.Y.1.

Purpose and scope

Section 5 'Recommendations for international aquatic animal health certification and export and import procedures' provides recommendations on how Member Countries' *Competent ~~Veterinary~~ Authorities* ensure safety of *international trade*~~,~~ (i.e. transboundary movements of *commodities*), taking into account Chapter 5.3. These include ~~through~~ official operational assurance including ~~through~~ international *aquatic animal* health certification and border controls, applicable to exporting, transit and importing countries. As a pillar of WOAH's mandate to improve *aquatic animal* health worldwide, this is a core responsibility of the *Aquatic Animal Health Services* of ~~WOAH~~ Member Countries.

Section 5 covers obligations and procedures for international *aquatic animal* health certification; border operational measures including communication, roles and responsibilities (for *Veterinary Authorities* and other relevant *Competent Authorities*, as well as private sector ~~for~~ operators), documentation, transportation, planning for unexpected events, and verifications/ inspections as applicable to exporting, transit and importing countries. Section 5 also covers recommendations for the operation of *frontier posts* and *quarantine* facilities~~centres~~, as well as detailed recommendations and models for the import and *aquatic animal* health certification of a range of general and specific *commodities*.

Article 5.Y.2.

International certification

Export consignments of ~~relevant~~ *commodities* should, where relevant, be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country*. This certificate provides assurances to the *importing country* regarding *aquatic animal health disease status,* traceability and the safety of the *commodities* imported and lists the *aquatic animal* health and veterinary public health requirements for the exported *commodity*. To maximise harmonisation of the sanitary aspects of *international trade*, *Competent Authorities* should base their import requirements on WOAH standards and import *risk analysis* in accordance with

Chapter 2.1. The agreed *international aquatic animal health certificate* ~~with its importing requirements~~ is the final result of sanitary negotiations between trading partners, ~~whereby confidence in the exporting (or transit) country veterinary~~ The signature of the certifying official from the exporting (or transit) country on the certificate provides confidence of the implementation of *sanitary measures* ~~attests to the performance or verification of the sanitary measures listed~~ as required by the importing (or transit) country. Border checks that match imported *commodities* to the correct, signed *international aquatic animal health certificate* before release are a key operational assurance measure to facilitate safe *international trade*.

Article 5.Y.3.

Cooperation and communication

Effective implementation of the Section 5 standards for safe *international trade* in *commodities* requires cooperation and communication between multiple actors including the *Veterinary Authorities,* other relevant *Competent Authorities* and private sector operators, ~~and~~ in each of the exporting, transit and importing countries. It is important that the *Aquatic Animal Health Services* collaborate closely with other border agencies such as customs or police to manage the risks from informal or illegal trade in *commodities*. For the purpose of Section 5, operators are defined as “any natural or legal entity or person responsible for the export, transit or import of *commodities* subject to the provisions of the respective chapters” of the *Aquatic Code*.

Article 5.Y.4

Import requirements

Standards within the~~The~~ *Aquatic Code* ~~provides standards that~~ deliver essential sanitary information, recommendations and technical guidance to trading partners ~~Member Countries~~ for the development ~~determination~~ and agreement of science-based import requirements, as reflected in certification. As per provisions of the different Sections of the *Aquatic Code*, this includes providing:

a) Transparency ~~transparency~~ through a WOAH *notification* of *listed disease(s)* and *aquatic animal health status;*

b) Guidance ~~guidance~~ on science-based import *risk-analysis* and *safe commodities;*

c) Recommendations ~~recommendations~~ on the quality of *Aquatic Animal Health Services* including those giving ~~to give~~ confidence in their certification procedures;

d) Guidance ~~guidance~~ on *aquatic animal* welfare ~~of farmed fish~~ including for trade in *aquatic animals*; and

e) Recommendations ~~recommendations~~ by *listed disease* for the safe *international trade* of various commodities.

Section 5 provides standards for the practical operation of these requirements through key assurance mechanisms including international aquatic animal health certification, border inspection and quarantine.

Annex 12. Item 5.7. Chapter 6.2. 'Responsible and prudent use of antimicrobial agents in aquatic animals'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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CHAPTER 6.2.

~~PRINCIPLES FOR~~ RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN AQUATIC ANIMALS

Article 6.2.1.

Purpose

~~These principles provide guidance for the responsible and prudent use of *antimicrobial agents* in *aquatic animals*, with the aim of protecting both animal and human health. The *Competent Authorities* responsible for the registration and marketing authorisation of products and the control of all organisations involved in the production, distribution and use of *antimicrobial agents* have specific obligations.~~

To provide recommendations for the responsible and prudent use of *antimicrobial agent*s in veterinary medicine for treatment, prevention and control of *diseases* in *aquatic animals* for human consumption (food-producing *aquatic animal*s) and for other purposes (non-food producing *aquatic animals*), with the aim of protecting both animal and human health as well as minimising and containing antimicrobial resistance *risks* in the relevant aquatic environment, as part of a One Health approach.

Article 6.2.2.

~~**Objectives of responsible and prudent use**~~

~~Responsible and prudent use includes a set of practical measures and recommendations intended to reduce the *risk* associated with the selection and dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants in *aquatic animal* production to:~~

~~1. maintain the efficacy of *antimicrobial agents* both for veterinary and human medicine and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety;~~

~~2. comply with the ethical obligation and economic need to keep *aquatic animals* in good health;~~

~~3. prevent or reduce the transfer of both resistant microorganisms and resistance determinants from *aquatic animals* to humans and terrestrial animals;~~

~~4. prevent antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food.~~

Scope

This chapter defines the respective responsibilities of ~~describes recommendations on responsible and prudent use of *antimicrobial agents* for~~ *Competent Authorities* and stakeholders such as the veterinary pharmaceutical industry, *veterinarians* and *aquatic animal health professionals*, aquatic animal feed manufacturers, distributors, and aquatic animal producers, owners and keepers, who are involved in any or all of the following activities: regulatory approval, production, control, importation, exportation, sales, advertising, distribution, prescription and use of veterinary medicinal products containing *antimicrobial agent*s

Article 6.2.3.

~~**Definition**~~

~~Pharmacovigilance of *antimicrobial agent* means the detection and investigation of the effects of the use of these products, mainly aimed at safety and efficacy in *aquatic animals* and safety in people exposed to the products~~

Introduction

Responsible and prudent use of antimicrobial agents is determined by taking into account the importance of the *antimicrobial agent* to veterinary and human medicine, the *risk* of development of antimicrobial resistance, the specifications detailed in the relevant regulatory approval and the indications for use, including off-label use when *antimicrobial agent*s are administered to *aquatic animals*. It is part of good veterinary practice.

Measures to keep aqu*atic animals* healthy, such as good husbandry practices that minimize stress and provide a suitable rearing environment, ~~and~~ *biosecurity* measures (in accordance with Chapter 4.1.), and vaccination contribute to a decreased need of using *antimicrobial agent*s in aqu*atic animals*, thereby reducing the *risk* of the development and spread of antimicrobial resistance.

Activities associated with the responsible and prudent use of *antimicrobial agent*s should involve all relevant stakeholders. Coordination of these activities at the national or regional level is recommended and may support the implementation of targeted actions by the stakeholders involved and enable clear and transparent communications.

Article 6.2.~~2~~4.

Objectives of responsible and prudent use

~~Responsible and prudent use includes a set of practical measures and recommendations intended to reduce the *risk* associated with the selection and dissemination of antimicrobial resistant microorganisms and antimicrobial resistance determinants in aquatic animal production to:~~

The objectives of responsible and prudent veterinary medical use of *antimicrobial agents* are to:

1) ~~maintain~~preserve the effectiveness~~efficacy~~ of *antimicrobial agents* both for veterinary and human medicine ~~and to~~ by ensur~~e~~ing the rational use of *antimicrobial agents* in *aquatic animals* ~~with the purpose of optimising both their efficacy and safety~~;

2) comply with the ethical obligation and economic need to ~~keep *aquatic animals* in good health~~ maintain the health and welfare of the *aquatic animals*;

3) prevent or reduce the transfer of both resistant microorganisms and resistance determinants within *aquatic animal* populations and between animals, humans and the environment;

4) ~~prevent antimicrobial residues that exceed the established maximum residue limit (MRL) occurring in the food~~ protect human health by ensuring the safety of food of *aquatic animal* origin with respect to residues of *antimicrobial agent*s.

To achieve these objectives, priority should be given to preventive measures intended to improve the health, welfare and resilience of *aquatic animals* and reduce reliance on antimicrobial use~~ a range of measures intended to improve the health of aquatic animals for human consumption and for other purposes (i.e. non-food producing aquatic animals) should be implemented~~. These measures include implementation of good husbandry practices, *biosecurity plans*, vaccination, early *disease* detection and alternatives to the use of antimicrobials~~, which can help to minimise the need for antimicrobial use in *aquatic animals*.~~

Article 6.2.5

General principles

The general principles to achieve responsible and prudent veterinary medical use of *antimicrobial agent*s are:

1) *Competent Authorities* shall ensure an independent, science-based regulatory framework for *antimicrobial agents* in *aquatic animals*, applying a One Health approach to minimise antimicrobial resistance, as described in Article 6.2.6.

2) The veterinary pharmaceutical industry shall ensure *antimicrobial agents* meet approved quality, safety and efficacy standards and support stewardship through responsible promotion and pharmacovigilance, as described in Article 6.2.7.

3) Wholesale and retail distributors shall distribute *antimicrobial agents* in compliance with legislation, ensuring proper information, record-keeping and traceability, as described in Article 6.2.8.

4) *Veterinarians* and authorised *aquatic animal health professionals* shall practise evidence-based antimicrobial stewardship, prioritising prevention and regulatory compliance, as described in Article 6.2.9.

5) Animal feed manufacturers shall produce and supply medicated feed under veterinary prescription, in compliance with relevant legislation and good manufacturing practices, ensuring safe and traceable use, as described in Article 6.2.10.

6) *Aquatic animal* producers shall implement effective health and *biosecurity* programmes and use *antimicrobial agents* only under authorised prescription with proper record-keeping, as described in Article 6.2.11.

7) Owners and keepers of aquatic animals not intended for human consumption shall, under professional guidance, implement health and *biosecurity* measures to reduce antimicrobial use, as described in Article 6.2.12.

8) All stakeholders shall ensure appropriate training to promote responsible antimicrobial use, stewardship and effective monitoring, as described in Article 6.2.13.

9) *Competent Authorities* and stakeholders shall promote coordinated One Health research and innovation to address knowledge gaps and develop alternatives to antimicrobial use, as described in Article 6.2.14.

Article 6.2.4.~~6~~.

Responsibilities of Competent Authorities

1. National Action Plan on Antimicrobial Resistance

Competent Authorities should design and oversee the implementation of the parts of their National Action Plan relevant to their responsibilities, considering the findings of the situational analysis of the country, the objectives of the WOAH, WHO, FAO and UNEP Global Action Plan (GAP) for Antimicrobial Resistance and existing guidance for developing National Action Plans for antimicrobial resistance. *Competent Authorities* in cooperation with animal health, plant health, environment and public health professionals, and other relevant stakeholders should adopt a One Health approach to promote the responsible and prudent use of *antimicrobial agents* as an element of a national strategy to minimise and contain antimicrobial resistance. Furthermore, *Competent Authorities* should allocate budgetary resources for the design and implementation of the parts of their National Action Plan relevant to their responsibilities including communication strategies and professional training programmes. The *Competent Authorities* should also conduct regular monitoring and evaluation of the National Action Plan.

National Action Plans should incorporate and inform best management practices, including *disease* prevention and control measures and implementation of *biosecurity* and *aquatic animal* health programmes to reduce the burden of *aquatic animal diseases* thereby reducing the need for antimicrobial use. As part of National Action Plans, *Competent Authorities* should ensure that monitoring for antimicrobial use and surveillance of antimicrobial resistance in the *aquatic animal* health sector is in place and should work closely together with ~~human and~~ other relevant sectors on the harmonisation, analysis and integration of monitoring and surveillance across sectors. The *Competent Authorities* should implement a programme in accordance with Chapters 1.4. and 6.4.

National Action Plans should include recommendations on specific tasks for relevant professional organisations to develop evidence-based species or sector-specific antimicrobial use guidelines where risk has been determined (see Chapter 6.5).

2. Regulatory approval

A *Competent Authority* must be responsible for granting relevant regulatory approval for antimicrobial use in aquatic animals which should be done in accordance with the provisions of the Aquatic Code. The *Competent Authority* has a significant role in specifying the terms of this approval and in providing the appropriate information to *veterinarians*, authorized *aquatic animal health professionals*, and all other relevant stakeholders.

The *Competent Authority* should establish and implement efficient statutory registration procedures that evaluate the quality, safety and efficacy and post-marketing monitoring programmes for veterinary medicinal products containing *antimicrobial agents*. In accordance with Article 3.1.2., the *Competent Authority* should be free from any commercial, financial, hierarchical, political or other pressures which might influence its judgement or decisions.

Member Countries lacking the necessary resources to implement an efficient registration procedure for veterinary medicinal products containing *antimicrobial agents*, and which are importing them, should undertake the following measures:

a) Evaluate the effectiveness of administrative controls on the import of these veterinary medicinal products;

b) Evaluate the validity of the registration procedures of the exporting or manufacturing country as appropriate;

c) Develop the necessary technical co-operation with an experienced *Competent Authority* to check the quality of imported veterinary medicinal products as well as the validity of the recommended conditions of use.

The *Competent Authority* of importing countries should request the veterinary pharmaceutical industry to provide certificates of quality prepared by the *Competent Authority* of the exporting or manufacturing country as appropriate.

Regulatory approval is granted for veterinary medical use on the basis of the data submitted by a pharmaceutical company or other applicant and only if the criteria of quality, safety and efficacy are met.

The *Competent Authority* is encouraged to consult and apply, as appropriate, the guidelines based on the technical requirements for veterinary product registration established by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

An evaluation of the *risks* and benefits to both animals and humans resulting from the use of *antimicrobial agents* in *aquatic animals* should be carried out. The evaluation may focus on each individual *antimicrobial agent;* the findings from one agent should not be generalised to the antimicrobial class to which the particular active ingredient belongs. Guidance on use should be provided for all target species, route of administration, dosage regimen (dose, dosing interval and duration of the administration), and withdrawal period as relevant.

The *Competent Authority* should implement timely regulatory approval processes for new *antimicrobial agents* or other options, including alternatives to the use of antimicrobials, in order to address specific needs for the treatment of *aquatic animal diseases* and should take into account recommendations included in the WOAH List of Antimicrobials of Veterinary Importance.

3. Quality of *antimicrobial agents* and veterinary medicinal products containing *antimicrobial agents*

The *Competent Authority* should make sure that the quality of the veterinary medicinal products was determined by the applicant in accordance with national and international guidance to ensure that:

a) The specifications of *antimicrobial agents* used as active ingredients comply with the provisions of registration documentations (such as monographs) approved by the relevant *Competent Authority;*

b) The quality of *antimicrobial agents* in the marketed dosage forms is maintained until the expiry date, established under the recommended storage conditions;

c) *Antimicrobial agents* are stable and compatible when mixed with feed or water (where mixing with water is permitted by the relevant~~national~~ regulation);

d) All *antimicrobial agents* and the veterinary medicinal products containing them are manufactured to the appropriate quality and in compliance with the provisions of good manufacturing practices.

4. Assessment of efficacy

The *Competent Authority* should conduct an assessment of the efficacy based on data provided in the relevant regulatory approval application submitted by the applicant to enable marketing:

a) Preclinical trials

i) Preclinical trials should:

– establish the spectrum of activity of *antimicrobial agents* against relevant *pathogenic agents* and non-pathogenic agents (commensals);

– assess the capacity of the *antimicrobial agents* to select for resistance *in vitro* and *in vivo*, taking into consideration intrinsically resistant strains and strains with acquired resistance;

– establish an appropriate dosage regimen and route of administration necessary to ensure the efficacy of the *antimicrobial agents* and limit the selection of antimicrobial resistance. Pharmacokinetic and pharmacodynamic data and models can assist in this appraisal. Such data together with clinical data could be used by independent experts to establish clinical breakpoints per *aquatic animal* species, *antimicrobial agent* and *pathogenic agent* combination. Data from standard setting organisations like CLSI and EUCAST should also be considered.

ii) The activity of *antimicrobial agents* towards the targeted microorganism should be established by pharmacodynamic investigations. The following characteristics should be taken into account, as appropriate:

– Spectrum of activity and mode of action;

– Minimum inhibitory concentration (MIC) and minimum bactericidal concentration (MBC) against recent isolates;

– Time-kill kinetics;

– Time-dependent or concentration-dependent activity, or co-dependency;

– Activity and concentration at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial concentrations should be informed by pharmacokinetic and pharmacodynamics investigations and should take into account:

– Any potential routes of administration proposed by the applicant;

– Absorption, distribution, metabolism and elimination, and concentration at the site of *infection*.

Further dose determination studies may be conducted to examine the microbiological and clinical response to several dose levels or dosing intervals.

Any proposed use of combinations of *antimicrobial agents* should be scientifically supported.

b) Clinical trials

Clinical trials in the target *aquatic animal* species should be performed to confirm the validity of the claimed indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

– Diversity of the clinical *cases* encountered when performing multi-centre trials;

– Compliance of protocols with good clinical practice;

– Eligibility of studied clinical *cases*, based on appropriate criteria of clinical and bacteriological diagnoses;

– Parameters for qualitatively and quantitatively assessing the efficacy of the treatment~~and impact on the aquatic environment.~~

5. Assessment of the potential of *antimicrobial agents* to select for resistance

Other studies may be requested in support of the assessment of the potential of *antimicrobial agents* to select for resistance. The applicant for regulatory approval should, where possible, supply data derived in target *aquatic animal* species under the intended conditions of use.

For this assessment the following may be considered:

a) The concentration of active *antimicrobial agents* and, where appropriate, active metabolites in the gut, skin and gill mucus of the *aquatic animal* (where the majority of pathogenic and commensal bacteria reside) usingat the defined dosage level ~~and discharged into the water~~;

b) The antimicrobial activity of the *antimicrobial agents* and, where appropriate, metabolites in the intestinal environment ~~and discharged into the water~~;

c) The pathway for human exposure to antimicrobial resistant microorganisms, antimicrobial resistance determinants and antimicrobial residues in the relevant *aquatic animal* ~~production~~ environment;

d) The presence of and potential for co-selection, co-resistance and cross-resistance;

e) The baseline level of resistance, including intrinsic and acquired resistance, in the pathogenic, commensal and food-borne bacteria of human health relevance in both *aquatic animals* and humans.

6. Assessment of the impact of the antimicrobial agent on the relevant *aquatic animal* ~~production~~ environment

The *Competent Authority* should consider the results of an antimicrobial resistance environmental *risk* assessment in accordance with Chapter 6.5. For both food- and non-food producing *aquatic animals* the *risk* factors for acquisition and transmission of AMR should be taken into consideration. These may include, as relevant ~~For example~~: aquaculture effluent, sediments, water exchange, discharge into shared water bodies, exposure to wild aquatic species, reuse of wastewater for irrigation, ~~use of manure from terrestrial animals~~, use of sludge and other waste-based fertilisers for soil fertilisation, ~~that could lead into~~ which may contribute to the transfer ~~and spread~~ of antimicrobial resistant microorganisms and resistance determinants into the aquatic environment. When a significant antimicrobial resistance *risk* is determined the need for monitoring and proportionate *risk* management measures should be discussed.

7. Establishment of acceptable daily intake (ADI), maximum residue limit (MRL) and withdrawal periods in *aquatic animals* and *aquatic animal products* for human consumption

a) The establishment of an ADI for each *antimicrobial agent,* and an MRL for each *aquatic animal product* for human consumption, should be undertaken before a veterinary medicinal product containing an *antimicrobial agent* is granted regulatory approval~~. National MRLs may be harmonised with Codex MRLs and in cases where Codex MRLs do not exist, the procedure outlined in Codex Procedural Manual may be followed to determine National MRLs~~

b) When setting the ADI and MRL for an *antimicrobial agent,* the safety evaluation should also include the potential microbiological effects on the intestinal microbiota of humans to derive ADI.

c) For all veterinary medicinal products containing *antimicrobial agents* for use in *aquatic animals* for human consumption, withdrawal periods should be established for each a*quatic animal* species in order to ensure compliance with the MRLs, taking into account:

- the MRLs established for the *antimicrobial agent* in the target *aquatic animal* edible tissues;
- the composition of the product and the pharmaceutical form;
- the dosage regimen;
- the route of administration.

d) Methods used for regulatory testing of residues in food should be described and based on the established marker residues.

8. Establishment of a summary of product characteristics or equivalent for each veterinary medicinal product containing *antimicrobial agents*

The *Competent Authority* should ensure that the Summary of Product Characteristics (SPC) or equivalent, the package insert, and labelling includes the information necessary for the appropriate use of veterinary medicinal products containing *antimicrobial agents*. The SPC or equivalent summary should contain the following items as appropriate:

a) Name of the veterinary medicinal product;

b) Active ingredient and class;

c) Pharmaceutical form;

d) Quantitative composition;

e) Pharmacological properties;

f) Any potential adverse effects;

g) Target *aquatic animal* species and, as appropriate, age or production category;

h) Therapeutic indications;

i) Target microorganisms;

j) Dosage regimen (i.e. dose, frequency of dosing, and route and duration of administration) ;

k) Withdrawal periods;

l) Incompatibilities and interactions;

m) Storage conditions and shelf-life;

n) Operator safety;

o) Particular precautions before use;

p) Precautions for the protection of the environment including water stability;

q) Use in gravid *aquatic animals* and *eggs*;

r) Particular precautions for the proper disposal of unused or expired products;

s) Information on conditions of use relevant to minimise the development of resistance;

t) Contraindications;

u) Known signs of overdosage and information about its treatment.

9. Post-marketing antimicrobial resistance surveillance and monitoring

The *Competent Authority* should assess the information collected through existing pharmacovigilance, AMR surveillance and AMU monitoring programmes, including reporting of lack of response, and any other relevant scientific data. These information sources should form part of the comprehensive strategy to detect and minimise antimicrobial resistance.

In addition, specific AMR surveillance and AMU monitoring should be considered to assess the impact of the use of a specific veterinary medicinal product, where scientific evidence indicates a specific *risk* and may be implemented after the granting of the relevant regulatory approval. The surveillance and monitoring programmes should evaluate not only resistance in target *aquatic animal pathogenic agents*, but also in foodborne and other relevant zoonotic pathogens, and commensals if relevant and possible. This will also contribute to general epidemiological AMR surveillance and AMU monitoring ~~of antimicrobial resistance~~.

10. Distribution and administration of *antimicrobial agents* or veterinary medicinal products containing *antimicrobial agents*

The *Competent Authority* should ensure that all the *antimicrobial agents* used in *aquatic animals* ~~and~~via medicated feed and water (where mixing with water is permitted by the relevant regulation), are:

a) supplied only through licensed or authorised distribution systems;

b) not illegal, substandard, falsified medicines or unapproved formulations and that these are prevented from entering distribution systems;

c) prescribed by a *veterinarian* or *aquatic animal health professional* authorised to prescribe veterinary medicinal products containing *antimicrobial agents* in accordance with the ~~national~~ relevant legislation;

d) administered to *aquatic animals* under the supervision or by direction of a *veterinarian*, other authorised *aquatic animal health professional*, breeders, owners or carers of *aquatic animals*, as appropriate.

The *Competent Authority* should encourage the availability of authorised products on the market and in collaboration with the veterinary pharmaceutical industry follow-up any potential drug shortages.

Competent Authorities and stakeholders should work together to develop and implement effective procedures for the safe collection, transportation and disposal of unused or expired veterinary medicinal products containing *antimicrobial agents*. Their labels should have appropriate instructions for disposal and destruction.

11. Control of advertising

All advertising of *antimicrobial agents* should be compatible with the principles of responsible and prudent use and should be controlled by codes of advertising standards. *Competent Authorities* should aim to ensure that:

a) the advertising of these products complies with the regulatory approval granted, in particular regarding the content of the summary of product characteristics or equivalent;

b) advertising is restricted to a *veterinarian* or *aquatic animal health professional* authorised to prescribe veterinary medicinal products containing *antimicrobial agents*, or to persons permitted to supply veterinary medicinal products in accordance with the relevant ~~national~~ legislation; and

c) their promotion is done in a manner consistent with specific regulatory recommendations for the product.

12. Establishing clinical breakpoints

The *Competent Authority* should encourage and support the development of clinical breakpoints for each ~~bacteria~~ pathogenic agent-antimicrobial-*aquatic animal* species combination to interpret the results of susceptibility tests. CLSI and EUCAST procedures could be used as guidance.

13. Training related to the use of *antimicrobial agents* and antimicrobial resistance

The *Competent Authority* should take a key role in promoting targeted training for responsible and prudent use of antimicrobials and on antimicrobial resistance. The target audiences for training on the use of *antimicrobial agents* should include all the relevant stakeholders and organisations, such as the veterinary pharmaceutical industry, veterinary education establishments and establishments of education for *aquatic animal health professionals*, research institutes, veterinary professional and *aquatic animal health professional* organisations, manufacturers of medicated feed, and other approved users such as ~~breeders~~producers, owners and keepers of *aquatic animals*. The training may include the points described in Article 6.2.13.

14. Monitoring of antimicrobial use

In accordance with Chapter 6.3., the *Competent Authority* should collate data on antimicrobial use in a harmonised manner to improve the understanding of the extent and trends of antimicrobial use and antimicrobial resistance in *aquatic animal* populations at national level and identify areas for further research. The data collected on antimicrobial use at country level should:

a) give an indication of the trends in the use of *antimicrobial agents* in *aquatic animals* over time and potential associations with antimicrobial resistance in *aquatic animals*;

b) help in the interpretation of antimicrobial ~~resistance~~susceptibility testing ~~monitoring~~ data and assist in responding to ~~problems~~ reports of antimicrobial resistance in a precise and targeted way;

c) assists in *risk* management to evaluate the effectiveness of efforts and mitigation strategies;

d) inform *risk* communication strategies;

e) foster improved antimicrobial stewardship, ensuring continued availability of safe and effective *antimicrobial agents* for animal and human health.

The *Competent Authority* should provide the data to the 'Animal Antimicrobial Use Global database of the World Organisation for Animal Health' (ANIMUSE) on a yearly basis.

15. Knowledge gaps and research

The *Competent Authority* should encourage coordination of public- and private-funded research, including in the areas described in Article 6.2.14.

16. *Competent Authorities* should implement appropriate regulatory measures to ~~control~~prohibit the manufacture, compounding, importation, advertisement, trade, distribution, storage and use of unlicensed, adulterated and counterfeit veterinary medicinal products containing *antimicrobial agents,* including bulk active ingredients.

Article 6.2.~~5~~.7

Responsibilities of the veterinary pharmaceutical industry

The veterinary pharmaceutical industry has responsibilities for providing information requested by *Competent Authorities* on the quality, efficacy and safety of *antimicrobial agents*. The responsibilities of the veterinary pharmaceutical industry cover pre- and post-marketing phases, including manufacturing, sale, importation, labelling, advertising and pharmacovigilance.

The veterinary pharmaceutical industry has the responsibility to provide the *Competent Authority* with the information necessary to evaluate the amount of *antimicrobial agent*s marketed. ~~The veterinary pharmaceutical industry should ensure that the advertising of antimicrobial agents directly to the *aquatic animal* producer is discouraged.~~

The veterinary pharmaceutical industry should be encouraged to ensure the availability of authorised products and cooperate with the *Competent Authority* to forecast and avoid any drug shortage.

The veterinary pharmaceutical industry should provide the Competent Authority with the information necessary to evaluate the amount of antimicrobial agents marketed.

The veterinary pharmaceutical industry has responsibility to implement, and report in a timely manner, a pharmacovigilance programme, and on request, specific monitoring for ~~bacterial~~antimicrobial susceptibility data. For the latter, the veterinary pharmaceutical industry should isolate and identify bacteria and collect relevant data and submit them to the *Competent Authority*. These data may enable independent experts to establish clinical breakpoints for use in the laboratory to guide antimicrobial therapy.

The veterinary pharmaceutical industry should respect principles of responsible and prudent use and should comply with established codes of advertising practices, including~~to~~; distributinge information in compliance with the provisions of the granted approval; not advertisinge veterinary medicinal products containing *antimicrobial agents* directly to *aquatic animal* producers, owners and keepers or to the general public.

Article 6.2.~~6~~.8.

Responsibilities of wholesale and retail distributors

Distributors should ensure that their activities are in compliance with the relevant legislation.

Distributors should ensure that information for the appropriate use and disposal of the *antimicrobial agent* accompany all distributed products and should also be responsible for maintaining and disposing of the product in accordance with the manufacturer recommendations.

The recommendations on the responsible and prudent use of *antimicrobial agent*s should be reinforced by retail distributors who should keep for an appropriate period detailed sales record of:

a) date of sale;

b) name and contact information of the prescriber;

c) name of ~~user~~ buyer;

d) name of product;

e) batch number;

f) expiration date;

g) quantity ~~supplied~~ sold;

h) copy of prescription ~~or equivalent~~;

i) other information as required by ~~national~~ relevant legislation.

Article 6.2.~~7~~.9.

Responsibilities of *veterinarians* ~~and~~ or ~~other~~ authorised *aquatic animal health professionals*

The *veterinarian*'s and authorised *aquatic health professional*'s responsibility is to promote *aquatic animal* health and *aquatic animal* welfare, as well as public health, through antimicrobial stewardship, prevention, detection, *diagnosis*, control and treatment of *aquatic animal diseases*. The promotion of sound aquatic animal husbandry methods, hygiene procedures, *biosecurity* and vaccination strategies can help to minimise the need for using ~~agent~~ antimicrobials agents~~use~~ in *aquatic animals*.

~~Responsibilities of *veterinarians* or authorised *aquatic animal health professionals* include identifying, preventing and treating *aquatic animal diseases*, as well as the promotion of sound animal husbandry methods, hygiene procedures, vaccination and other alternative strategies to minimise the need for antimicrobial use in *aquatic animals*~~.

~~*Veterinarians* or other *aquatic animal health professionals* authorised to prescribe veterinary medicines should only prescribe, dispense or administer a specific course of treatment with an *antimicrobial agent* for *aquatic animals* under their care.~~

Veterinarians or other aquatic animal health professionals authorised to prescribe veterinary medicines should only prescribe, dispense or administer a specific course of treatment with an antimicrobial agent for aquatic animals under their care.

The *veterinarian* or authorised *aquatic animal health professional* should consider safe and effective alternatives to the use of antimicrobials before prescribing *antimicrobial agents*.

1. Pre-requisites for using *antimicrobial agent*s

~~The responsibilities of~~ ~~*v*~~*Veterinarians* and other *aquatic animal health professionals* are to obtain a detailed history and carry out a ~~thorough~~ proper clinical ~~assessment~~ examination of the *aquatic animal*(s) under their care, including as appropriate: clinical examination, post-mortem examination, bacteriology with culture and ~~sensitivity~~ antimicrobial susceptibility, and other laboratory tests to arrive at the most definitive *diagnosis* possible before initiating a specific course of treatment with an *antimicrobial agent*. Evaluation of environmental factors and husbandry at the ~~production site~~ *aquaculture establishment* (~~e.g. water quality~~) should be considered as potential primary factors leading to *infection* and should be addressed prior to prescribing a course of *antimicrobial agent* treatment. If the provisional or definitive *diagnosis* is a microbial *infection*, then the *veterinarian* and other *aquatic animal health professional*, should:

a) prescribe, dispense or administer *antimicrobial agent*s only when necessary to treat~~, or~~ control or prevent infectious *diseases* in *aquatic animal*s;

b) if therapy with an *antimicrobial agent* is deemed necessary it should be initiated as soon as possible;

c) avoid the use of *antimicrobial agent*s to compensate for inadequate *aquatic animal* husbandry practices;

d) take into consideration the WOAH List of *Antimicrobial agent*s of Veterinary Importance and follow science-based species or sector-specific antimicrobial use guidelines for responsible and prudent use when available and follow the principles of antimicrobial stewardship;

e) make an appropriate choice of *antimicrobial agent* based on clinical experience and available diagnostic laboratory information (*pathogenic agent* isolation, identification and antimicrobial susceptibility testing);

f) provide a detailed treatment protocol, including precautions and withdrawal period (if applicable), especially when prescribing extra-label or off-label use.

~~The selection of the agent should be based on the knowledge and experience of the *veterinarian* or other *aquatic animal health professional* authorised to prescribe veterinary medicines.~~

~~As soon as possible, susceptibility testing of the target microorganism should be used to confirm the choice of treatment. Results of all susceptibility tests should be retained and should be available to the *Competent Authority*.~~

2. Choosing antimicrobial agents

The choice of an effective treatment is based on:

a) the clinical experience of the *veterinarians* and authorised *aquatic animal health professionals*, their diagnostic insight and therapeutic judgement;

b) diagnostic laboratory information (*pathogenic agent* isolation, identification and antimicrobial susceptibility testing);

c) pharmacodynamic properties of the selected *antimicrobial agent*, including the activity towards the *pathogenic agents* involved;

d) the appropriate dosage regimen (i.e. dose, frequency of dosing, and route and duration of administration);

e) pharmacokinetics and tissue distribution to ensure that the selected therapeutic agent is effective at the site of *infection*;

f) the epidemiological history relevant to the *aquatic animal* or animals being treated, particularly in relation to the antimicrobial resistance profiles of the *pathogenic agents* involved.

Should a first-line antimicrobial treatment fail or should the *disease* recur, an investigation should be undertaken to reassess the circumstances including reviewing the *diagnosis*, conducting additional diagnostic testing as needed, and then formulate and implement a new treatment plan, which may or may not include another *antimicrobial agent*.

When prescribing, dispensing or administering a veterinary medicinal product containing antimicrobial agents intended for veterinary medical use to an individual or a group of animals to treat, control or prevent an infectious disease, the veterinarian or other aquatic animal health professional authorised to prescribe veterinary medicines should give specific consideration to their categorisation in the WOAH List of Antimicrobial Agents of Veterinary Importance and its recommendations for the use of antimicrobial agents considered to be Highest Priority Critically Important by WHO.

3. Appropriate veterinary medical use of the selected product containing antimicrobial agents

The prescription of an *antimicrobial agent*s should indicate the dosage regimen, the withdrawal period where applicable, and when considering group treatments, the total amount of veterinary medicinal products containing *antimicrobial agent*s to be provided, which will depend on the dosage, duration of treatment, and the number of animals to be treated.

The *veterinarian* or authorised *aquatic animal health professionals* should ensure that instructions for the administration of the product are clearly explained and understood by producers or any other person responsible for administering the product. The *veterinarian* or other *aquatic animal health professional* authorised to prescribe veterinary medicines should indicate precisely to the *aquatic animal* producer the treatment regime, including the dose, the route of administration, the treatment intervals, the duration of the treatment, the withdrawal period (if appropriate) and the amount of *antimicrobial agent*s to be delivered, depending on the dosage and the number of *aquatic animals* to be treated.

The ~~use of~~ ~~*antimicrobial agents*~~ extra-label~~/~~ or off-label use of an *antimicrobial agent* and of a compounded product containing antimicrobial agents may be permitted in certain appropriate circumstances and should be for treatment, ~~and~~control and prevention of *diseases*, in ~~conformity~~ agreement with the ~~relevant~~ ~~national~~ relevant legislation in force including the withdrawal period, as applicable. It is the *veterinarian*'s responsibility to define the conditions of responsible and prudent use in such a case including the dosage regimen, the route of administration and the withdrawal period.

The use of compounded veterinary medicinal products containing *antimicrobial agent*s and extra-label or off-label use of registered veterinary medicinal products containing *antimicrobial agent*s should be limited to circumstances where an appropriate registered product is not available and should take into account recommendations provided in the WOAH List of *Antimicrobial Agents* of Veterinary Importance.

~~Records on the use of antimicrobial agents should be kept in conformity with the relevant legislation. *Veterinarians* or *aquatic animal health professionals* should also periodically review farm records on the use of the antimicrobial agents to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens. Suspected adverse reactions, including a lack of efficacy, should be reported to the *Competent Authority*. Associated susceptibility data should accompany the report of lack of efficacy.~~

4. Recording of data

Records of veterinary medicinal products containing *antimicrobial agent*s should be kept in conformity with the ~~national~~ relevant legislation. Records should include the following, as appropriate:

a) commercial name of the veterinary medicinal products;

b) name of the *antimicrobial agent*s in the veterinary medicinal products;

c) quantities used in animals or supplied to each *aquaculture establishment* or animal breeder, owner or keeper;

d) route of administration;

e) dosage of veterinary medicinal products

f~~e~~) *aquatic animal* species;

g~~f~~) number of *aquatic animals* treated;

h~~g~~) clinical condition treated;

i~~h~~) treatment schedules including *aquatic animal* identification and length of the withdrawal period;

j~~i~~) laboratory records of *pathogenic agent* isolation, identification and susceptibility testing; such records should also be shared with the *aquatic animal* producers;

k~~j~~ comments concerning the response of the *aquatic animals* to treatment;

l~~k~~) the investigation of adverse reactions associated with antimicrobial treatment, including lack of effectiveness. Suspected adverse reactions should be reported to the holder of the regulatory approval or appropriate *Competent Authority* in accordance with ~~national~~ relevant legislation;

m) identify use, label or off label usage, including modifications.

Records must include, as a minimum, the treatment prescription in either physical or digital format, in accordance with current legislation.

Veterinarians and other *aquatic animal health professionals* should also periodically review *aquaculture establishment* records on the use of veterinary medicinal products containing *antimicrobial agents* to ensure compliance with their directions or prescriptions and use these records to evaluate the effectiveness of treatments. Prescriptions should be kept for a prudent period of time according to relevant legislation.

5. Labelling

All veterinary medicinal products containing *antimicrobial agent*s, supplied by a *veterinarian* or authorised *aquatic animal health professionals* should be labelled in accordance with the ~~national~~ relevant legislation.

Article 6.2.10

Responsibilities of aqua*tic animal* feed manufacturers

Aquatic animal feed manufacturers preparing medicated feed should:

1. Only manufacture and supply medicated *feed* and premixes containing *antimicrobial agent*s for aquatic animals on the prescription of a *veterinarian* or authorised *aquatic animal professional* in accordance with the ~~national~~relevant legislation.

2. Prepare medicated *feed* containing *antimicrobial agent*s following rules put in place by the *Competent Authority* in accordance with the ~~national~~ relevant legislation. All medicated *feed* and medicated premixes should be appropriately labelled.

3. Keep detailed records for medicated *feed* and premixes for a suitable period of time according to ~~national~~ relevant legislation.

4. Add only approved sources of pharmaceutical products to *feed* at a level, and for a species and purpose as permitted by the medicated premix label or a veterinary prescription ~~or equivalent~~.

5. Ensure medicated *feed* and premixes containing *antimicrobial agent*s is labelled with the appropriate information (e.g., level of medication, approved claim, target species, directions for use, warning, cautions, withdrawal period) to ensure effective and safe use by the users of the medicated feed.

6. Implement appropriate production practices to prevent contamination of unmedicated *feed* such as good manufacturing practices to avoid carry over and cross contamination from medicated *feed*.

Article 6.2.~~8.~~11.

Responsibilities of producers of aquatic animal ~~producers~~ for human consumption

~~*Aquatic animal* producers should implement health programmes on their *aquaculture establishments* in order to promote *aquatic animal* health, welfare and food safety, as well as environmental sustainability. This can be done through adequate planning of culture strategies to maintain *aquatic animal* health through *biosecurity* programmes, husbandry, nutrition, vaccination, maintenance of good water quality, etc.~~

Aquatic animal producers are responsible for implementing *aquatic animal* health and welfare programmes, including good husbandry practices and *biosecurity plans* in *aquaculture establishments* (in accordance with Chapter 4.1) to reduce the need for the use of *antimicrobial agent*s in *aquatic animal*s, and to promote aquatic animal health, ~~and~~ food safety and environmental sustainability.

Aquatic animal producers should use *antimicrobial agent*s only in accordance with~~on~~ the prescription ~~or equivalent~~ of a *veterinarian* or other *aquatic animal health professional* authorised to prescribe veterinary medicines, and follow directions on the dosage, ~~method~~ route of ~~application~~administration, and withdrawal period.

Aquatic animal producers should ensure that *antimicrobial agent*s are properly stored, handled, and disposed.

Aquatic animal producers should keep ~~adequate~~records according to relevant legislation of *antimicrobial agent*s used, treatment prescriptions, bacteriological identification and antimicrobial susceptibility tests, and make such records available to the *veterinarian* or ~~other~~ authorised *aquatic animal health professional*.

Aquatic animal producers should inform the *veterinarian* or other *aquatic animal health professional* of recurrent *disease* problems and lack of efficacy of *antimicrobial agent* treatment regimes.

Article 6.2.12.

Responsibilities of owners and keepers of aquatic animals for purposes other than human consumption

Aquatic animal owners and keepers of *aquatic animals* for purposes other than human consumption, (e.g. for ornamental, research, bait, and stock enhancement uses; and sea lice 'cleaner' fish) guided by a *veterinarian* or authorised *aquatic animal health professional*, have a responsibility to implement *aquatic animal* health and welfare programs, including *biosecurity*, to reduce the need to use *antimicrobial agents* to promote the health and well-being of *aquatic animals*.

Article 6.2.~~9.~~13.

Training of users of *antimicrobial agents*

~~The training of users of *antimicrobial agents* should involve all the relevant organisations, such as relevant regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, and veterinary professional organisations and other approved users such as *aquatic animal* owners.~~

Training related to the use of *antimicrobial agent*s in *aquatic animals* is a shared responsibility of all stakeholders. The training may include:

a) the resistance potential ~~ability~~ of *antimicrobial agents* ~~to select for resistant microorganisms~~ in *aquatic animals* and the aquatic environment and the importance of that resistance to public health and animal health and the relevant animal environment;

b) the need to observe responsible and prudent use principles for the use of *antimicrobial agent*s in *aquatic animals* in agreement with the provisions of the regulatory approval, national and international guidelines and recommendations from the WOAH List of *Antimicrobial Agent*s of Veterinary Importance;

c) information on the appropriate storage conditions of antimicrobial agents before and during use and proper administration at the farm level, as well as disposal of unused or expired veterinary medicinal products;

d) training in existing and new methodologies for pathogen identification, susceptibility testing, molecular detection of resistance determinants and *risk assessment* models;

e) interpretation of relevant *risk assessment* outputs for antimicrobial resistance derived from the use of *antimicrobial agent*s in *aquatic animals* and how to use these outputs to inform the development of *risk management* and *risk communication* strategies;

f) the collection and reporting of antimicrobial resistance and antimicrobial use data to the *Competent Authority* to complement existing national and international monitoring programmes;

g) information on *disease* prevention, management and *biosecurity* mitigation strategies that can contribute to reducing the need to use *antimicrobial agent*s in *aquatic animal*s.

Article 6.2.~~10~~.14.

Knowledge gaps and ~~R~~research

Relevant regulatory authorities and other stakeholders should encourage public- and private-funded research, and public-private partnerships in a One Health approach ~~T~~to address ~~the significant lack~~ knowledge gaps ~~of information~~ for numerous species of *aquatic animals* including~~, the relevant regulatory authorities and other stakeholders should encourage public- and private-funded research,~~ the following areas:

a) improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of *antimicrobial agents* to optimize the dosage regimens for veterinary medical use and their effectiveness;

b) improve the knowledge about the mechanisms of selection, co-selection, emergence and transmission of resistance determinants and resistant microorganisms in *aquatic animal* populations, and between *aquatic animals,* humans and the relevant *aquatic animal* production environment, including along the food chain;

c) develop practical models for applying the concept of *risk analysis* to assess the animal and public health concerns linked to the development of antimicrobial resistance in *aquatic animals* and *aquatic animal*-derived foods;

d) further develop protocols to predict, during the regulatory approval process, the impact of the proposed use of the *antimicrobial agents* in *aquatic animals* on the rate and extent of antimicrobial resistance development and spread to animals, humans, plants and the environment, following a One Health approach;

e) assess the primary drivers leading to use of *antimicrobial agents* in *aquatic animals*, and the effectiveness of different interventions to change behaviour and reduce the need to use *antimicrobial agents* in *aquatic animals;*

f) develop safe and effective alternatives to the use of *antimicrobial agents* including disease prevention, new *antimicrobial agents*, rapid diagnostics, and vaccines for infectious *diseases* to reduce the need for antimicrobial use in a*quatic animals*;

g) improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms in the relevant *aquatic animal* production environment.

Annex 13. Item 7.1.1.1. Chapter 9.3. 'Infection with infectious decapod iridescent virus 1', the Chapter title and revised viral taxonomy in Article 9.3.1.

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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Chapter title and revised viral taxonomy in Article 9.3.1.

SECTION 9

DISEASES OF CRUSTACEANS

CHAPTER 9.3.

INFECTION WITH ~~INFECTIOUS~~ DECAPOD IRIDESCENT VIRUS 1

Article 9.3.1.

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

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

[…]

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Annex 14. Item 7.1.1.1. Chapter 2.2.3. 'Infection with infectious decapod iridescent virus 1', the Chapter title and revised viral taxonomy in Section 1.

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

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CHAPTER 2.2.3.

INFECTION WITH ~~INFECTIOUS~~ DECAPOD IRIDESCENT VIRUS 1

1. Scope

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

[…]

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

CHAPTER 2.3.7

INFECTION WITH *MEGALOCYTIVIRUS PAGRUS1*

1. Scope

Infection with *Megalocytivirus pagrus1* (hereafter referred to as *M. pagrus1*) means infection with viruses assigned to the species *M. pagrus1* of the genus *Megalocytivirus*, Family *Iridoviridae*. These viruses are in genogroups comprising red sea bream iridovirus (RSIV), infectious spleen and kidney necrosis virus (ISKNV) and turbot reddish body iridovirus (TRBIV).

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

The *M. pagrus1* is observed as an icosahedral virion 120−200 nm in diameter consisting of a central electron-dense core and an electron translucent zone in the infected cells (He *et al.*, 2000; Inouye *et al.*, 1992; Jung & Oh, 2000; Shi *et al.*, 2004; Sudthongkong *et al.*, 2002). Matured virus is a spherical virion 140−180 nm in diameter surrounded by an envelope-like structure (Dong *et al.*, 2011; Kawato *et al.*, 2017; 2020). The virus contains a single double-stranded DNA genomes of approximately 110 kbp with a G+C content of 53–55%, encoding about 120 potential open reading frames (ORFs) (Do *et al.*, 2004; He *et al.*, 2001; Kurita *et al.*, 2002; Shi *et al.*, 2010).

Whole genome sequence analysis (Hannaford et al 2026) and phylogenetic analyses based on the major capsid protein (MCP) and ATPase genes indicate that viruses causing similar clinical signs can be divided into three different genogroups (Go *et al.* 2016; Koda *et al.* 2018; Kurita & Nakajima, 2012): the RSIV genogroup, primarily originating from marine fish; the ISKNV genogroup, reported from both marine and freshwater fish; and the turbot reddish body iridovirus (TRBIV) genogroup, mainly associated with marine flatfish. Infection with *M. pagrus1* induces common and characteristic histopathological changes across these genogroups, most notably the presence of enlarged cells within affected organs.

The first outbreak of *M. pagrus1* infection associated with RSIV was recorded in net-pen cultured red sea bream (*Pagrus major*) in Japan in 1990 (Inouye *et al.*, 1992), from which the viral species name was derived. This mortality event represented the first instance in which *M. pagrus1* infection was recognised as a significant threat to the aquaculture industry. ISKNV was the first genogroup of *M. pagrus1* to be identified by complete genome sequencing, and Chinese perch, also known as mandarinfish (*Siniperca chuatsi*) was the first reported host of ISKNV (He *et al.*, 2000; 2001). TRBIV was initially reported in turbot (*Scophthalmus maximus*) in 2004 (Shi *et al.*, 2004; 2010), and subsequently, another TRBIV genogroup was identified in archived samples of ornamental fish from the 1980s (Go *et al.*, 2016). Genetic recombination between *M. pagrus1* genogroups has also led to the emergence of several mixed-type strains (Hannaford et al. 2026).

Numerous synonyms of *M. pagrus1* have been reported from both food fish, including rock bream iridovirus (RBIV) (Do *et al.,* 2004; Jung & Oh 2000), Taiwan grouper iridovirus (TGIV) (Chou *et al.,* 1998), large yellow croaker iridovirus (LYCIV) (Chen *et al.,* 2003), orange-spotted grouper iridovirus (OSGIV) (Lu *et al.,* 2005), flounder iridovirus (FLIV) (Do *et al.* 2005), spotted knifejaw iridovirus (SKIV) (Dong *et al.,* 2010), giant seaperch iridovirus (GSIV) (Wen & Hong, 2016), and pompano iridovirus (PIV) (Lopez-Porras *et al.,* 2018), and from ornamental fish, including dwarf gourami iridovirus (DGIV) (Go *et al.*, 2016; Sudthongkong *et al.*, 2002), Banggai cardinalfish iridovirus (BCIV) (Weber *et al.*

2009), South American cichlid iridovirus (SACIV), three spot gourami iridovirus (TSGIV) (Go *et al.*, 2016; Koda *et al.*, 2018), angelfish iridovirus (AFIV) (Kawato *et al.*, 2020). A broad host range of *M. pagrus1* is shown in Section 2.2.1.

Threespine stickleback iridovirus (TSIV) has been reported to induce the enlarged cells within affected organs in threespine stickleback (*Gasterosteus aculeatus*) (Waltzek *et al.*, 2012). However, the nucleotide sequence of TSIV is divergent from that of *M. pagrus1* viruses, suggesting that TSIV represents a candidate for a novel species designation (Waltzek *et al.*, 2012; Yoxsimer *et al.*, 2024; Hannaford et al 2026). Therefore, TSIV is excluded from this chapter. European chub iridovirus (ECIV) has also been proposed as novel Megalocytivirus species (Waltzek et al. 2012; Halaly et al. 2019; Yoxsimer et al. 2024; Hannaford et al. 2026).

Megalocytivirus lates1, also known as scale drop disease virus, is a distinct species of the genus *Megalocytivirus* that causes different clinical signs in Asian seabass (*Lates calcarifer*) and yellowfin seabream (*Acanthopagrus latus*) (de Groof *et al.,* 2015; Fu *et al.,* 2021), and it is therefore excluded from this chapter.

2.1.2. Survival and stability inside the host tissues

Viral infectivity is maintained in frozen tissue at –20°C from 7 days to 2 years (Becker *et al.*, 2026; Kawato *et al.*, 2020).

2.1.3. Survival and stability outside the host

M. pagrus1 (RSIV genogroup) is inactivated in natural seawater, but the inactivation duration varied from 1 to 7 days depending on the water temperature, abundance and/or composition of the microbial communities (Ito *et al.*, 2013a; Kawato *et al.*, 2026). The virus can be inactivated by sunlight, although an exposure time of approximately 3 hours was required to achieve more than 99.9% inactivation when ultraviolet irradiation (290–390 nm) was 3–4 mW/cm^2 (a sunny day in summer) (Kawato *et al.*, 2026). Viral infectivity is maintained for at least 30 days under dry conditions after drying on a cellulose fiber paper disc at 25°C (Kawato *et al.*, 2026). *M. pagrus1* (RSIV and ISKNV) is inactivated at 50°C for 30 minutes but not for 5 min (He *et al.*, 2002; Kawato *et al.*, 2026). Rapid inactivation is observed at 60°C for 30 seconds (Kawato *et al.*, 2026). Freezing and thawing cycles drastically decrease virus infectivity when the viral storage media does not contain fetal bovine serum (Jeong *et al.*, 2025).

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 *Megalocytivirus pagrus1* according to Chapter 1.5. of the *Aquatic Animal Health Code* (*Aquatic Code*) are:

Family	Scientific name	Common name
Apogonidae	*Pterapogon kauderni*	Banggai cardinalfish
Butidae	*Oxyeleotris marmorata*	Marble goby
Carangidae	*Pseudocaranx dentex*	White trevally
	Seriola spp. (all species)	N/A
	Trachinotus spp. (all species)	N/A
	Trachurus japonicus	Japanese jack mackerel
Centrarchidae	*Lepomis macrochirus*	bluegill
Cichlidae	*Astronotus ocellatus*	Oscar
	Etroplus suratensis	Pearlspot
	Oreochromis niloticus	Nile tilapia
	Pterophyllum spp. (all species)	N/A
Cyprinidae	*Epalzeorhynchos frenatum*	Rainbow sharkminnow
Danionidae	*Danio rerio*	Zebrafish

Family	Scientific name	Common name
Ephippidae	*Platax orbicularis*	Orbiculate batfish
Girellidae	*Girella punctata*	Largescale blackfish
Haemulidae	*Parapristipoma trilineatum*	Chicken grunt
	Plectorhinchus cinctus	Crescent sweetlips
Latidae	*Lates calcarifer*	Barramundi
Lethrinidae	*Lethrinus spp.* (all species)	N/A
Mugilidae	*Mugil cephalus*	Flathead grey mullet
Nothobranchiidae	*Physician gardneri*	Steel blue killifish
Oplegnathidae	*Oplegnathus spp.* (all species)	N/A
Osphronemidae	*Macropodus opercularis*	Paradise fish
	Osphronemus goramy	Giant gourami
	Trichogaster lalius	Dwarf gourami
	Trichopodus spp. (all species)	N/A
Paralichthyidae	*Paralichthys olivaceus*	Bastard halibut
Percichthyidae	*Maccullochella peelii*	Murray cod
Pleuronectidae	*Verasper variegatus*	Spotted halibut
Poeciliidae	*Poecilia spp.* (all species)	N/A
	Xiphophorus spp. (all species)	N/A
Procatopodidae	*Poropanchax normani*	Norman's lampeye
Rachycentridae	*Rachycentron canadum*	Cobia
Sciaenidae	*Larimichthys crocea*	Large yellow croaker
	Sciaenops ocellatus	Red drum
Scombridae	*Scomber japonicus*	Chub mackerel
	Scomberomorus niphonius	Japanese Spanish mackerel
	Thunnus orientalis	Pacific bluefin tuna
Scophthalmidae	*Scophthalmus maximus*	Turbot
Serranidae	*Epinephelus spp.* (all species)	N/A
Sinipercidae	*Siniperca chuatsi*	Mandarin fish
Sparidae	*Acanthopagrus schlegelii*	Blackhead seabream
	Dentex tumifrons	Yellowback seabream
	Pagrus major	Red sea bream
Synanceiidae	*Inimicus japonicus*	N/A
Tetraodontidae	*Takifugu rubripes*	Tiger pufferfish

N/A: No English common name is currently registred for this species in *FishBase*

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 *M. pagrus1* according to Chapter 1.5. of the Aquatic Code are:

Family	Scientific name	Common name
Cichlidae	*Cleithracara maronii*	Keyhold cichlid
	Mikrogeophagus ramirezi	Ram cichlid
Helostomatidae	*Helostoma temminckii*	Kissing gourami
Lateolabracidae	*Lateolabrax japonicus*	Japanese seabass
Osphronemidae	*Betta splendens*	Siamese fighting fish

Family	Scientific name	Common name
Sebastidae	*Sebastes schlegeli*	Rockfish
Sparidae	*Rhabdosargus sarba*	Goldlined seabream

N/A: No English common name is currently registred for this species in *FishBase*

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
Carangidae	*Alepes djedaba*	Shrimp scad
	Caranx sexfasciatus	Bigeye trevally
	Decapterus maruadsi	Japanese scad
	Scomberoides lysan	Doublespotted queenfish
	Scomberoides tala	Barred queenfish
	Selaroides leptolepis	Yellowstripe scad
Characidae	*Moenkhausia costae*	Tetra fortune
Clupeidae	*Konosirus punctatus*	Dotted gizzard shad
Cobitidae	*Misgurnus anguillicaudatus*	Pond loach
Cynoglossidae	*Cynoglossus sinicus*	N/A
Cyprinidae	*Carassius auratus*	Goldfish
	Cyprinus carpio	Common carp
Danionidae	*Danio albolineatus*	Pearl danio
Engraulidae	*Thryssa mystax*	Moustached thryssa
Haemuliae	*Plectorhinchus pictus*	Trout sweetlips
Hemiodontidae	*Hemiodus gracilis*	N/A
Leiognathidae	*Deveximentum insidiator*	Pugnose ponyfish
	Leiognathus brevirostris	Shortnose ponyfish
	Leiognathus equulus	Common ponyfish
	Photopectoralis bindus	Orangefin ponyfish
Loricariidae	*Hypostomus plecostomus*	Suckermouth catfish
Lutjanidae	*Lutjanus argentimaculatus*	Mangrove red snapper
	Lutjanus johnii	John’s snapper
	Lutjanus russelli	Russell’s snapper
	Lutjanus sanguineus	Humphead snapper
Monacanthidae	*Paramonacanthus japonicus*	Hair-finned leatherjacket
Osphronemidae	*Macropodus opercularis*	Paradise fish
	Trichogaster labiosa	Thick lipped gourami
Pangasiidae	*Pangasianodon hypothalymus*	Striped catfish
Polynemidae	*Eleutheronema tetradactylum*	Fourfinger threadfin
Pomacanthidae	*Pomacanthus navarchus*	Bluegirdled anglefish
Sciaenidae	*Dendrophysa russelii*	Goatee croaker
	Otolithes ruber	Tigertooth croaker
	Pennahia argentata	Silver croaker
	Pennahia macrocephalus	Big-head pennah croaker
Scombridae	*Scomberomorus commerson*	Narrow-barred Spanish mackerel
Serranidae	*Cephalopholis boenak*	Chocolate hind
Serrasalmidae	*Pygocentrus nattereri*	Red piranha

Family	Scientific name	Common name
	Serrasalmus gibbus	N/A
Siganidae	*Siganus canaliculatus*	Rabbitfish
Stromateidae	*Pampus argenteus*	Silver pomfret
Synodontidae	*Saurida elongata*	Slender lizardfish
Syphyraenidae	*Sphyraena forsteri*	Bigeye barracuda
Terapontidae	*Prelates quadrilineatus*	Fourline grunter
	Terapon jarbua	Jarbua terapon
Tetraodontidae	*Lagocephalus spadiceus*	Half-smooth golden pufferfish
	Takifugu alboplumbeus	N/A
	Takifugu xanthopterus	Yellowfin pufferfish

N/A: No English common name is currently registred for this species in *FishBase*

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

Juvenile through to adult stages are susceptible; however, the susceptibility of juveniles is generally higher than that of adults.

The RSIV genogroup is a major pathogen of marine farmed fish including Barramundi (*Lates calcarifer*) (Girisha *et al.*, 2020), red sea bream (*Pagrus major*) (Inouye *et al.*, 1992), barred knifejaw (*Oplegnathus fasciatus*) (Jung & Oh, 2000), Japanese amberjack (*Seriola quinqueradiata*) (Ito *et al.* 2013b), and Pacific bluefin tuna (*Thunnus orientalis*) (Kawato *et al.*, 2025).

The ISKNV is the most detected genogroup in ornamental fish including freshwater species of cichlids, live-bearers, gouramis, as well as marine species like the Banggai cardinalfish (*Pterapogon kauderni*) (Weber *et al.* 2009). It also infects marine and fresh water farmed food fish including mandarinfish (He *et al.*, 2001), red drum (*Sciaenops ocellatus*) (Weng *et al.*, 2002), Barramundi (*Lates calcarifer*) (Zhu *et al.*, 2021), and Nile tilapia (*Oreochromis niloticus*) (Figueiredo *et al.*, 2021).

The TRBIV genogroup mainly infects flatfish (Do *et al.*, 2005; Shi *et al.*, 2004) but can also cause disease in Barramundi (*Lates calcarifer*) (Tsai *et al.*, 2020). The TRBIV genogroup has been detected in archived ornamental fish samples (Go *et al.*, 2016; Koda *et al.*, 2018).

2.2.4. Distribution of the pathogen in the host

Infected cells and viral genome are detected in the spleen, kidney, heart, liver, intestine, gills, and/or other organs. Among these, the spleen serves as the primary site of *M. pagrus1* replication, harbouring the largest viral load (Chao *et al.*, 2004; Inouye *et al.*, 1992; Ito *et al.*, 2013b; Sudthongkong *et al.*, 2002).

2.2.5. Aquatic animal reservoirs of infection

RSIV and ISKNV has been detected in numerous wild fish populations in saltwater areas surrounding fish farms (Kawato *et al.*, 2024; Wang *et al.*, 2007). However, the detected virus may have originated from outbreaks of *M. pagrus1* in cultured fish, suggesting spillover from aquaculture to wild populations (Kawato *et al.*, 2024). Subclinically infected fish in farms can serve as potential carriers, facilitating outbreaks in other cultured populations (Kawato *et al.*, 2021b; Kim *et al.*, 2023). Furthermore, many internationally traded ornamental fish may also act as potential carriers, contributing to interspecies transmission of *M. pagrus1* (Go *et al.*, 2016; Go & Whittington, 2019; Jeong *et al.*, 2008; Rimmer *et al.*, 2015).

2.2.6. Vectors

Bivalve molluscs inhabiting areas around fish farms may serve as potential vectors (Jin *et al.*, 2014).

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Mortality rates in spontaneous outbreaks of *M. pagrus1* infection can reach 50 to 100%, depending on host fish species, fish size, age, water temperature, and other culture conditions (He *et al.*, 2000; Inouye *et al.*, 1992; Jung & Oh, 2000; Shi *et al.*, 2004). For RSIV, morbidity is generally comparable

to mortality under such conditions. In red sea bream aquaculture, cumulative mortality rates during outbreaks in the juvenile stage typically range from 10% to 60%, mainly at water temperatures above 25°C, whereas little or no mortality is observed in fish older than one year (Inouye *et al.*, 1992; Kawato *et al.*, 2021b). Daily mortality rates increase with rising water temperature (Kawato *et al.*, 2021b). The prevalence in cultured fish populations during outbreaks ranges from 50% to 100% (Kawato *et al.*, 2021a; 2021b; 2024; 2025). In contrast, the prevalence in wild fish populations in saltwater areas near fish farms has been reported to be 9.1% and 1.0% (Kawato *et al.*, 2024; Wang *et al.*, 2007). ISKNV has caused mortalities of 50-75% in tilapia fry in the US (Subramaniam et al 2016) and 40-50% in barramundi in Thailand (Kerdee et al 2021). Though less frequently reported, TRBIV has caused mortalities of up to 70% in turbot fry and up to 90% in barramundi (Shi et al 2004; Tsia et al 2020)

Internationally traded ornamental fish (*Trichogaster* spp.) are frequently infected with *M. pagrus1*, with prevalences reported to reach up to nearly 50% in some cases (Jeong *et al.*, 2008; Mohr *et al.* 2015; Rimmer *et al.*, 2015). Mortality and morbidity rates in spontaneously diseased ornamental fish are unknown.

2.3.2. Clinical signs, including behavioural changes

Affected fish become lethargic, develop a dark body coloration, show abnormal swimming behaviour and exhibit conspicuous breathing disturbances.

2.3.3. Gross pathology

Fish exhibit severe anaemia (pale gills), petechiae in the gills, and enlargement of the spleen and kidney. Haemorrhaging of the fins and skin, as well as coelomic distension associated with ascites, are sometimes observed depending on the host species and viral genogroup.

2.3.4. Modes of transmission and life cycle

The principal mode of transmission is horizontal, primarily via waterborne exposure (He *et al.*, 2002). The transmission can be strongly influenced by the distance between farming units (Kawato *et al.*, 2023). Fomite transmission associated with equipment used for collecting dead fish (carcasses) is also important route (Kawato *et al.*, 2025). Although vertical transmission of RSIV has not yet been investigated, no disease outbreaks have been reported in the larval stage in hatcheries. Subclinically infected fish older than one year in fish farms can serve as a source of infection for the outbreaks in cultured populations (Kawato *et al.* 2021b). Apparently healthy ornamental fish that are traded internationally harbour *M. pagrus1*, suggesting the potential for spillover to other fish species (Go & Whittington, 2019; Jeong *et al.*, 2008; Mohr *et al.*, 2015; Rimmer *et al.*, 2015).

2.3.5. Environmental factors

Outbreaks have been seen mostly in the summer season at water temperatures of 25°C and above.

2.3.6. Geographical distribution

The initial outbreaks of the RSIV, ISKNV, and TRBIV genogroups were reported in cultured fish across Asian countries (He *et al.*, 2000; Inouye *et al.*, 1992; Jung & Oh 2000; Shi *et al.*, 2004). Since then, the geographical range of *M. pagrus1* genogroups has expanded throughout South-East Asia and beyond, and has now been reported in fish from Africa, the Americas, Asia, Europe, the Middle East and Oceania (Azad *et al.*, 2024; Figueiredo *et al.*, 2021; Fusianto *et al.*, 2023; Go *et al.* 2016; Girisha *et al.*, 2020; Jung-Schroers *et al.*, 2016; Lopez-Porras *et al.*, 2018; Ramírez-Paredes *et al.*, 2021). TRBIV and ISKNV genogroups have also been detected in archived samples of internationally traded ornamental fish originating from South-East Asia in the 1980s and 1990s (Go *et al.*, 2016).

See WAHIS (https://wahis.woah.org/#/home) for recent information on distribution at the country level.

2.4. Biosecurity and disease control strategies

2.4.1. Vaccination

Vaccines consisting of formalin-inactivated virus propagated in cell culture have been shown to be effective both experimentally and in field trials for all genogroups (Dong *et al.*, 2013a; 2013b; Fan *et al.*, 2012; Nakajima *et al.,* 1997; 1999). Formalin-inactivated vaccines have also been reported to confer cross-protection between the ISKNV and RSIV genogroups (Fu *et al.*, 2023a; 2023b). Although protection of fish belonging to the genus *Oplegnathus* by vaccination has been difficult, a high-dose formalin-inactivated vaccine is reported to be effective (Kwon *et al.*, 2020; Min *et al.*, 2024).

These formalin-inactivated vaccines are commercially available in several Asian countries, whereas other types of vaccines, such as subunit and DNA vaccines have been reported at the experimental stages (Qin *et al.*, 2023).

2.4.2. Chemotherapy including blocking agents

Not available.

2.4.3. Immunostimulation

Not applicable.

2.4.4. Breeding resistant strains

An RSIV-resistant strain of red sea bream (*Pagrus major*) has been developed using marker-assisted selection combined with DNA-based family selection (Sawayama *et al.*, 2019).

2.4.5. Inactivation methods

For physical inactivation, *M. pagrus1* is inactivated by heating at 50°C for 30 minutes or 60°C for 30 seconds (He *et al.*, 2002; Kawato *et al.*, 2026). The effects of extreme pH (pH 3.0 and pH 11.0) on virus inactivation have been inconsistent among studies (Fusianto *et al.*, 2019; He *et al.*, 2002; Nakajima & Sorimachi, 1994). Ultraviolet irradiation (254 nm) at approximately 2 mW/cm² for 30 minutes has been reported to result in complete inactivation, although shorter exposure times may also be effective (He *et al.*, 2002).

For chemical inactivation, *M. pagrus1* can be inactivated by treatment with either ether, chloroform or formalin (0.2%) (He *et al.* 2002; Nakajima & Sorimachi, 1994). Recommended conditions for rapid inactivation using disinfectants, considering the presence of organic matter, are as follows: sodium hypochlorite at 100–1000 ppm, benzalkonium chloride at 1000 ppm, and Virkon™ at 1% (Fusianto *et al.*, 2019; He *et al.*, 2002; Kawato *et al.*, 2026). With sodium hypochlorite, although purified virus can be rapidly inactivated at concentrations as low as 0.5 ppm, concentrations of more than 100 ppm are required under practical fish farming conditions, because free chlorine levels decrease in the presence of organic matter such as fish carcasses (Kawato *et al.*, 2026). Ethanol is effective for rapid inactivation of *M. pagrus1*, especially for hand sanitisation. However, its virucidal activity is markedly reduced at concentrations below 30% (Kawato *et al.* 2026).

2.4.6. Disinfection of eggs and larvae

Unknown.

2.4.7. General husbandry

High stocking density increases the mortality rate associated with *M. pagrus1* infection in experimental settings (Tanaka & Inoue, 2005). This effect may be related to hypoxic conditions, which can enhance viral replication through viral hypoxia response elements in the viral genome (He *et al.*, 2022). Maintaining high water quality when farming susceptible species is important given that outbreaks of ISKNV are known to intensify under conditions of elevated ammonia levels in the rearing water (Azad *et al.*, 2024).

3. Specimen selection, sample collection, transportation and handling

This section draws on information in 2.2, 2.3 and 2.4 to identify populations, individuals and samples which are most likely to be infected.

3.1. Selection of populations and individual specimens

Clinical inspections should be carried out during a period when water temperature is conducive to development of clinical disease (see Section 2.3.5). All production units (ponds, tanks, etc.) should be inspected for the presence of dead, weak or abnormally behaving fish. For the purposes of disease surveillance, fish to be sampled are selected as follows:

i) The most susceptible species should be sampled preferentially (see Section 2.2.3). Other susceptible species listed in Section 2.2.1 should be sampled proportionally.

ii) Risk-based criteria should be employed to preferentially sample lots or populations with a history of abnormal mortality, potential exposure events or where there is evidence of poor water quality or

husbandry. If more than one water source is used for fish production, fish from all water sources should be included in the sample.

iii) If weak, abnormally behaving, or freshly dead fish are present, such fish should be selected. If such fish are not present (e.g. during surveillance of apparently healthy populations), the fish selected should include normal appearing, healthy fish collected in such a way that all parts of the farm as well as all year classes are proportionally represented in the sample.

iv) Smaller fish may be more appropriate, because *M. pagrus1* infection can cause higher mortality in juvenile or yearling fish. However, adult fish are also susceptible to the virus, as viral genomes have been detected in apparently healthy individuals. Infection with *M. pagrus1* has not been reported in larval stages in hatcheries.

3.2. Selection of organs or tissues

Although gill and visceral organs such as spleen, heart, kidney, liver and intestine can be used, it is recommended to sample spleen or kidney tissues; spleen is the most appropriate organ for the preparation of imprints for use in the IFAT. For surveillance of apparently healthy populations, spleen or kidney should be sampled.

3.3. Samples or tissues not suitable for pathogen detection

Fish carcasses showing advanced signs of tissue decomposition are not suitable for testing by any method.

3.4. Non-lethal sampling

Not available.

3.5. Preservation of samples for submission

For guidance on sample preservation methods for the intended test methods, see Chapter 2.3.0.

3.5.1. Samples for pathogen isolation

The success of pathogen isolation depends 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.

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 can be frozen as described above.

Standard sample collection, preservation and processing methods for molecular techniques can be found in Section B.2.5 of Chapter 2.3.0 *General information* (diseases of fish).

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.2.2 of Chapter 2.3.0 *General information* (diseases of fish).

3.5.4. Samples for other tests

The optimal sample for tissue imprints is fresh spleen and/or kidney.

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. Early life stages such as eggs and larvae 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.

4.1. Tissue imprints

Samples to be tested include tissue imprints of spleen from affected fish. Use a tissue imprint of spleen from known uninfected fish as a negative control and if possible, use a tissue imprint of spleen from confirmed *M. pagrus1* -infected fish as a positive control.

i) Bleed the fish thoroughly.

ii) Make spleen imprints on cleaned glass microscope slides.

iii) Store the spleen pieces at 4°C together with the other organs that may be required for virus isolation or PCR tests later.

iv) Allow the imprints to air-dry for 10-20 minutes.

v) Fix the imprints with cold acetone.

vi) Stain with Giemsa or Diff-Quik.

vii) Mount the microscope slides with cover-slips using a drop of mounting fluid.

viii) Examine under light microscopy using ×40–100 magnification.

A presumptive positive result is indicated by the presence of abnormally enlarged cells. Negative control slides should not exhibit any abnormally enlarged cells. If enlarged cells are observed in the test samples, identification procedures, namely PCR followed by amplicon sequencing must be undertaken immediately.

4.2. Histopathology and cytopathology

Examination of histological sections from diseased fish may reveal abnormally enlarged cells from the spleen, heart, kidney, liver, intestine or gill. These enlarged cells react to anti-RSIV MAb M10 (see Section 4.9.1.) using an immunohistochemistry test (Bermudez *et al.,* 2018; Kawato *et al.*, 2025). However, this method is not validated.

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
Tissue imprints	+	+	+	1	+	+	+	1				
Histopathology	+	+	+	1	++	++	++	1	++	++	++	1
IFAT	+	+	+	1	++	++	++	1	++	++	++	1
Cytopathology												
Cell culture	+	+	+	1	++	++	++	1	++	++	++	1
Real-time PCR	+++	+++	+++	2	+++	+++	+++	3	++	++	++	2
Conventional PCR[3]	++	++	++	2	++	++	++	2	+++	+++	+++	2
Conventional PCR followed by amplicon sequencing									+++	+++	+++	2
In-situ hybridisation												
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
Other antigen detection methods[4]												
Other serological method[4]												

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. [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.

4.3. Cell culture for isolation

Cell lines should be monitored to ensure that susceptibility to targeted pathogens has not decreased.

Isolation of RSIV and ISKNV is undertaken using the Grunt fin (GF) cell line or the SKF-9 cell with the SKF-9 cell line preferable (Kawato *et al.,* 2017). From the limited work done, TRBIV is a more difficult to grow and may not grow on GF and SKF-9 cells. For optimal growth of RSIV and ISKNV in the SKF-9 cell line, spleen and/or kidney tissues from fish are suitable samples. Cells should be grown in Eagle's basal medium (BME) for GF cell line and Hank's minimum essential medium (HMEM) for SKF-9 cell line, supplemented with 10% fetal bovine serum (FBS) at 25°C in a temperature-controlled incubator. Use uninfected cells as negative control. Following development of viral cytopathic effect (CPE), virus identification would be undertaken using conventional PCR and sequencing. An *M. pagrus1* isolate to be used as positive control, and the SKF-9 cell line can be obtained from the WOAH Reference Laboratory for *Megalocytivirus pagrus1*. Note that an SKF-9 cell line with a passage number of less than 40 should be used to ensure susceptibility to *M. pagrus1* (Kawato et al., 2017).

4.3.1. Virus isolation in cell cultures

4.3.1.1. Inoculation of cell monolayers

i) Cell cultures maintained at 25°C and passaged at 7–14-day intervals should be used for virus isolation to ensure virus susceptibility. Prepare cell monolayers in 25 cm^2 flasks, 6-well, 24-well, or 96-well plates according to the purpose and sample size on the day before sample inoculation.

ii) Following the virus isolation procedure described in Chapter 2.3.0 *General information* (on diseases of fish), Section A.2.3.2, make an additional tenfold dilution of the 1/10 spleen homogenate supernatants and transfer an appropriate volume of each of the two dilutions onto the cell monolayers. To avoid cytotoxic effect (CTE), final concentration of the organ in the cultured medium should be less than 1% w/v.

iii) Without withdrawing the inoculum, incubate at 25°C.

4.3.1.2. Monitoring incubation

i) Follow the course of infection in positive controls and other inoculated cell cultures by daily microscopic examination at ×10–40 magnification for 14 days. The use of a phase-contrast microscope is recommended.

ii) If CPE appears in those cell cultures inoculated with dilutions of the test homogenates, identification procedures by PCR followed by amplicon sequence analysis must be undertaken immediately.

iii) If no CPE develops in the inoculated cultures (despite normal progression of CPE in the positive controls cultures) after 14 days incubation, the inoculated cultures should be subcultured and incubated for a further 14 days. Should the virus control fail to develop CPE, the process should be repeated with fresh susceptible cells and new batches of samples.

4.3.1.3. Subcultivation procedure

i) Collect aliquots of cell culture medium from all monolayers inoculated with dilutions of each supernatant of the test homogenates.

ii) Inoculate cell monolayers as described above (Section 4.3.1.1 Inoculation of cell monolayers, steps i and ii).

iii) Incubate and monitor as described above (Section 4.3.1.1 Inoculation of cell monolayers, steps ii and iii and Section 4.3.1.2 Monitoring incubation steps i and ii).

If no CPE occurs, the test may be declared negative.

4.4. Nucleic acid amplification

PCR assays should always be run with the controls specified in Section B.2.5 *Use of molecular techniques for surveillance testing, confirmatory testing and diagnosis* of Chapter 2.3.0 *General information* (diseases of fish). Each sample should be tested in duplicate.

Extraction of nucleic acids

Different kits and procedures can be used for nucleic acid extraction. The quality and concentration of the extracted nucleic acid is important and can be checked using a suitable method as appropriate to the circumstances.

4.4.1. Real-time PCR

Three real-time PCR assays are recommended for the detection of all genogroups of *M. pagrus1*. Method 1 (Cummins real-time PCR: Kawato *et al.*, 2021a) and Method 2 (Koda real-time PCR: Koda *et al.*, 2023) are probe-based methods, and the limit of detection (LOD) for these assays are less than 10 copies per reaction. Method 3 (Rimmer real-time PCR: Rimmer *et al.*, 2012) is a SYBR-based assay with a LOD of 100 copies per reaction. Method 1 and Method 3 are designated to detect a major capsid protein (MCP) gene, whereas Method 2 targets a hypothetical protein gene (ISKNV104R) that is highly conserved among the genogroups.

Primer and probe concentrations and cycling parameters shown in the table below are those described in each publication. These conditions may be optimised depending on the real-time PCR reagents used in each laboratory.

The conventional PCR followed by amplicon sequence analysis (see Section 4.5) is required for confirmatory diagnosis.

Pathogen/ target gene	**Primer/probe (5'–3')**	**Concentration**	**Cycling parameters[(a)]**
Method 1 (Cummins real-time PCR): Kawato *et al.,* 2021a; GenBank Accession No.: AF371960 etc.			
Megalocytivirus pagrus1 all genogroups/MCP	AFDL Megalo F: GGC-GAC-TAC-CTC-ATT-AAT GTG AFDL Megalo R: CAC-CAG-GTC-GTT-AAA-TGA-CA AFDL Megalo Pr: FAM-CTG-CGT-GTT-AAG-ATC-CCC-TCC-A-TAMRA	900 nM for each primer, 250 nM for probe	45 cycles of: 95°C/15 sec and 60°C/60 sec
Method 2 (Koda real-time PCR): Koda *et al.,* 2023; GenBank Accession No.: AF371960 etc.			
Megalocytivirus pagrus1 all genogroups/ISKNV ORF104R	ISKNV104R-F: GGC-CCT-TCA-GTT-GTA-TGC ISKNV104R-R: TAG-GGC-ACA-GTC-CAA-TGG ISKNV104R-P: FAM-ACT-GTG-ATT-GAA-GTC-TTC-MGB	900 nM for each primer, 250 nM for probe	40 cycles of: 95°C/3 sec and 60°C/30 sec
Method 3 (Rimmer real-time PCR): Rimmer *et al.,* 2012; GenBank Accession No.: AF371960 etc.			
Megalocytivirus pagrus1 all genogroups/MCP	C1073: AAT-GCC-GTG-ACC-TAC-TTT-GC C1074: GAT-CTT-AAC-ACG-CAG-CCA-CA	500 nM for each primer	40 cycles of: 95°C/30 sec, 62°C/30 sec, and 72°C/30 sec Melt Curve: 60°C to 95°C

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

4.4.2. Conventional PCR and nested PCR

A conventional PCR followed by a nested PCR method for the detection of all *M. pagrus1* genogroups targeting the MCP gene is shown in the table below. The WOAH Reference Laboratory has confirmed that Method 1 (primary PCR) occasionally produces cross-reactive amplicons with the host genome at the same target size. Therefore, if a faint PCR amplicon is detected, Method 2 (nested PCR) using the amplicons from Method 1 is highly recommended, unless amplicon sequencing is performed.

Primer concentrations and cycling parameters shown in the table below are those described in each publication. These conditions may be optimised depending on the PCR reagents used in each laboratory. The protocol in use at the WOAH Reference Laboratory is as follows: Template (2 µl) is added to 18 µl reaction mixture containing 10 µl 2 × GoTaq® G2 Master Mixes (Promega), 0.25 µM each primer, and molecular grade water. After 1 cycle of 95°C for 3 minutes, PCR amplification consists of 35 cycles of 95°C for 30 seconds, 60°C for 30 seconds, and 72°C for 30 seconds, followed by final extension at 72°C for 2 minutes. Amplified DNA (430 or 167 bp) is analysed by agarose gel

electrophoresis using a 2.0% agarose/TAE (Tris-acetate-EDTA) gel containing SYBR™ Safe (Thermo Fisher Scientific) or equivalent.

The conventional PCR followed by amplicon sequence analysis (see Section 4.5.) is required for confirmatory diagnosis.

Pathogen/ target gene	Primer (5'–3')	Concentration	Cycling parameters[a]
Method 1 (Primary PCR): Rimmer *et al.,* 2012; GenBank Accession No.: AF371960, amplicon size: 430 bp			
Megalocytivirus pagrus1 all genogroups/MCP	C1105: GGG-TTC-ATC-GAC-ATC-TCC-GCG C1106: AGG-TCG-CTG-CGC-ATG-CCA-ATC	1000 nM for each primer	30 cycles of: 95°C/30 sec 55°C/30 sec, and 72°C/60 sec 1 cycle of 72°C/5 min
Method 2[b] (nested PCR): Rimmer *et al.,* 2012; GenBank Accession No.: AF371960, amplicon size: 167 bp			
Megalocytivirus pagrus1 all genogroups/MCP	C1073: AAT-GCC-GTG-ACC-TAC-TTT-GC C1074: GAT-CTT-AAC-ACG-CAG-CCA-CA	1000 nM for each primer	30 cycles of: 95°C/30 sec 55°C/30 sec, and 72°C/60 sec 1 cycle of 72°C/5 min

[a]A denaturation step prior to cycling has not been included.
[b]Undertaking this nested PCR is highly recommended, as cross-reactions with the host genome is occasionally observed.

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. The PCR product must be sequenced and analysed in comparison with reference sequences.

4.6. *In-situ* hybridisation

Not applicable.

4.7. Immunohistochemistry

Not applicable.

4.8. Bioassay

Not applicable.

4.9. Antibody-based or antigen detection methods

4.9.1. Antibody-based antigen detection methods: indirect fluorescent antibody test (IFAT)

Reagent and protocols for detecting *M. pagrus1* proteins with a monoclonal antibody (MAb) M10 have been published (Kawato *et al.*, 2017; 2020; Nakajima & Sorimachi, 1995). The MAb M10-reactive epitope has been demonstrated to be a 7 amino acid sequence (EYDCPEY) of a non-structural protein encoded by the laminin-type epidermal growth factor-like domain gene in all genogroups of *M. pagrus1* (Takano *et al.,* 2019). Reactivity of MAb M10 are confirmed in both RSIV- and ISKNV-infected cells (Kawato *et al.*, 2020) but it does not detect ranaviruses (Nakajima & Sorimachi, 1995). Although the reactivity against TRBIV genogroup has not yet been confirmed, the epitope sequence is confirmed to be conserved in the genogroup. MAb M10 can be obtained from the WOAH Reference Laboratory.

Samples to be tested include tissue imprints of spleen from affected fish. Use a tissue imprint of spleen from uninfected fish as a negative control and if possible, use a tissue imprint of spleen from confirmed *M. pagrus1* -infected fish as a positive control. Similarly, IFAT can be conducted directly

after virus isolation in cell culture. Samples to be taken for testing include acetone-fixed infected cell monolayers that have developed CPE. Use an uninfected cell monolayer as a negative control and if possible, use a confirmed *M. pagrus1* -infected cell monolayer as a positive control. The protocol for tissue imprints is as follows and can be adapted for IFAT on cell cultures.

i) Bleed the fish thoroughly.

ii) Make spleen imprints on cleaned glass microscope slides.

iii) Store the spleen pieces at 4°C together with the other organs that may be required for virus isolation or molecular detection.

iv) Allow the imprints to air-dry for 20 minutes.

v) Fix the imprints with cold acetone.

vi) Prepare a diluted solution of MAb M10 in PBS (1/100)

vii) Treat the imprints with the MAb M10 solution for 30 minutes at 37°C in a humid chamber.

viii) Rinse three times with PBS.

ix) Incubate the imprints for 30 minutes at 37°C in a humid chamber with a solution of a specific anti-mouse FITC-conjugated antibody prepared according to the supplier's instructions.

x) Rinse three times with PBS.

xi) Mount the microscope slides with cover-slips using glycerol saline prior to microscopic observation.

xii) Examine using a fluorescence microscope. Positive and negative controls must be found to give the expected results prior to any other observation.

A positive result is indicated by the presence of abnormally enlarged cells with strong fluorescence. Negative control slides should not exhibit any strong fluorescence.

If the test is positive, the fish from which the samples were obtained is considered infected with *M. pagrus1*

Alternatively, a peroxide-conjugated second antibody could be used rather than fluorescence conjugate.

4.10. Other methods

Not applicable.

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

As indicated in Table 4.1, real-time PCR is the most appropriate method of screening healthy fish populations for *M. pagrus1*. Any real-time positive samples should be tested by conventional PCR or nested PCR followed by amplicon sequence analysis for confirmatory diagnosis.

6. Corroborative diagnostic criteria

This section only addresses the diagnostic test results for detection of infection in the absence (Section 6.1.) or in the presence of clinical signs (Section 6.2.) but does not evaluate whether the infectious agent is the cause of the clinical event.

The case definitions for a suspect and confirmed case have been developed to support decision making related to trade and confirmation of disease status at the country, zone or compartment level. Case definitions for disease confirmation in endemically affected areas may be less stringent. If a Competent Authority does not have the capability to undertake the necessary diagnostic tests it should seek advice from the appropriate WOAH Reference Laboratory, and if necessary, refer samples to that laboratory for confirmatory testing of samples from the index case in a country, zone or compartment considered free.

6.1. Apparently healthy animals or animals of unknown health status[1]

Apparently healthy populations may fall under suspicion, and therefore be sampled, if there is an epidemiological link(s) to an infected population. Hydrographical proximity to, or movement of animals or animal products or equipment, etc., from a known infected population equate to an epidemiological link. Alternatively, healthy populations are sampled in surveys to demonstrate disease freedom.

6.1.1. Definition of suspect case in apparently healthy animals

The presence of infection with *M. pagrus1* shall be suspected if at least one of the following criteria is met:

i) Positive result by real-time or conventional PCR

ii) Histopathological changes consistent with infection with *M. pagrus1*

iii) Cytopathic effect typical for *M. pagrus1* infection in cell culture

iv) Positive result from IFAT

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *M. pagrus1* is considered to be confirmed if at least one of the following criteria is met:

i) Positive result by a recommended antigen detection test and positive result by conventional PCR and sequence analysis, with sequence consistent with a genotype of *M. pagrus1*

ii) Histopathological changes consistent with the presence of infection with *M. pagrus1* and positive result of conventional PCR with amplicon sequence consistent with a genotype of *M. pagrus1*

iii) Cytopathic effect in cell culture with identification of *M. pagrus1* by conventional PCR with amplicon sequence consistent with a genotype of *M. pagrus1*

iv) Positive result by real-time PCR and positive result by conventional PCR with amplicon sequence consistent with *M. pagrus1*

6.2 Clinically affected animals

Clinical signs (see Section 2.3.2) 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. pagrus1* shall be suspected if at least one of the following criteria is met:

i) Presence of gross pathology or clinical signs associated with infection with *M. pagrus1* as described in this chapter, with or without elevated mortality

ii) Histopathological changes consistent with the presence of infection with *M. pagrus1*

iii) Positive result from IFAT

iv) Cytopathic effect typical for *M. pagrus1* infection in cell culture

v) Positive result by real-time PCR or conventional PCR

6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection with *M. pagrus1* is confirmed if at least one of the following criteria is met:

i) Positive result by a recommended antigen detection test and positive result by conventional PCR and sequence analysis, with amplicon sequence consistent with a genotype of *M. pagrus1*

ii) Histopathological changes consistent with the presence of infection with *M. pagrus1* and positive result by conventional PCR with amplicon sequence consistent with a genotype of *M. pagrus1*

1 For example transboundary commodities.

iii) Cytopathic effect in cell culture with identification of *M. pagrus1* by conventional PCR with amplicon sequence consistent with a genotype of *M. pagrus1*

iv) Positive result by real-time PCR and positive result by conventional PCR with sequence consistent with a genotype of *M. pagrus1*

6.3. Diagnostic sensitivity and specificity for diagnostic tests [under study]

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with *M. pagrus1* 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

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Real-time PCR (Method 1: Cummins real-time PCR)	Diagnosis	Dead fish during an RSIV outbreak and apparently healthy fish from another population with no evidence of the disease.	Spleen from individual fish	Japanese amberjack (*Seriola quinqueradiata*)	100% (n = 10)	100% (n = 10)	A real-PCR from Kawato *et al.,* 2017	Kawato *et al.,* 2021a

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction.

6.3.2. For surveillance of apparently healthy animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study

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NB: There is a WOAH Reference Laboratory for infection with *Megalocytivirus pagrus1* (please consult the WOAH web site at: https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/). Please contact the WOAH Reference Laboratories for any further information on infection with *Megalocytivirus pagrus1*.

NB: FIRST ADOPTED IN 2000 AS RED SEA BREAM IRIDOVIRAL DISEASE. MOST RECENT UPDATES ADOPTED IN 2027.

CHAPTER 2.3.9

INFECTION WITH SPRING VIRAEMIA OF CARP VIRUS

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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.

4.4. Nucleic acid amplification

PCR assays should always be run with the controls specified in Section B.2.5 *Use of molecular techniques for surveillance testing, confirmatory testing and diagnosis* of Chapter 2.3.0 *General information* (diseases of fish). Each sample should be tested in duplicate.

~~Real-time RT-PCR assays have been developed to detect and confirm SVCV (Clouthier *et al.*, 2021; Misk *et al.*, 2017; Rice, 2022; Shoa *et al.*, 2016; Yue *et al.*, 2008; Zhang *et al.*, 2009), however, sensitivity and specificity might not be acceptable for all genotypes of SVCV. Based on the genome sequences of SVCV strains of variant genotypes, an optimised real-time RT-PCR has been validated and is recommended (Rice, 2023; Zhu *et al.*, 2026).~~

~~A conventional nested RT-PCR has been widely used for the detection and confirmation on cell culture and fish tissue extracts, and the sequence of the nested-PCR amplified products can be used for genotyping phylogenetic analyses (Stone *et al.*,2003). Additional conventional RT-PCR assays are available for the detection and confirmation of SVCV infections (Koutna *et al.*, 2003; Shimahara *et al.*, 2016), while only the conventional RT-PCR assay developed by Shimahara *et al.* (2016) was sufficiently validated to identify the full range of SVCV genotypes on cell culture.~~

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												
Cytopathology												
Cell culture		++	++	1		++	++	1		++	++	1
Real-time RT-PCR		+++	+++	1		+++	+++	3		+++	+++	3
Conventional RT-PCR		++	++	1		++	++	1		++	++	1
Amplicon sequencing										+++	+++	1
In-situ hybridisation												
Immunohistochemistry						++	++	1				
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA						++	++	1				
IFAT						++	++	1				

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.
[1]For confirmatory diagnoses, methods need to be carried out in combination (see Section 6).
[2]Early and juvenile life stages have been defined in Section 2.2.3.
Shading indicates the test is inappropriate or should not be used for this purpose.

4.4.1. Real-time RT-PCR

Real-time RT-PCR assays have been developed to detect and confirm SVCV (Clouthier *et al.*, 2021; Misk *et al.*, 2017; Rice, 2022; Shoa *et al.*, 2016; Yue *et al.*, 2008; Zhang *et al.*, 2009), however, sensitivity and specificity might not be acceptable for all genotypes of SVCV. Based on the genome sequences of SVCV strains of variant genotypes, an optimised real-time RT-PCR has been validated and is recommended (Rice, 2023; Zhu et al., 2026).

~~The following controls should be run with each assay: negative extraction control; positive control; no template control; internal PCR control if available and validated.~~

~~Real-time RT-PCR assays are available to detect and confirm SVCV (Yue *et al.*, 2008; Zhang *et al.*, 2009), however, they are not currently recommended as they have not been sufficiently validated.~~

Table 4.4.1.1. Real-time RT-PCR: primer/probe sequences and cycling parameters

Pathogen/target gene	Primer/probe (5'-3')	Concentration	Cycling parameters[(a)]
Method 1: (Rice 2023; Zhu *et al.*, 2026; GenBank Accession No.: U18101)			
SVCV/RNA polymerase gene	SVCV Cefas AR-F: CAA-TGG-GAA-TGA-GTG-CTT-CT SVCV Cefas AR-R: TGA-TTT-GGT-TTT-GAA-TTG-TRT-C SVCV Cefas AR-P: AGA-CAG-AGG-TRA-AAG-GAC-ATC-TGA-T	0.4 µm of each primer 0.2 µm of probe	Reverse transcription step at 45°C/15 min 40 cycles of 95°C/15 sec and 58°C/60 sec

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

4.4.2. Conventional RT-PCR

A conventional nested RT-PCR has been widely used for the detection and confirmation on cell culture and fish tissue extracts, and the sequence of the nested-PCR amplified products can be used for genotyping phylogenetic analyses (Stone *et al.*, 2003). Additional conventional RT-PCR assays are available for the detection and confirmation of SVCV infections (Koutna *et al.*, 2003; Shimahara *et al.*, 2016), while only the conventional RT-PCR assay developed by Shimahara *et al.* (2016) was sufficiently validated to identify the full range of SVCV genotypes on cell culture.

~~Positive and negative controls should be run with each stage of the assays: extraction, RT-PCR and second round PCR. Due to the sensitive nature of PCR based assays it is highly recommended that master mix, template addition and PCR amplification occur in designated hoods or spatially separated areas.~~

~~Nested reverse-transcription polymerase chain reaction (RT-PCR) (confirmation of virus identity from cell culture isolation or directly from fish tissue extracts)~~

~~The genome of SVCV consists of a single strand of RNA of approximately 11 kb, with negative polarity. Amplification of a 714 bp fragment of SVCV cDNA is performed using primers derived from sequences of the region coding for the glycoprotein gene: 5'-TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC-3' (SVCV F1) and 5'-AGA-TGG-TAT-GGA-CCC-CAA-TAC-ATH*-ACN*-CAY*-3' SVCV R2), using a modification of the method of Stone *et al.* (2003).~~

~~i) Total RNA is extracted from 100 µl of supernatant from cell cultures exhibiting CPE or 50 µl of fish tissue extract and dissolved in 40 µl molecular biology grade DNase- and RNase-free water.~~

~~A number of total RNA extraction kits are available commercially that will produce high quality RNA suitable for RT-PCR.~~

~~ii) For cDNA synthesis, a reverse transcription reaction is performed at 37°C for 1 hour in a 20 µl volume consisting of 1 × M-MLV RT reaction buffer (50 mM Tris, pH 8.3, 75 mM KCl, 10 mM DTT, 3 mM $MgCl_2$) containing 1 mM dNTP, 100 pmol SVCV R2 primer, 20 units M-MLV reverse transcriptase (Promega, Southampton, UK) or an equivalent reverse transcriptase system and 1/10 of the total RNA extracted above.~~

~~iii) RT-PCR is performed in a 50 µl reaction volume 1 × PCR buffer (50 mM KCl, 10 mM Tris/HCl, pH 9.0, and 0.1% Triton X-100) containing 2.5 mM $MgCl_2$, 200 µM dNTPs, 50 pmol each of the SVCV R2 and SVCV F1 primers, 1.25 units of Taq DNA polymerase, and 2.5 µl reverse transcription reaction mix. The reaction mix is subjected to 35 temperature cycles of: 1 minute at 95°C, 1 minute at 55°C and 1 minute~~

at 72°C followed by a final extension step of 10 minutes at 72°C. Amplified DNA (714 bp) is analysed by agarose gel electrophoresis.

iv) If the CPE in culture is not extensive it is possible that a visible product will not be generated using a single round of amplification. To avoid such problems, use the semi-nested assay using primers: 5' TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC-3' (SVCV F1) and 5'-CTG-GGG-TTT-CCN*-CCT-CAA-AGY*-TGY*-3' (SVC R4) according to Stone *et al.* (2003).

v) The second round of PCR is performed in a 50 µl reaction volume 1 × PCR buffer (50 mM KCl, 10 mM Tris/HCl, pH 9.0, and 0.1% Triton X-100) containing 2.5 mM $MgCl_2$, 200 µM dNTPs, 50 pmol each of the SVCV R4 and SVCV F1 primers, 1.25 units Taq DNA polymerase, and 2.5 µl of the first round product. The reaction mix is subjected to 35 temperature cycles of: 1 minute at 95°C, 1 minute at 55°C and 1 minute at 72°C followed by a final extension step of 10 minutes at 72°C. Amplified DNA (606 bp) is analysed by agarose gel electrophoresis.

vi) All amplified products are confirmed as SVCV in origin by sequencing, and the SVCV subtype (Ia-Id) is identified using a BLAST search (http://www.ebi.ac.uk/blastall/index.html) or by phylogenetic analysis using the SVCV sequences available in public sequence databases. Phylogenetic analysis is undertaken using a 426 bp region corresponding to nucleotides 429–855 of the glycoprotein gene.

vii) In cases where the CPE is extensive and the virus replicates to a high titre, or where a semi-nested RT-PCR assay was used, sufficient PCR amplicon will be available for direct sequencing. Where the amplified product is weak it is recommended that the product be inserted into an appropriate sequencing vector (e.g. pGEM-T, pCR® 4-TOPO®) prior to undertaking the sequencing. At least two independent amplification and sequencing events should be undertaken to eliminate potential sequence errors introduced by the Taq polymerase.

Reverse transcription polymerase chain reaction (*RT-PCR*) (*confirmation of virus identity*)

Additional conventional RT-PCR assays are available to detect and confirm SVCV infections (Koutna *et al.*, 2003; Shimahara *et al.*, 2016). A generic primer set based on the polymerase gene also identifies viruses from both the Sprivivirus and Perhabdovirus genera and can be used to screen a virus culture (Ruane *et al.*, 2014). With the exception of the conventional RT-PCR assay developed by Shimahara *et al.* (2016) the other assays were not sufficiently validated against representatives from each of the recognised SVCV genogroups and they may fail to detect the full range of SVCV genotypes.

A summary of the Shimahara *et al.* (2016) RT-PCR method follows. Amplification of a 369 bp fragment of SVCV glycoprotein gene is performed using primers as follows: SVCV-G1: 5'-TGA-AGA-YTG-TGT-CAA-TCA-AGTC-3' and SVCV-G2: 5'-GCG-ART-GCA-GAG-AAA-AAG-TG-3'. Preparation of RNA template is the same as nested RT-PCR above. Reverse transcription of SVCV RNA and amplification of cDNA are carried out using SuperScript III one-step RT-PCR with PlatinumR Taq (Invitrogen) according to the manufacturer's instructions. The RT-PCR reaction mixture contained 10 pmol of each primer, 12.5 µl of 2× reaction mix, 1 µl of SuperScript III RT/Platinum Taq Mix and 2.5 µl template. After reverse transcription at 50°C for 30 minutes and 94°C for 2 minutes, 40 amplification cycles of 94°C for 15 seconds, 56°C for 30 seconds and 68°C for 1 minute followed by a final extension step at 68°C for 7 minutes is performed. All amplified products are confirmed as SVCV in origin by sequencing.

Primer	Sequence (5'-3')	Product size (bp)	Final primer concentration	Reference
SVCV F1	TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC	714	0.15µM	Stone *et al.*,2003
SVCV R2	AGA-TGG-TAT-GGA-CCC-CAA-TAC-ATH*-ACN*-CAY*		0.05µM	
SVCV F1	TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC	606	0.05µM	
SVC R4	CTG-GGG-TTT-CCN*-CCT-CAA-AGY*-TGY*		0.05µM	
SVCV-G1	TGA-AGA-YTG-TGT-CAA-TCA-AGT-C	369	0.05µM	Shimahara *et al.*, 2016
SVCV-G2	GCG-ART-GCA-GAG-AAA-AAG-TG		0.05µM	

Table 4.4.2.1. Conventional RT-PCR: primer sequence and cycling parameters

Pathogen/ target gene	Primer (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Stone *et al.*, 2003; GenBank Accession No.: U18101; amplicon size: 714/606 bp			
SVCV/ glycoprotein gene	SVCV R2: AGA-TGG-TAT-GGA-CCC-CAA-TAC-ATH*-ACN*-CAY* SVCV F1: TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC SVCV F1: TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC SVC R4: CTG-GGG-TTT-CCN*-CCT-CAA-AGY*-TGY*	Reverse transcription:100 pmol SVCV R2 For primary amplification: 50 pmol each of R2 and F1 For nested amplification: 50 pmol each of R4 and F1	Reverse transcription: 37°C/60 min For primary amplification: 305 cycles of: 95°C/60sec, 55°C/60 sec and 72°C/60 sec For nested amplification: 35 cycles of: 95°C/60 sec, 55°C/60 sec and 72°C/60 sec
Method 21 (Shimahara *et al.*, 2016; GenBank Accession No. U18101, amplicon size: 369 bp ~~Stone et al., 2003; GenBank Accession No.U18101, amplicon size: 714/606 bp~~)			
SVCV/ glycoprotein gene	SVCV-G1: TGA-AGA-YTG-TGT-CAA-TCA-AGT-C SVCV-G2: GCG-ART-GCA-GAG-AAA-AAG-TG*	10 pmol	Reverse transcription: 50°C/30 min 40 cycles of: 945~~5~~°C/15 sec, 565~~5~~°C/60 sec and 68°C/60 sec

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

. . .

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

~~The method for surveillance of apparently healthy populations for declaration of freedom from infection with SVCV is inoculation of cell culture with tissue homogenates (as described in Section 4.3). Cell culture is considered the most suitable method despite the lack of validation data for diagnostic methods for SVCV.~~

Virus isolation in cell culture or real-time RT-PCR are the recommended tests for surveillance to demonstrate freedom from infection with SVCV.

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 (Section 6.2) of clinical signs 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. It is recommended that all samples that yield suspect positive test results in an otherwise pathogen-free country or zone or compartment should be referred immediately to the WOAH Reference Laboratory for confirmation, whether or not clinical signs are associated with the case. If a laboratory does not have the capacity to undertake the necessary diagnostic tests it should seek advice from the appropriate WOAH Reference Laboratory.

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 to an infected population. Geographical proximity to, or movement of animals or animal products or equipment from a known infected population equate to an epidemiological link. Alternatively, healthy populations are sampled in surveys to demonstrate disease freedom.

2 For example transboundary commodities.

6.1.1. Definition of suspect case in apparently healthy animals

The presence of infection with SVCV shall be suspected if at least one of the following criteria is met:

i) Positive result by conventional RT-PCR

ii) Positive result by real-time RT-PCR

iii) SVCV-typical CPE~~.~~ in cell culture

6.1.2. Definition of confirmed case in apparently healthy animals

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

i) Virus isolation with SVCV-typical CPE in cell culture and virus identification by conventional RT-PCR followed by ~~virus identification by conventional RT-PCR test and~~ amplicon sequencing.

ii) Virus isolation with SVCV-typical CPE in cell culture and virus identification by real-time RT-PCR

iii) Positive result by real-time RT-PCR in tissue preparations and positive result by conventional RT-PCR followed by sequencing of the amplicon

6.2. Clinically affected animals

Clinical signs are not pathognomonic for infection with SVCV; 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 SVCV 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) Positive result by conventional RT-PCR

iii) Positive result by real-time RT-PCR

~~ii~~ iv) Positive result by antigen ELISA

~~i~~ v) Positive result by IFAT

vi) Positive result by immunohistochemistry

vii) SVCV-typical CPE in cell culture

6.2.2. Definition of confirmed case in clinically affected animals

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

i) Virus isolation with SVCV-typical CPE in cell culture ~~followed by~~ and virus identification by conventional RT-PCR ~~test and~~ followed by amplicon sequencing

ii) Virus isolation with SVCV-typical CPE in cell culture and virus identification by real-time RT-PCR

iii) Positive result by real-time RT-PCR in tissue preparations and positive result by conventional RT-PCR followed by sequencing of the amplicon

6.3. Diagnostic sensitivity and specificity for diagnostic tests

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with SVCV is provided in Tables 6.3.1. and 6.3.2 (no data are currently available ~~for either~~). This information can be used for the design of surveys for infection with SVCV, however, it should be noted that diagnostic performance is specific to the circumstances of each diagnostic accuracy study (including the test purpose, source population, tissue sample types and host species) and diagnostic performance may vary under different conditions. Data is 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 RT-PCR	Clinical diagnosis	Fish collected in surveillance programmes and experimentally infected fish	Cell culture	Common carp and koi	100 (249)	100 (15)	Conventional RT-PCR with sequencing	Zhu *et al.*, 2026
Real-time RT-PCR	Clinical diagnosis	Fish collected in surveillance programmes and experimentally infected fish	~~Gill, k~~Kidney and spleen	Common carp and koi	96.6 (189)	100 (15)	~~Cell culture~~ Virus isolation and identification by conventional RT-PCR with amplicon sequencing	Zhu *et al.*, 2026

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of samples used in the study.

6.3.2. For surveillance of apparently healthy animals (no data 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 samples used in the study.

7. References

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* *

NB: There are WOAH Reference Laboratories for spring viraemia of carp (~~see Table at the end of this *Aquatic Manual* or~~ please consult the WOAH web site: http://www.woah.org/en/scientific-expertise/reference-laboratories/list-of-laboratories/). Please contact the WOAH Reference Laboratories for any further information on spring viraemia of carp

NB: First adopted in 1995 as spring viraemia of carp. Most recent updates adopted in 2023.

Annex 17. Item 7.1.2.3. Chapter 2.3.11. 'Infection with tilapia lake virus'

MEETING OF THE WOAH AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 16 to 23 September 2026

CHAPTER 2.3.X.

INFECTION WITH TILAPIA LAKE VIRUS (TILV)

1. Scope

Infection with ~~t~~Tilapia lake virus (TiLV) means infection with the pathogenic agent *Tilapinevirus tilapiae* of the family Amnoonviridae.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

First described by Eyngor *et al.* (2014), TiLV was originally identified as an orthomyxo-like virus tentatively assigned, because of its similarity, to the family Orthomyxoviridae (Bacharach *et al.,* 2016). ICTV (2023) classified it as species *Tilapinevirus tilapiae*, genus *Tilapinevirus*, within a new family, Amnoonviridae ~~(Realm Riboviria, kingdom Orthornavirae, phylum Negarnaviricota, class Insthoviricetes, order Articulavirales)~~.

Virions are spherical, pleomorphic, enveloped, and 55–100 nm in diameter (Eyngor *et al.*, 2014; del-Pozo *et al.*, 2017). The genome consists of 10 segments of linear negative sense RNA of varying lengths totalling approximately 10.3 kb (Bacharach *et al*., 2016). Each genomic segment encodes a single open reading frame (ORF). RNA segment 1 (1641 nt) encodes a protein with an RNA-dependent RNA polymerase (RdRP) domain homologous to the Polymerase basic (PB) protein 1 of influenza C virus (Acharya *et al.*, 2019; Bacharach *et al.*, 2016; Ortiz-Baez *et al.*, 2020). Segment 2 ORF (1471 nt) and Segment 3 ORF (1371 nt) encode PB protein 2 and Polymerase acidic (PA) protein polymerase subunit homologs of orthomyxoviruses, respectively, and RNA segment 4 (1250 nt) encodes a nucleoprotein (Abu Rass *et al*., 2022a). The identities and functions of proteins encoded by the remaining RNA segment 5: 1099 nt; RNA segment 6: 1044 nt; RNA segment 7: 777 nt; RNA segment 8: 657 nt; RNA segment 9: 548 nt; and RNA segment 10: 465 nt (Bacharach *et al.*, 2016) are unknown.

~~Each genomic segment encodes a single open reading frame (ORF). RNA1 (1641 nt) encodes a protein with an RNA-dependant RNA polymerase (RdRP) domain homologous to the PB1 of influenza C virus (Acharya *et al.*, 2019; Bacharach *et al.*, 2016; Ortiz-Baez *et al.*, 2020). RNA2 (1471 nt) and RNA3 (1371 nt) ORFs encode the PB2 and PA polymerase subunit homologs of orthomyxoviruses (Arragain *et al.*, 2023) and RNA4 (1250 nt) encodes a nucleoprotein (Abu Rass *et al*., 2022a). The identities and functions of proteins encoded by the remaining segments RNA5: 1099 nt; RNA6: 1044 nt; RNA7: 777 nt; RNA8: 657 nt; RNA9: 548 nt; and RNA10: 465 nt (Bacharach *et al*., 2016) are unknown.~~

~~Virions are spherical, pleomorphic, enveloped, of 55–100 nm in diameter and contain 10 segments of linear negative sense RNA of varying lengths totalling approximately 10.3 kb (Bacharach *et al.*, 2016; Eyngor *et al.*, 2014). The replication cycle of TiLV is not currently known. All segments have conserved, complementary sequences at their 5'- and 3'-ends, similar to those found in orthomyxoviridae genome sequences (Bacharach *et al*., 2016). TiLV does not hemagglutinate red blood cells, suggesting that entry into host cells is different to orthomyxoviruses which do (Chengula *et al*., 2019). It is also known that entry occurs via dynamin-mediated endocytosis in a cholesterol-dependent, cytoskeleton-dependent manner that is independent of clathrin and pH (Abu Rass *et al*., 2022b).~~ Reassortment of genomic segments has been observed on several occasions (Abbadi *et al* 2023; Chaput *et al*., 2020; Verma *et al*., 2022).

2.1.2. Survival and stability in processed or stored samples

Infectious virus, capable of infecting cell cultures, was shown to persist for up to 28 days in tilapia fillets stored at –20°C. Genomic RNA was detectable by PCR in fillets collected from both non-clinical and clinical fish stored frozen for 90 to 120 days but this material did not infect cell cultures. Fillets from non-clinical PCR positive fish failed to transmit disease after 14 days frozen storage (Thammatorn et al., 2019). Sample preservation studies by Rawiwan et al. (2021), indicated genomic RNA persists for at least 1 year under sample storage methods at –20 °C for subsequent detection by molecular methods. Genome quantification was not impacted for samples preserved in RNALater™ or stored at-20°C for one year. A rapid loss of up to approximately two logs occurred in the first 30 days for samples stored in ethanol or on Whatman FTA cards.

~~Genomic RNA and viable virus, capable of infecting cell cultures, were shown to persist for up to 28 days in tilapia fillets at –20°C. Genomic RNA was detectable by PCR methods but not able to infect cell cultures when the fillets were from subclinical fish or when clinically affected material was stored frozen for 90 and 120 days. Subclinically affected fillets failed to transmit disease after 14 days frozen storage (Thammatorn *et al.*, 2019). Sample preservation studies by Rawiwan *et al.* (2021), indicated genomic RNA will persist for at least 1 year under most common sample storage methods (–20°C, 70% and 95% ethanol, RNAlater, Whatman FTA cards) for subsequent detection by molecular methods. Genomic quantity was hardly changed in RNALater or frozen storage over the period, compared with a rapid loss of up to approximately two logs in the first 30 days followed by limited further loss for the other methods.~~

2.1.3. Survival and stability outside the host

TiLV genomic RNA remained detectable in faeces and water samples collected from experimental challenge tanks 10 days post infection (Pierezan *et al*., 2019). In studies using spiked water samples incubated at 27°C, TiLV genomic RNA was shown to persist for at least 14 days in sterile distilled water, with 1 log reduction during the period whilst 4 log reductions to below detectable levels were seen after 3 and 7 days respectively in freshwater from fish rearing tanks or natural pond water (Yamkasem *et al.,* 2022). In the same studies the virus was shown to lose infectivity in E-11 cells after 1 day of incubation at 27°C in each of the water types.

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 TiLV~~Tilapia lake virus~~ according to Chapter 1.5 of *Aquatic Animal Health Code* (*Aquatic Code*) are:

Family	Scientific name	Common name
Cichlidae	~~*Oreochromis aureus × O. niloticus*~~ *O. niloticus ×Oreochromis aureus*	blue-Nile tilapia hybrid
	Sarotherodon galilaeus	mango tilapia
	Oreochromis mossambicus	Mozambique tilapia
	Oreochromis niloticus	Nile tilapia
	Oreochromis niloticus × *O. mossambicus*	red hybrid tilapia

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 TiLV according to Chapter 1.5 of the *Aquatic Code* are:

Family	Scientific name	Common name
Cyprinidae	*Barbonymus schwanenfeldii*	tinfoil barb

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but an active infection has not been demonstrated:

Family	Scientific name	Common name
Latidae	*Lates calcarifer*	barramundi

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

Fingerlings are mainly affected, particularly when juveniles are stocked into grow out ponds and cages, although infection and mortality can occur across all life stages. Dong *et al*. (2017) reported approximately 90% mortality in red tilapia fingerlings within one months of stocking into cages. ~~Mortality j~~Just over 9% of mortality in medium to large sized Nile tilapia was noted by Fathi *et al*. (2017). Experimental evidence demonstrates that TiLV susceptibility is weight-dependent; smaller fish are significantly more vulnerable than larger individuals, with higher mortality, earlier clinical onset, and more severe pathology in the liver and spleen Roy *et al.* (2021).

2.2.4. Distribution of the pathogen in the host

The main organ consistently affected is the liver. Kidney, brain, spleen and gills are also commonly affected and are organs the virus can be observed and detected (Dong *et al.,* 2017; Eyngor *et al.,* 2014; Jansen *et al.,* 2019 for reviews).

2.2.5. Aquatic animal reservoirs of infection

Low levels of viable virus and genomic RNA haves been detected in asymptomatic fish (Senapin *et al.* 2018).

2.2.6. Vectors

To date, no living organisms have been identified as vectors for TilV.

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Though morbidity and mortality vary significantly across both wild and farmed populations, ranging from 10% to over 90% depending on environmental conditions and management practices, evidence suggests that fish with no prior exposure to TiLV are highly susceptible with high mortality. Field data and experimental studies suggest that smaller fingerlings (0.5–50 g) are more vulnerable, though larger, older fish that are naïve will succumb.

2.3.2. Clinical signs, including behavioural changes

Disease was observed in both natural and cultured conditions with a range of signs and behaviours currently not pathognomonic. These include lethargy, seclusion, anorexia, poor body condition, skin discoloration, severe anaemia, ocular alterations including opacity, bilateral exophthalmia, skin abrasion and congestion, scale protrusion, and abdominal swelling (Eyngor *et al.,* 2014; Jaemwimol *et al*., 2018; Kembou Tsofack *et al*., 2017; Surachetpong *et al*., 2017). Affected animals can show loss of appetite, pale coloration of the body, aggregation near the bottom, sluggish movement, abnormal swimming, and isolation (Dong *et al*., 2017).

2.3.3 Gross pathology

Gross pathologies often observed include protrusion of scales, exophthalmia, paleness of gill and liver, clear ascitic fluid in abdomen and congestion of brain, liver and sometimes spleen. Other lesions included skin erosions and haemorrhages in the leptomeninges (Eyngor *et al.,* 2014; Fergu~~s~~sson *et al.,* 2014; Surachetpong *et al*., 2017).

2.3.4. Modes of transmission and life cycle

TiLV is transmitted horizontally between fish via waterborne exposure, physical transfer or ingestion of infected material potentially including shed mucus (Eyengor *et al.,* 2014; Liamnimitr *et al.,* 2018; Pierezan *et al.,* 2019). Vertical transmission of TiLV has been suggested based on the detection of viral RNA in broodstock reproductive tissues and early life stages (Aich *et al.,* 2022; Dong *et al.,* 2020; Yamkasem *et al.,* 2019).

2.3.5. Environmental factors

Environmental factors and seasonality are drivers of TiLV outbreaks, which peak during the summer months at water temperatures between 22–32°C. Outbreak severity is further exacerbated by high stocking densities, frequent production cycles, and low stocking weights (Kabuusu *et al.,* 2018). In recirculating aquaculture systems (RAS), the water column may act as a viral reservoir; without sufficient UV disinfection, viral particles can accumulate and significantly increase the impact on infected farms (Sresung *et al.,* 2026).

2.3.6. Geographical distribution

TiLV was first reported in Israel in 2014 from mortality events that were ongoing since 2009 (Eyngor *et al*., 2014). Infection with TiLV has since been reported from South America (Ferguson *et al*., 2014; Kembou Tsofack *et al*., 2017), Africa (Fathi *et al*., 2017; Mugimba *et al*., 2018), Asia (Abdullah *et al.,* 2018, Amal *et al*., 2018; Behera *et al*., 2018; Chaput *et al*., 2020; Debnath *et al.,* 2020; Dong *et al*., 2017; Surachetpong *et al*., 2017; Tran *et al*., 2022) and North America (Ahasan *et al*., 2020).

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

There are currently no commercially available vaccines for controlling TiLV.

2.4.2. Chemotherapy including blocking agents

There are currently no chemotherapeutics for controlling TiLV disease.

2.4.3. Immunostimulation

There are no available recognised probiotics for TiLV.

2.4.4. Breeding resistant strains

There are currently no recognised TiLV resistant tilapia commercially available. However, heritable variation in resistance to TiLV disease has been demonstrated in various natural and farmed tilapia populations (Adamek *et al*., 2022; Barria *et al*., 2021; Ferguson *et al*., 2014) indicating selective breeding for resistance to TiLV ~~should be~~ is possible.

2.4.5. Inactivation methods

Common disinfectants are likely to be effective for TiLV inactivation. Viral reductions of >4 $\log_{10}$ median tissue culture infective dose ($TCID_{50}$)/ml were obtained with ≥20 ppm free chlorine and ≥50 ppm available iodine after 30 min contact time (temperature and soiling levels not indicated, Soto *et al*., 2019). Reductions of >5 $\log_{10}$ $TCID_{50}$/ml were observed by Jaemwimol *et al*. (2019) with 2.5 ppm iodine, 10 ppm sodium hypochlorite (NaOCl), 300 ppm hydrogen peroxide (H_2O_2) and 5000 ppm (0.5%) Virkon® after 10 min contact time at 28 ºC.

2.4.6. Disinfection of eggs and larvae

Disinfection of eggs ~~according to standard procedures~~ is suggested as a~~n important~~ control measure~~, (see chapter 4.4 of the *Aquatic Code*)~~ and iodophore and chlorine disinfectants are likely to be effective (Soto *et al*., 2019).

2.4.7. General husbandry

Introducing live fish without adequate quarantine increases the risk of outbreaks. There is currently no definitive report on the transmission dynamics between wild and farmed fish, nor on the impact of processing facilities on disease spread. Biosecurity practices can be used to reduce the risk of TiLV infection including adequate quarantine, efficient disinfection, optimal water quality and proper carcass disposal.

In recirculating aquaculture systems (RAS), the continuous reuse of water may allow the virus to accumulate in both the water column and sediment, which intensifies infection pressure and sustains prolonged outbreaks (Sresung *et al.,* 2026). Decreased stocking densities may be beneficial to reduce environmental viral loads.

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

Routine sampling should prioritise the testing of sick or recently dead fish, in accordance with Chapter 2.3.0. General information (diseases of fish).

3.2. Selection of organs or tissues

TiLV replication and transcription occurs at sites of pathology with a generally broad tissue tropism. Liver, kidney, spleen and gills are suitable organs to target for diagnostic sampling. In clinically acute and symptomatic fish (spiral swimming) the brain can be targeted (Aich *et al.,* 2022; Jansen *et al.,* 2019).

3.3. Samples or tissues not suitable for pathogen detection

TiLV is not consistently detected in faeces (Liamnimitr *et al.,* 2018), and in asymptomatic fish the brain is frequently not positive, making this an unsuitable target for surveillance (Mugimba *et al.,* 2018).

3.4. Non-lethal sampling

Mucus but not faeces can be taken as a non-lethal sample for detection of TiLV with both viral RNA and viable virus capable of causing cytopathic effect (CPE) in cell culture detected in mucus of experimental and field samples at similar diagnostic sensitivities to liver samples (Liamnimitr *et al.,* 2018).

3.5. Preservation of samples for submission

For guidance on sample preservation methods for the intended test methods, see Chapter 2.3.0 General information (diseases of fish).

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. For recommendations on transporting samples for virus isolation to the laboratory, see Section B.2.4 of Chapter 2.3.0 *General information* (diseases of fish).

3.5.2. Preservation of samples for molecular detection

Tissue samples for PCR testing should be preserved in 70–90% (v/v) analytical/reagent-grade (absolute) ethanol.~~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.2.5 of Chapter 2.3.0 *General information* (diseases of fish).

~~The best preservation of TiLV genomic RNA in tissue samples for PCR testing was observed with RNALater and storage at –20°C (Rawiwan *et al.,* 2021). Ethanol 70% or 95% and Whatman FTA cards were inferior with approximately a 3 log drop in viral copy number after 30 days with much of that occurring within the first 7 days. They do however represent suitable options for high titre clinical samples if expense of proprietary storage reagents and cold chain difficulties are a factor.~~

~~The recommended ratio of analytical/reagent-grade (undenatured) ethanol to tissue is 10:1. Samples in RNA stabilisation reagents should be prepared according to the recommendation from the manufacturers and placed in at least five volumes of the reagent. Samples in RNA stabilising reagents can be shipped frozen or on ice or at room temperature if transport time does not exceed 24 hours.~~

Samples may ~~also~~ be frozen at –80°C and kept frozen until assayed.

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.2.2 of Chapter 2.3.0 *General information* (diseases of fish).

3.5.4. Samples for other tests

~~Viral nucleic acids can be detected in blood samples using molecular methods, while s~~Serological testing for antibodies ~~can~~ has been used in some situations to confirm prior exposure in fish (Tattiyapong *et al.,* 2020).

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 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.

4.1. Wet mounts

Not applicable

4.2. Histopathology and cytopathology

The brains of TiLV infected fish reveal multifocal haemorrhages, edema, proliferative glial cells and capillary congestion (Amal *et al.,* 2018; Eyngor *et al.,* 2014; Kembou Tsofack *et al.,* 2017). In the liver of infected fish, syncytial cell formation and massive hepatocellular necrosis with pyknotic and karyolitic nuclei are most commonly observed (Behera *et al.,* 2018; Dong *et al.,* 2017; Ferguson *et al.,* 2014; Jaemwimol *et al.,* 2018; Kembou Tsofack *et al.,* 2017; Senapin *et al.,* 2018). Eosinophilic intracytoplasmic inclusion bodies were present in the liver cells and splenic cells of infected fish. In the kidney, multiple necrotic foci were observed in the anterior kidney with increased melanomacrophage centres (MMCs), and in spleen dispersion of melanin granules were observed (Tattiyapong *et al.,* 2017).

4.3. Cell culture for isolation

Suitable cell lines For TiLV isolation include the established E-11 (from snakehead fish) and newly developed cell lines OnlL, OnlB, OnH, OmB, TmB, and RHTiB, from liver, brain and heart tissues of *Oreochromis niloticus* or related hybrids (reviewed in Aich *et al.,* 2022). E-11 is recognised for quick development of observable CPE. Primary tilapia brain cell cultures are also effective but more time consuming and less user-friendly. The optimal temperature range is 25–30°C with 28°C most often cited as optimum using enriched media such as L-15 supplemented with 10% FBS.

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				
Cell culture	+	+	+	1	++	++	++	1				
Real-time RT-PCR	+	+++	+++	3	+	+++	+++	3	+	+++	+++	3
Conventional RT-PCR	+	+	+	1	++	++	++	2				
Nested conventional RT-PCR	+	+	+	1	++	++	++	2				
Conventional RT-PCR followed by amplicon sequencing									+++	+++	+++	2
In-situ hybridisation										+	+	NA
Bioassay												
LAMP												
Ab-ELISA		+	+	NA								
Ag-ELISA												
Other antigen detection methods: immunohistochemistry										+	+	NA
Other methods: transmission electron microscopy										+	+	NA

LV = level of validation, refers to the stage of validation in the WOAH Pathway (chapter 1.1.2); NA = not available; PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; Ab- or Ag-ELISA = antibody or antigen enzyme-linked immunosorbent assay, respectively.
[1]For confirmatory diagnoses, methods need to be carried out in combination (see Section 6). [2]Susceptibility of early and juvenile life stages is described in Section 2.2.3.
Shading indicates the test is inappropriate or should not be used for this purpose.

Cell lines should be monitored regularly (e.g. every 6 months) to ensure that susceptibility to targeted pathogens has not changed.

4.4. Nucleic acid amplification

PCR assays should always be run with the controls specified in Section 2.5 *Use of molecular techniques for surveillance testing, confirmatory testing and diagnosis* of Chapter 2.3.0 *General information* (diseases of fish). 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.

The following published assays were evaluated through an inter-laboratory comparison coordinated by WOAH: ~~A~~a reverse transcriptase PCR (RT-PCR) ~~has been developed~~ (Eyngor *et al*., 2014), ~~followed by a more sensitive~~ nested RT-PCR ~~suitable for detection of TiLV in clinical cases~~ (Kembou Tsofack *et al*., 2017), a semi-nested RT-PCR with ~~an improved analytical sensitivity (7.5 viral copies per reaction)~~ (Dong *et al*., 2017), real-time SYBR assay, ~~with analytical sensitivity of two copies of plasmid~~ (Tattiyapong *et al*., 2018), and a real-time probe-based assay (Waiyamitra *et al.*, 2018)~~, for which diagnostic sensitivity has not yet been determined~~.

~~All the above assays were used in an inter-laboratory panel testing, together with t~~Two additional ~~, at the time~~ unpublished~~,~~ assays from ~~the laboratories of~~ the WOAH Reference Laboratories for SVCV were also included (WOAH *ad hoc* Group reports 2018a, b and 2021).

The three real-time probe-based PCR assays had the highest sensitivity, repeatability and robustness of all assays evaluated and ~~were~~ are the recommended assays for detecting TiLV. The SYBR-based PCR assay (Tattiyapong RT-qPCR) produced acceptable results but would require optimisation of reaction components and conditions and definition of assay interpretation criteria, prior to implementation for routine use. However, this assay still exhibited acceptable sensitivity, repeatability and robustness and would be an appropriate assay for use in laboratories that do not have access to real-time probe-based assays.

The conventional semi-nested assay (RT-nPCR) described ~~(Dong *et al*., 2017; Eyngor *et al*., 2014; Kembou Tsofack *et al*., 2017)~~ was the least sensitive assay, which is not unusual when conventional and real-time assays are compared. The Dong RT-nPCR assay is of sufficient sensitivity for confirmatory testing of samples screened positive by real-time PCR, for the purpose of confirmation of TiLV by sequence analysis, when investigating clinical disease or as follow-up testing of samples screened positive by real-time PCR from surveillance testing of apparently healthy animals.

4.4.1. Real-time RT-PCR

Virus nucleic acid can be purified from: aliquots of cell culture medium from infected monolayer cells; tissue/organs homogenised in media specified in Section 3.5.1, tissue samples in RNA stabilising reagent, fresh or frozen tissue samples. In the case of culture medium from infected monolayer cells, or in tissue homogenised in MEM, aliquots should be centrifuged at 1000 ***g*** for 5 minutes to remove cell debris.

Two real-time RT-PCR assays targeting the putative polymerase acidic (PA) protein gene encoded by segment 3 have been validated to stage 1 and are described herein (assays 3 and 4). The sensitivity of two additional real-time RT-PCR assays targeting the putative RNA dependant RNA polymerase (RdRP/PB1) gene encoded by segment 1 and the putative polymerase acidic (PA) protein gene encoded by segment 3 respectively, (assays 1 and 2) compared favourably and have been validated to stage 2 and in part to stage 3 (repeatability and reproducibility by interlaboratory test) are also described. Finaly a recent sensitive probe-based real-time RT-PCR assay targeting the hypothetical protein gene encoded by segment 10 and validated to stage 2 (stage 3 in part) is described in assay 5 (Megarani *et al.*, 2022). Assays 1, 3 or 5 are recommended based on sensitivity, level of validation and target conservation supporting ability to detect multiple geographical strains.

Positive and negative controls should be included.

Total RNA from infected cells and/or tissues is extracted using a phase-separation method or by use of a commercially available RNA isolation kit used according to the manufacturer's instructions.

~~In one-step RT-PCR gene-specific primers are used both to generate a cDNA transcript and for real-time RT-PCR. Both reactions occur in the same tube, which minimises the risk of contamination. Primers are used at a final concentration of 900 nM and the final probe concentration is 250 nM. 2.5 µl of extracted RNA (50 ng–2 ug) is added to each 25 µl RT-PCR reaction.~~

~~Alternatively, a two-step assay can be performed~~

~~Step 1: Reverse transcription: extracted RNA is reverse transcribed non-discriminately into cDNA using random primers. The cDNA synthesis reactions and cycling conditions are best performed using manufacturer's instructions for commercially available kits which have been extensively tested with a variety of RNA templates, including GC- and AU-rich targets and RNAse expressed at low levels.~~

~~Step 2: Real-time PCR: the TaqMan real-time PCR assay uses forward primer, reverse primer and probe. Primers are used at a final concentration of 400 nM, and the final concentration of the probe is 200 nM. 2.5 µl of cDNA product is added to each 25 µl PCR reaction. Thermal cycling conditions are 50°C for 2 minutes, 95°C for 10 minutes followed by 40 cycles of 95°C for 15 seconds and 60°C for 1 minute (Garver *et al.*, 2011). A sample is negative if no Ct (threshold cycle) is recorded, while samples with a Ct of 1-40 are considered positive for TiLV. Samples with Ct values of >40 are considered inconclusive.~~

***Primers and probes* (*sequence*)**

Pathogen/ target gene	Primer/probe (5–3)	Concentration	Cycling parameters[(a)]
Method 1. Stone *et al.* (in WOAH 2021 and Soto *et al.*, 2024 Supplement) 73 bp, GenBank Accession No.: MN687695.1			
TiLV Segment 1 putative RdRP [PB1]	TiLV CEFAS qFor2: AGA-CAC-ACT-GCT-AAA-AGT-GTG TiLV CEFAS qRev: GCG-CAC-CAT-GTA-AGC-GAG-C TiLV CEFAS qProbe 6FAM AAT-AGG-CAT-GGG-GTC-AAT-YGG-AGT-TAMRA	900 nM (primers) 250 nM (probe) for 1-step or 400 nM 200 nM (respectively) for 2-step	48°C/30 min followed by 95°C/10 min, followed by 40 cycles of 95°C/15 sec and 60°C/60 sec
Method 2: Liu *et al.* (in WOAH 2021 and Soto *et al.*, 2024 Supplement), 67 bp, GenBank Accession No.: OQ437056.1			
TiLV Segment 3 putative polymerase acidic [PA] protein	TiLV-F1: CGA-ACT-GTT-GCC-TTT-GGA-AAT-T TiLV-R1: TGA-AGA-ATA-AGT-GGA-TTG-CCT-TTG TiLV-P1-6FAM CCG-CGG-CTG-GCC-TTC-CAG-Iowa Black FQ	900 nM 250 nM or 400 nM 200 nM	48°C/30 min followed by 95°C/10 min, followed by 40 cycles of 95°C/15 sec and 60°C/60 sec
Method 3: Waiyamitra *et al.* (2018); 93 bp, GenBank Accession No.: MN939374.1			
TiLV Segment 3 putative polymerase acidic [PA] protein	TiLV-93F: AGC-CTG-CCA-CAC-AGA-AG TiLV-93R: CTG-CTT-GAG-TTG-TGC-TTC-T TiLV-93Probe: F6AM-CTC-TAC-CAG-CTA-GTG-CCC-CA-Iowa Black FQ	900 nM 250 nM or 400 nM 200 nM	48°C/30 min followed by 95°C/10 min, followed by 40 cycles of 95°C/15 sec and 60°C/60 sec
Method 4: Tattiyapong *et al.* (2018); 112 bp, GenBank Accession No.: PP600911.1			
TiLV Segment 3 putative polymerase acidic [PA] protein	TiLV-112F: CTG-AGC-TAA-AGA-GGC-AAT-ATG-GAT-T TiLV-112R: CGT-GCG-TAC-TCG-TTC-AGT-ATA-AGT-TCT	900 nM	48°C/30 min followed by 95°C/10 min, followed by 40 cycles of 95°C/15 sec and 60°C/60 sec
Method 5: Megarani *et al.* (2022); 91 bp, GenBank Accession No.: MN687724.1			
TiLV Segment 10 Hypothetical protein	TiLV-F: GGC-AAG-AAA-GCT-GCT-TCA-AAG-A TiLV-R: CGC-TCT-CGT-CAG-CAC-CAT-AC TiLV -P: 6FAM-CGA-AGT-TGG-AAG-AAT-G-MGB	900 nM 250 nM	50°C/5 min followed by 95°C/20 sec, followed by 40 cycles of 95°C/3 sec and 62°C/30 sec (fast protocol)

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

4.4.2. Conventional RT-PCR

***Primers* (*sequence*)**

Pathogen/ target gene	Primer (5–3)	Concentration	Cycling parameters[(a)]
Method 1. Dong *et al.* (2017); product size 415 bp in first round, 250 bp in second round; GenBank Accession No.: MK392374.1			
TiLV Segment 3 putative polymerase acidic [PA] protein	TiLV-Nested ext-1: TAT-GCA-GTA-CTT-TCC-CTG-CC TiLV-ME1: GTT-GGG-CAC-AAG-GCA-TCC-TA	180 nM	50°C/30 min followed by 94°C/2 min followed by 30–35 cycles* of 94°C/30 sec, 60°C/30 sec, 68°C/30 sec then 68°C/7 min
TiLV Segment 3 putative polymerase acidic [PA] protein	TiLV-7450/150R/ME2: TAT-CAC-GTG-CGT-ACT-CGT-TCA-GT TiLV-ME1: GTT-GGG-CAC-AAG-GCA-TCC-TA	360 nM	94°C/15 min followed by 30–35 cycles* of 94°C/30 sec, 60°C/30 sec, 68°C/30 sec then 68°C/7 min
Method 2: Stone *et al.* (in WOAH 2021 and Soto *et al.,* 2024 Supplement), 689 bp, GenBank Accession No.: MN687695.1			
TiLV Segment 1 putative RdRP [PB1]	TiLV For: AGA-GAC-GCA-CGC-TAG-ATC-TG TiLV Rev: TGT-AAG-TGG-GGT-TGT-TAT-ACC	100 nM	50°C/30 min followed by 94°C/2 min followed by 35 cycles of 94°C/30 sec, 60°C/30 sec, 68°C/30 sec then 68°C/7 min
TiLV Segment 1 putative RdRP [PB1]	TiLV Fint: GGT-CTC-AGC-AGT-GTA-CAC-CG TiLV Rint: ATC-TGG-AAC-AGA-CGT-TCT-GC	100 nM	94°C/15 min followed by 35 cycles of 94°C/30 sec, 60°C/30 sec, 68°C/30 sec then 68°C/7 min

*Data not shared in the paper – trail in-house 30–35 recommended.

4.4.3. Other nucleic acid amplification methods

There are many various molecular detection methods that have been developed for TiLV in recent years, some more research orientated. A rapid, one-step reverse transcription, loop-mediated, isothermal amplification (RT-LAMP) method for the detection of TiLV in fish tissues was developed by Phusantisampan *et al*. (2020). Although the assay was capable of detecting virus from different geographical locations in Thailand, it has not been evaluated using the full range of global isolates. A droplet digital PCR has been developed by Shahi *et al*. (2023) * consistent with TiLV morphology in infected tissues or cell culture preparations. However, due to limited specificity and sensitivity, TEM should only be used in combination with molecular identification methods and is not recommended as a standalone diagnostic assay.

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

For surveillance to demonstrate freedom from infection with TiLV in apparently healthy populations, real-time RT-PCR is the recommended test due to its high analytical sensitivity, specificity, and suitability for high-throughput screening across susceptible life stages. Surveillance testing should target appropriate tissues and be conducted in accordance with the principles outlined in the *Aquatic Code*. Positive screening results should be followed by confirmatory testing as described in Section 6 to support official disease status determination.

If real-time PCR apparatus is not available, nested or semi-nested PCR can be used for surveillance acknowledging and accommodating (e.g. by increased sample numbers and appropriate controls) the lower sensitivity and greater risk of amplicon contamination and false positive results associated with these methods.

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 (Section 6.2.) of clinical signs 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[3]

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 TiLV shall be suspected in apparently healthy animals if at least one of the following criteria is met:

i) Positive result by conventional RT-PCR

ii) Positive result by nested conventional RT-PCR

iii) Positive result by real-time RT-PCR

iv) TiLV-typical CPE in cell culture observed in a susceptible fish cell line, without confirmatory identification of the virus

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with TiLV is considered to be confirmed in apparently healthy animals if at least one of the following criteria is met:

i) Positive result on tissue preparations by real-time RT-PCR and positive result by conventional RT-PCR followed by sequencing of the amplicon

ii) TiLV-typical CPE in cell culture followed by virus identification by conventional RT-PCR and sequencing of the amplicon

6.2 Clinically affected animals

Clinical signs are not pathognomonic for a single disease; however they may narrow the range of possible diagnoses, mortality may be the only or most dominant observation.

6.2.1. Definition of suspect case in clinically affected animals

The presence of infection with TiLV shall be suspected in clinically affected animals 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) Histo- or cytopathological changes consistent with the presence of the pathogen or the disease

iii) Positive result by a real-time RT-PCR

iv) Positive result by a conventional RT-PCR

v) Positive result by a recommended antigen or antibody detection test

vi) TiLV-typical CPE in cell culture

6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection with TiLV is considered ~~in~~ to be confirmed in clinically affected animals if ~~at least~~ at least one of the following criteria is met:

i) Positive result on tissue preparations by real-time RT-PCR and positive result by conventional RT-PCR followed by sequencing of the amplicon

ii) TiLV-typical CPE in cell culture followed by virus identification by conventional RT-PCR and sequencing of the amplicon

6.3. Diagnostic sensitivity and specificity for diagnostic tests

3 For example transboundary commodities.

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with TiLV are provided in Tables 6.3.1. and 6.3.2 (no data are currently available). 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 RT-PCR	Diagnosis	Clinically diseased fish from farms and processing plants	Liver, spleen, kidney, brain, mucus and blood for nonlethal samples	*Oreochromis niloticus*, hybrid, other *Oreochromis* and susceptible species	96.8 (278)	100 (278)	Conventional RT-PCR and alternative real-time RT-PCR	Megarani *et al.*, 2022

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of samples used in the study,
RT-PCR: = reverse-transcriptase polymerase chain reaction.

6.3.2. For surveillance of apparently healthy animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of samples used in the study,
PCR: = polymerase chain reaction.

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NB: Currently (2026) there is no WOAH Reference Laboratory for infection with Tilapia lake virus (please consult the WOAH web site for the list: https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3).

NB: FIRST ADOPTED IN 20XX.

CHAPTER 2.4.2.

INFECTION WITH *BONAMIA EXITIOSA*

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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 (Section 6.2.) 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[4]

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 and ~~real-time~~ positive result by PCR ~~and conventional PCR and combined with~~ followed by amplicon sequencing

4 For example transboundary commodities.

ii) Positive result by histology and positive result by PCR followed by amplicon sequencing

iii) Positive result by *in-situ* hybridisation and positive result by PCR followed by amplicon sequencing

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

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

Given the routine use of parasite visualisation methods for the detection of mollusc diseases, laboratories may decide to use those methods to support the confirmatory tests recommended above.

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

i) Positive result by tissue imprints and ~~real-time~~ positive result by PCR ~~and conventional PCR and combined with~~ followed by amplicon sequencing

ii) Positive result by histology and positive result by PCR followed by amplicon sequencing

iii) Positive result by *in-situ* hybridisation and positive result by PCR followed by amplicon sequencing

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

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

Given the routine use of parasite visualisation methods for the detection of mollusc diseases, laboratories may decide to use those methods to support the confirmatory tests recommended above.

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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 (Section 6.2.) 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[5]

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 and ~~real-time~~ positive result by PCR ~~and conventional PCR and combined with~~ followed by amplicon sequencing

5 For example transboundary commodities.

ii) Positive result by histology and positive result by PCR followed by amplicon sequencing

iii) Positive result by *in-situ* hybridisation and positive result by PCR followed by amplicon sequencing

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

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

Given the routine use of parasite visualisation methods for the detection of mollusc diseases, laboratories may decide to use those methods to support the confirmatory tests recommended above.

6.2 Clinically affected animals

Clinical signs are not pathognomonic for a single disease; however, they may narrow the range of possible diagnoses.

6.2.1. Definition of suspect case in clinically affected animals

The presence of infection with *B. ostreae* shall be suspected if at least one of the following criteria is met:

i) Gross pathology or clinical signs associated with the disease as described in this chapter

ii) Observation of parasite cells in tissue imprints

iii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iv) Positive result by real-time PCR

v) Positive result by conventional PCR

6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection with *B. ostreae* is considered to be confirmed if at least one of the following criteria is met:

i) Positive result by tissue imprints and ~~real-time~~ positive result by PCR ~~and conventional PCR and combined with~~ followed by amplicon sequencing

ii) Positive result by histology and positive result by PCR followed by amplicon sequencing

iii) Positive result by *in-situ* hybridisation and positive result by PCR–followed by amplicon sequencing

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

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

Given the routine use of parasite visualisation methods for the detection of mollusc diseases, laboratories may decide to use those methods to support the confirmatory tests recommended above.

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