*Original: English*

*September 2021*

**REPORT OF THE MEETING OF THE OIE   
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION**

**Virtual meeting, 22–29 September 2021**

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The OIE Aquatic Animal Health Standards Commission (the Aquatic Animals Commission) held its meeting electronically from 22 to 29 September 2021. The list of participants is attached as [**Annex 1**](#A1).

The Aquatic Animals Commission wished to thank the following Members for providing written comments on draft texts for the OIE *Aquatic Animal Health Code* (hereinafter referred to as the *Aquatic Code*) and OIE *Manual of Diagnostic Tests for Aquatic Animals* (hereinafter referred to as the *Aquatic Manual*) circulated in Part B of the Commission’s February 2021 report: Australia, Bangladesh, Canada, Chile, China (People’s Republic of), Chinese Taipei, Japan, Korea (Republic of), New Zealand, Thailand, United Kingdom (the UK), United States of America (the USA), the African Union Interafrican Bureau for Animal Resources (AU-IBAR) on behalf of African Member Countries of the OIE, the Permanent Veterinary Committee of the Southern Cone (CVP) on behalf of Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay, and the Member States of the European Union (EU). The Commission also wished to acknowledge the valuable advice and contributions from numerous experts of the OIE scientific network.

The Commission reviewed all comments that were submitted on time and were supported by a rationale. The Commission made amendments to draft texts, where relevant, in the usual manner by ‘double underline’ and ‘~~strikethrough~~’. In relevant Annexes, amendments proposed at this meeting are highlighted with a coloured background in order to distinguish them from those made previously. Due to the large number of comments, the Commission was not able to provide a detailed explanation for the reasons for accepting or not each of the comments considered, and focused its explanations on significant issues. Where amendments were of an editorial nature, no explanatory text has been provided. The Commission wished to note that not all texts proposed by Members to improve clarity were accepted; in these cases, it considered the text clear as currently written.

The Aquatic Animals Commission informed Members that *ad hoc* Group reports would no longer be annexed to its report. Instead a hyperlink will be provided for relevant *ad hoc* Group reports that will take the reader to the dedicated webpages for all *ad hoc* Group reports on the [OIE Website](https://www.oie.int/en/standard-setting/specialists-commissions-working-ad-hoc-groups/ad-hoc-groups-reports/). The Commission encourages Members to consider relevant information in previous Commission and *ad hoc* Group reports when preparing comments, especially on longstanding issues.

The table of contents includes all of the agenda items addressed by the Aquatic Animals Commission at this meeting and includes links to relevant items within this report.

Texts in **Annexes 2 to 24** are presented for Member comments.

Comments on relevant texts in this report must reach OIE Headquarters by the **9 January 2022** to be considered at the February 2022 meeting of the Aquatic Animals Commission.

All comments should be sent to the OIE Standards Department at: [AAC.Secretariat@oie.int](mailto:AAC.Secretariat@oie.int).

Comments should be submitted as Word files rather than pdf files because pdf files are difficult to incorporate into the Commission’s working documents.

Comments should be presented in the relevant Annex, and include any amendments to the proposed text, supported by a structured rationale or by published scientific references. Proposed deletions should be indicated in ‘~~strikethrough~~’ and proposed additions with ‘double underline’. Members should not use the automatic ‘track-changes’ function provided by Word processing software, as such changes may be lost in the process of collating Members’ submissions into working documents. Members are also requested not to reproduce the full text of a chapter as this makes it easy to miss comments while preparing the working documents.

The Aquatic Animals Commission strongly encourages Members to participate in the development of the OIE’s international standards by submitting comments on this report.

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1. **MEETING WITH THE DEPUTY DIRECTOR GENERAL**

Dr Matthew Stone, OIE Deputy Director General International Standards and Science, welcomed the Aquatic Animals Commission and congratulated members on their election. Dr Stone together with Dr Gillian Mylrea, Head of the Standards Department, conducted an induction session at the start of the meeting. This was the final session of the Specialist Commission induction programme. In previous months induction sessions had been conducted for new Commission members, Presidents and all Commission members and secretariats, to meet each other and share information relevant to this new term.

During this induction session, Dr Stone presented, for the consideration of members, a discussion on managing the workload, roles and responsibilities, process innovation, and the performance management system.

Dr Stone recalled that the February 2021 Commission reports had been produced in two parts, A (texts for adoption) and B (texts for comments and information) to ensure early publication of texts that were to be proposed for adoption ahead of the virtual General Session. He noted that the OIE will continue with this approach in 2022. Dr Stone also recalled that Pre-General Session webinars hosted by Commission members to explain the standards being proposed for adoption were well received and will be repeated in the future. Dr Stone also encouraged Commission members to conduct webinars in their respective regions for Delegates and relevant Focal Points after the September meeting to explain decisions made.

Dr Stone also informed the Aquatic Animals Commission that the OIE will undertake a one-year pilot study of an online commenting system for the collation and review of Member comments. Dr Stone explained that this pilot study will be applied to the work of the Aquatic Animals Commission using a small number of Members to assess whether the system should be applied to all Specialist Commissions.

Dr Mylrea facilitated a short session on agreed ways of working in which members discussed expectations and how they would like to work as a group in the coming 3 years. The President of the Aquatic Animals Commission, Dr Ingo Ernst, shared his expectations for the new term, and acknowledged the excellent support provided to them by the OIE Secretariat.

1. **MEETING WITH THE DIRECTOR GENERAL**

Dr Monique Eloit, the OIE Director General, met the Aquatic Animals Commission on 28 September 2021 and congratulated the new and re-elected members of the Commission. Dr Eloit provided an update on progress in the implementation of the 7th OIE Strategic Plan and highlighted one example of new work that will be undertaken to assess the OIE science system including OIE Reference Centres and expertise in OIE *ad hoc* Groups, Working Groups, and how the OIE can ensure the best use of these networks of experts. Dr Eloit also acknowledged the large workload of the Commission and highlighted that prioritisation of its work programme is critical during this coming period.

The members of the Commission congratulated Dr Eloit for her election for a second term as OIE Director General and expressed the commitment of the Commission to support the achievement of OIE objectives. Dr Ernst highlighted the importance of the new OIE Aquatic Animal Health Strategy that was launched at the 88th General Session in May 2021. In particular, he emphasised the need to continue to strengthen OIE resources and expertise to support Members to improve aquatic animal health and welfare to keep pace with the rapid growth of aquatic animal production and the increased risk of diseases.

1. **COOPERATION WITH OTHER SPECIALIST COMMISSIONS**

The Aquatic Animals Commission and the Terrestrial Animal Health Standards Commission (the Code Commission) continued to work together to coordinate their respective work on the revision of the glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Aquatic Animal Health Services’ in the *Aquatic Code* with the glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’ in the *Terrestrial Code*, noting the importance of ensuring alignment of these definitions, except where differences are required (see Item 5.1.2.2. for more details).

As part of the discussion of the next steps for the revision of Section 4 of the *Aquatic Code*, the OIE Secretariat provided the Aquatic Animals Commission with a summary report of relevant work completed or planned by the Code Commission. The Aquatic Animals Commission appreciated this information and acknowledged that some of the work of the Code Commission may be helpful for its work given that many of the topics addressed in Section 4 are relevant for both the aquatic and terrestrial domains.

The Aquatic Animals Commission also discussed the need for a review of some chapters in Section 5 and the importance of coordinating this work with parallel work being considered by the Code Commission.

The Aquatic Animals Commission will continue to work with the Code Commission on relevant items in their respective work programmes to share information and ensure alignment, as appropriate.

1. **WORK PLAN OF THE AQUATIC ANIMALS COMMISSION**

The Aquatic Animals Commission considered ongoing work plan items at this meeting and the anticipated milestones for their completion. The Commission agreed to convene an additional meeting to review and prioritise new work. Any new work that is prioritised will be added to the workplan and provided for Member comments in the Commission’s February 2022 report. Prioritisation of any new work will take into account multiple factors including the expected improvement to standards, benefit to Members, Member comments, activities of the OIE Aquatic Animal Health Strategy, capacity constraints, Headquarters’ comments, and progress on the previous Commission’s work plan.

The work plan of the Aquatic Animal Commission is presented as [**Annex 2**](#A2) for Member comments.

1. **THE OIE *AQUATIC ANIMAL HEALTH CODE***
   1. Texts for Member comment
      1. User’s Guide

The Aquatic Animals Commission amended the User’s Guide to include Chapter 4.1. Biosecurity for aquaculture establishments, that was adopted at the 88th General Session, to ensure that it was consistent with the 2021 version of the *Aquatic Code*. The Commission also proposed some additional amendments to improve readability.

The revised User’s Guide is presented as [**Annex 3**](#A3) for Member comments.

* + 1. Glossary definitions:
       1. *‘Basic biosecurity conditions’, ‘Early detection system’, ‘Passive surveillance’**and ‘Biosecurity plan’*

Comments were received from Australia, Canada, China (People’s Rep. of), Chinese Taipei, the USA, and the EU.

*Background*

In its September 2020 report, the Aquatic Animals Commission proposed amendments to the Glossary definitions for ‘Basic biosecurity conditions’ and ‘Early detection system’. It also proposed a new Glossary definition for ‘Passive surveillance’ to ensure alignment with proposed amendments to Chapter 1.4. Aquatic Animal Health Surveillance.

**Previous Commission reports where this item was discussed:**

February 2021 report (Part B: Item 1.1., page 3).

**September 2021**

The Commission did not agree with a comment to add a new definition for ‘Active surveillance’ to the Glossary as active surveillance had been removed from the amended Chapter 1.4. Aquatic Animal Health Surveillance.

**Basic biosecurity conditions**

The Commission did not agree to remove the reference to ‘a particular disease’ from the definition as the application of the standards is on a disease basis. The Commission did, however, agree to replace ‘particular’ with ‘specific’ in the same paragraph for improved clarity.

The Commission did not agree with a comment to add ‘aquaculture establishments’ as this definition applies at a higher level than an establishment.

**Biosecurity plan**

During the Commission’s review of the model Articles X.X.4.–X.X.8., it agreed that a reference to Chapter 4.1. Biosecurity for aquaculture establishments, should be included in the definition of ‘Biosecurity plan’ given that Chapter 4.1. provides specific recommendations for development of a biosecurity plan.

**Early detection system**

In the first sentence, the Commission agreed with comments to delete ‘an efficient’ and to replace ‘for ensuring’ with ‘which ensure’ for improved clarity.

The Commission agreed to delete ‘diagnostic’ before ‘investigation’ in the last sentence, as an investigation may extend beyond diagnostic activities.

**Passive surveillance**

The Commission agreed with comments to amend this definition to include more details on observational aquatic animal health surveillance information generated by an early detection system.

The revised Glossary definitions for ‘Basic biosecurity conditions’, ‘Biosecurity plan’, ‘Early detection system’ and ‘Passive surveillance’ are presented as [**Annex 4**](#A4) for Member comments.

* + - 1. *‘Competent Authority’, ‘Veterinary Authority’ and ‘Aquatic Animals Health Services’*

Comments on the Commission’s September 2020 report were received from Armenia, Canada, Chinese Taipei, Cuba, New Caledonia, Switzerland, Thailand, the UK and the EU.

*Background*

In September 2018, the Terrestrial Animal Health Standards Commission (the Code Commission) agreed to revise the Glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’ in the *Terrestrial Code* following Member requests and feedback from the *ad hoc* Group on Veterinary Services (2018 report). The revised definitions were circulated for comments in the Code Commission’s September 2018 report. The *ad hoc* Group on Veterinary Services considered the comments submitted in June 2019 and proposed revised definitions. The Code Commission and the Aquatic Animals Commission agreed to discuss the proposed amendments to ensure alignment between the *Aquatic* *Code* and *Terrestrial* *Code*, where relevant. The revised Glossary definitions for Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’ in the *Terrestrial Code* and Competent Authority’, ‘Veterinary Authority’ and ‘Aquatic Animal Health Services’ in the *Aquatic Code* were circulated for comments in the September 2020 reports of the Code Commission and the Aquatic Animals Commission, respectively.

In preparation for the September 2021 meeting, the Presidents of the two Commissions met to review all comments received and to consider if additional amendments were needed whilst also considering the importance of aligning these definitions, where relevant. They acknowledged that the comments received indicated some confusion amongst Members as to the intended meaning and use of these terms and that their September 2020 Commission reports did not provide sufficient information about the rationale for the proposed amendments. The Presidents agreed that the proposed definitions did not need significant changes and they proposed to provide a more detailed explanation of the rationale for the proposed amendments in the September 2021 Commission reports, as well as some more detailed information on the use of these terms in each Code.

At the September 2021 meeting, each President informed its respective Commission about these discussions and sought input and agreement from Commission members.

**Previous Commission reports where this item was discussed:**

September 2020 (Item 4.5.3., page 9).

**September 2021 meeting**

The Aquatic Animals Commission considered the comments received on its September 2020 report as well as the feedback from the President regarding discussion with the Code Commission President, and the outcome of the Code Commission’s discussions at its September 2021 meeting. The Code Commission had agreed that the proposed definitions did not need further edits and that its September 2021 report should include a more detailed explanation on the purpose and current use of these definitions, as well as a clearer explanation of the proposed changes.

The text presented below reflects the opinion of both Commissions and is presented in the September 2021 reports of the Aquatic Animals Commission and Code Commission to ensure a shared understanding in the context of both Codes.

***General consideration on Glossary definitions***

The objective of the glossaries in the *Aquatic* and *Terrestrial* *Codes* is to provide definitions of key terms that require precise interpretation for the purpose of their use in the Codes. These definitions might deviate from those provided by common dictionary definitions. It is desirable to pursue harmonisation where possible to assist interpretation by users of both Codes. Glossary terms should be used consistently throughout all chapters.

The Glossary definitions are expected to be concise and should not contain unnecessary descriptive detail or further elaborations beyond what is necessary to define the term. Further descriptive detail or explanation that may be necessary for the implementation of a standard are provided within the contents of the relevant chapters.

***Purpose of the definitions of ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’/‘Aquatic Animal Health Services’***

The purpose of these terms in the Codes is to differentiate responsibilities for implementation of the OIE standards. It is important to note that the definitions apply only for the purposes of each of the Codes and are not intended to dictate the administrative structure, or the naming of governmental authorities, within a Member Country. To achieve this purpose, the definitions must be applicable to the diversity of administrative arrangements among Members and must be sufficiently precise to provide clarity on the responsibilities for the implementation of the standards by relevant governmental authorities or public or private services.

***Current application of these definitions***

The *Aquatic Code* currently uses the terms ‘Competent Authority’ and ‘Aquatic Animal Health Services’ but uses ‘Veterinary Authority’ only in certain Glossary definitions and in Section 5, Trade measures, importation/exportation procedures and health certification. This approach was previously adopted (i.e. ‘Competent Authority’ in place of ‘Veterinary Authority’) because governmental responsibilities for aquatic animal health and welfare are not necessarily the responsibility of a veterinary governmental authority/agency. The Aquatic Animals Commission is aware that there are currently some inconsistent and incorrect uses of the terms within the *Aquatic Code*. Proposals to address these issues will be made and proposed for comments once the revised definitions have been adopted.

The *Terrestrial Code* uses the three terms extensively (‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’) across its different sections. The Code Commission considers that these terms are generally applied correctly in the *Terrestrial Code*, as explained above, and in line with the relevant horizontal recommendations in Section 3. Veterinary Services, notably Chapter 3.4. on Veterinary legislation. However, the use of the terms will be reviewed once the revised definitions have been adopted.

***Proposed changes to the definitions of ‘Competent Authority’, ‘Veterinary Authority’ and ‘Veterinary Services’ / ‘Aquatic Animal Health Services’***

A decision was made to revise these definitions because many users found they lacked clarity, which led to contradicting interpretations among Members, with significant discrepancies in the understanding of the terms. It is important to note that the changes proposed to the definitions are not intended to change their meaning or application, only to bring clarity.

Some cross-references between the Codes within these definitions have been removed because they are irrelevant (e.g. references to the *Aquatic Code* within definitions in the *Terrestrial Code*).

1. ***Competent Authority***

The proposed wordingrecognises that, in many countries, more than one governmental authority is responsible for implementing standards of the *Terrestrial* or *Aquatic* *Codes*. The term *Competent Authority* is intended to apply to any governmental authority with some responsibility for the implementation of some OIE standards.

Key changes to the definitions include:

‒ *‘responsibility … for implementation’ was* deemed simpler, clearer language than the current reference to ‘competence for ensuring implementation’;

‒ ‘*in the whole or part of the territory’* reflects that under some administrative arrangements government authorities may have responsibility for certain standards over the whole territory of a country, or just over a part of it, e.g. provincial or state authorities;

‒ ‘*certain standards’* reflects that governmental authorities may have responsibility for a clearly defined area of standards. Responsibility for implementation of other standards of the *Codes* would be part of the mandate of different Competent Authorities within the same country.

These revisions are consistent with Article 3.4.5. Competent Authorities, of the *Terrestrial Code*. There is no equivalent chapter on Veterinary Legislation within the *Aquatic Code*.

1. ***Veterinary Authority***

The level of detail in the existing definition was deemed unnecessary, and the definition was simplified to make it clearer. This term distinguishes the role of a single Competent Authority that has responsibility for communicating with the OIE and an overarching responsibility for implementation of OIE standards. Examples of the differentiated role for a Veterinary Authority include disease notification requirements or demonstrating compliance with international standards for international trade or for disease free status.

The Aquatic Animals Commission agreed that it was necessary to include reference to coordinating the implementation of standards ‘by Competent Authorities’ in the Glossary definition of ‘Veterinary Authority’ for the purpose of the *Aquatic Code*. These words add clarity given that ‘Competent Authority’ is the primary term used within the *Aquatic Code* (refer to the section ‘current application of the definitions’ above) and also reflects the fact that the Veterinary Authority itself may not always be the Competent Authority with responsibility for the implementation of specific standards of the *Aquatic Code*. The Code Commission did not consider this to be necessary in the definition for Veterinary Authority in the *Terrestrial Code*.

Key changes to the definitions include:

‒ ‘*comprising veterinarians, other professionals and paraprofessionals’* was removed as these words do not define the term and do not distinguish it from other governmental authorities;

‒ ‘*primary responsibility’* was included to distinguish the Veterinary Authority from other Competent Authorities;

‒ ‘*having the responsibility and competence for ensuring or supervising the implementation’* was changed to ‘*having the primary responsibility … for coordinating the implementation’* as this is more concise and direct language and reflects the fact that some standards may not be under the direct responsibility or competence of the Veterinary Authority;

‒ ‘*implementation of the standards of’* was included to replace *‘animal health and*welfare*measures, international veterinary certification and other standards of’* as the latter includes unnecessary detail*.*

1. ***Veterinary Services/Aquatic Animal Health Services***

This term covers a broad range of actors that are involved in the implementation of OIE standards and are not necessarily part of governmental authorities or regulatory agencies. This may be the case for standards that involve a complex chain of responsibilities to be appropriately implemented. The definition has been reduced substantially to the key defining elements.

This term does not refer to a defined governmental structure but to a combination of individuals and organisations, public and private, which cannot be individually listed in the definition.

Key changes to the definitions include:

‒ The word ‘*individuals’* was added to ensure that private veterinarians, aquatic animal health professionals, veterinary paraprofessionals and others, would be covered under the definition when appropriate.

‒ The terms ‘*Private sector organisations, aquatic animal health professionals*, *veterinarians,* veterinary *paraprofessionals or aquatic animal health professionals’* were removed as these were considered unnecessary, and could exclude other relevant actors.

‒ ‘*that implement animal health and welfare measures and other standards and recommendations’* was changed to ‘*that perform activities to implement standards’*, to better differentiate from the more specific role of responsible government authorities, which are covered by the terms Competent Authority and Veterinary Authority.

‒ ‘*implement standards of the Aquatic Code/Terrestrial Code’* was included to replace ‘*animal health and welfare measures and other standards and recommendations in the OIE Terrestrial Code* and *the OIE Aquatic Code’,* as the latter includes unnecessary detail.

‒ The current reference to the Veterinary Authority within the definition of Veterinary Services was not considered necessary, as the definition of Veterinary Authority is sufficiently clear, and was removed.

‒ ‘*Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health* professionals *are normally accredited or approved by the Veterinary Authority to deliver the delegated functions’* was deleted to keep the definition simple and to the point, and as these elements are described in the relevant chapters of Section 3 of the Codes.

The revised Glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Aquatic Animal Health Services’, are presented as [**Annex 5**](#A5) for Member comments.

* + 1. Chapter 1.3. Diseases listed by the OIE – Listing of infection with Tilapia Lake Virus

*Background*

Tilapia lake virus continues to be reported in new countries and poses a significant threat to many countries given the worldwide importance of tilapia farming and international trade in this species. In September 2017, the Aquatic Animals Commission reviewed the assessment of infection with tilapia lake virus (TiLV) against the criteria in Article 1.2.2. of Chapter 1.2. Criteria for listing aquatic animal diseases. The Commission agreed that the disease could not be proposed for listing at that time, as it did not meet criterion 3, ‘a precise case definition is available and a reliable means of detection and diagnosis exists’. The Commission convened an *ad hoc* Group to evaluate available diagnostic methods for TiLV.

**Previous Commission reports where this item was discussed:**

September 2016 (Item 5., page 7), February 2017 (Item 4.4., page 7), September 2017 (Item 2.3., page 8).

**September 2021**

The *ad hoc* Group on infection with tilapia lake virus conducted its work electronically between November 2017 and September 2021 and submitted its final report for the consideration of the Commission (also see Item 7.1.).

The Commission considered the *ad hoc* Group’s report and commended its members for its comprehensive work. The Commission encouraged Members to refer to the September 2021 *ad hoc* Group report available on the [OIE Website](https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/), for more details on the recommendations of the *ad hoc* Group.

In light of available information on diagnostic methods for TiLV, including the recommendations of the *ad hoc* Group, the Commission reviewed its assessment of infection with TiLV against the criteria in Article 1.2.2. The Commission agreed that criterion 3 of Article 1.2.2. was now met. The Commission also agreed that infection with TiLV meets criteria 1, 2, 4b and 4c of Article 1.2.2. and concluded that the disease should be proposed for listing in Article 1.3.1. of Chapter 1.3. Diseases listed by the OIE.

The Commission advised Members that should new scientific evidence become available that could impact the outcome of this assessment for listing, the Commission would review its assessment, and encouraged Members to provide any such information for its consideration.

The revised Article 1.3.1. of Chapter 1.3. Diseases listed by the OIE is presented as [**Annex 6**](#A6)for Member comments.

The revised Assessment for listing infection with tilapia lake virus is presented as [**Annex 6**](#ATiLV) for Members’ information.

* + 1. Approaches to demonstrate disease freedom

*Background*

A discussion paper, developed by the Aquatic Animals Commission, on approaches for determining periods required to demonstrate disease freedom, was first circulated for comments in the Commission’s September 2018 report. The Commission considered comments received and circulated a revised discussion paper in its September 2019 report. Model Articles to replace the existing Articles X.X.4.–X.X.6. within the disease-specific chapters of the *Aquatic Code* were provided for Member comments in the Commission’s February 2020 report.

At its September 2020 meeting, the Commission considered all comments received and agreed that a revised Chapter 1.4. Aquatic animal health surveillance, was necessary to complement the model articles and ensure all comments were addressed appropriately. The revised Chapter 1.4. and the model Articles to replace X.X.4.−X.X.6., were provided to Members for comment in its February 2021 report.

**Previous Commission reports where this item was discussed:**

September 2018 report (Item 2.10., page 11); September 2019 report (Item 6.6., page 9); February 2020 report (Item 7.2.2., page 15); September 2020 (Item 6.2., page 16), February 2021 (Part B: Item 1.2., page 4).

* + - 1. *Chapter 1.4. Aquatic Animal Health Surveillance*

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

**Previous Commission reports where this item was discussed:**

February 2021 report (Part B: Item 1.2.1., page 4).

**September 2021**

The Commission reminded Members that the revision of Chapter 1.4. is intended to align with the approaches proposed in the discussion paper previously provided to Members for comment. The revised Chapter 1.4. is focused on providing guidance for self-declaration of freedom from disease, rather than providing general guidance on aquatic animal health surveillance.

The Commission did not agree with comments to revert to the original title, as the revised title reflects the new approach for this chapter. The revised chapter provides recommendations for methods of surveillance to detect aquatic animal diseases, with a focus on self-declaration of freedom from disease.

The Commission did not agree with a comment to include some Glossary definitions in Chapter 1.4. and noted that definitions used in the *Aquatic Code* are provided in the Glossary.

**Article 1.4.1. Purpose**

The Commission agreed with a comment to add ‘...and maintain...’ to reflect that this chapter addresses the continued demonstration of freedom from disease.

**Article 1.4.2. Introduction and scope**

In point 3, the Commission agreed with a comment that additional clarification was required to specify the four pathways for claiming freedom, and added a reference to Article 1.4.3., as well as some additional details in other articles.

**Article 1.4.3. Pathways for demonstrating freedom from disease**

In point 2, the Commission did not agree with a comment to remove the reference to a country’s early detection system as the Commission considered that this clarifies that the role of the early detection system is to generate passive surveillance information.

In point 2, the Commission agreed with a comment that passive surveillance may provide more qualitative information than just data and replaced ‘passive surveillance data’ with ‘passive surveillance information’ as well as throughout the rest of the chapter. The Commission agreed with a comment that general knowledge generated through the awareness, readiness, and competence of the aquatic animal health infrastructure are key elements of passive surveillance, but decided that is better described in Article 1.4.7.

In the title of point 3, the Commission agreed with a comment to amend the title to ‘Targeted surveillance’, noting that while all pathways utilise ‘surveillance’ in some way, the third pathway is primarily the use of targeted surveillance to achieve freedom from disease. The Commission also added ‘targeted’ in the rest of this chapter to identify this pathway, where appropriate.

In the first sentence of point 3, the Commission reminded Members that a country may choose targeted surveillance rather than the first two pathways for many reasons and not only if Pathway 1 or 2 cannot be met.

The Commission agreed to add a sentence to point 3 that passive surveillance could be used within the targeted surveillance pathway. A similar sentence was also added to point 2 to provide consistency with this change.

The Commission did not agree with a comment that the key difference between passive surveillance and historical freedom is the generation of empirical data and explained that passive surveillance can be subject to quantitative analysis if required such as through scenario tree analysis.

In Table 1.1, the Commission agreed with comments to replace ‘Active Surveillance’ with specific types of primary surveillance evidence and added ‘Surveys, historical data, import records, environmental information’ to align with Article 1.4.11. that describes the type of evidence required. The Commission did not agree with a comment to add compartment as an applicable level of application for Pathway 1, as it considered that targeted surveillance should be undertaken to establish free status for a compartment.

**Article 1.4.4. Publication by the OIE of a self-declaration of freedom from disease by a Member Country**

The Commission reminded Members that the Standard Operating Procedure on the publication of the self-declaration of animal health status of Members as well as the list of self-declarations are available on the OIE website: [https://www.oie.int/en/what-we-offer/self-declared-disease-status/.](https://www.oie.int/en/what-we-offer/self-declared-disease-status/)

In the first paragraph, the Commission agreed to change ‘may’ to ‘should’ to indicate that all claimed statuses should be declared to the OIE given that it is the OIE that processes these self-declarations. The Commission also agreed to add ‘for a country, zone or compartment’ after ‘claimed status’ to reflect the three different types of self-declarations.

In point 1, the Commission agreed to add ‘or return to freedom’ to reflect a self-declaration using Pathway 4.

In point 2, the Commission agreed to replace ‘general requirements’ with a specific reference to ‘basic biosecurity conditions and the requirements’ to highlight the specific requirements for self-declaration.

In the fourth paragraph, the Commission agreed to add a sentence to inform Members of the linkage between OIE-WAHIS and the published list of self-declarations and to clarify that if a notification of a disease outbreak for a country, zone or compartment is received, for a self-declared status, the OIE website would be updated accordingly.

**Article 1.4.5. Biosecurity and surveillance system requirements**

In the first paragraph, the Commission agreed to add ‘biosecurity and’ before ‘surveillance system’ in line with the title of this article and the to reflect that the articles that follow are not solely concerned with surveillance system requirements. The Commission also agreed to add ‘in the given compartment, zone or country’ at the end of the paragraph to clarify the scope of the subitems.

The Commission did not agree to remove point 3, as it provided an explicit reference to early detection systems.

In point 5, the Commission agreed to add ‘and expertise’ after ‘capacity’ as both capacity and expertise are needed for disease investigations.

The Commission did not agree to delete point 5, as it considered that a reference to capacity and expertise for disease investigations emphasised the importance of these elements.

In point 6, the Commission agreed to add ‘(from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*)’ after ‘appropriate diagnostic capability’ to highlight the importance of a quality management in veterinary testing laboratories.

**Article 1.4.6. Basic biosecurity conditions**

The Commission agreed to delete point 1 on notification, as a compulsory requirement for reporting of a disease to the Competent Authority is addressed in point 5 of Article 1.4.7. Early detection system.

In the new point 1 (previously point 2), the Commission did not agree with a comment to add ‘how they support the Competent Authority’s’ before ‘early detection system’, noting that both the public and private sectors contribute to a functioning early detection system.

In the new point 2 (previously point 3), the Commission did not agree to delete ‘within or’ as the aim is to minimise the spread from infected establishments, including to other establishments in the infected zone and to establishments in the protection zone.

In the last paragraph, the Commission agreed with a comment to add ‘a specific’ after ‘self-declaration of freedom’ to emphasise that the self-declaration is for a specific disease. The Commission also added ‘continuously’ at the end of the paragraph to emphasise that the basic biosecurity conditions must be continuously met to make a self-declaration of freedom. The Commission agreed to simplify some other wording to improve clarity, including deletion of the second reference to ‘basic biosecurity conditions’.

**Article 1.4.7. Early detection system**

In the first paragraph, the Commission agreed to make the following amendments to improve clarity:

‒ ‘data’ was replaced by ‘information’ to reflect that passive surveillance may provide qualitative information or empirical data. Similar amendments were made in Articles 1.4.8., 1.4.12., 1.4.16. and 1.4.17.;

‒ ‘underpins any’ was replaced by ‘is important to collect’ to reflect the role of the early detection system in collecting passive surveillance information.

In the second paragraph, the Commission agreed to replace ‘five characteristics’ with ‘requirements’ as this is more appropriate wording.

In point 1, the Commission agreed to add the word ‘observers’ and to provide examples. The Commission highlighted the importance that awareness of the characteristic signs of listed and emerging diseases does not only apply to farmers.

In point 4, the Commission agreed to add ‘(from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*)’ to highlight the importance for the Aquatic Animal Health Services to have access to laboratories that meet the OIE standards for diagnostic testing. The Commission did not agree with a comment questioning the reference to emerging diseases in this point, and noted that the reference to emerging disease is important because investigations of morbidity and mortality may rule out listed diseases but there is also an obligation to investigate and report emerging diseases. The Commission also added ‘the capacity and expertise to investigate’ before ‘emerging diseases’ to reflect the change made in Article 1.4.5.

In point 5, in response to a comment that this point (a legal/compulsory requirement to report) is duplicated in point 1 of Article 1.4.6., the Commission noted that it had proposed to delete point 1 of Article 1.4.6. (also see above) and to retain point 5 in Article 1.4.7. as this is the more appropriate article to reference this requirement.

In point 5, the Commission agreed with a comment to include other relevant persons to report suspicions of disease occurrence such as ’others with an occupational role with aquatic animals’, in addition to veterinarians and aquatic animal professionals as they should also have a legal obligation to report.

In point 5, the Commission added ‘listed and emerging diseases’ after ‘report suspicion of’ to reflect that Article 1.4.2. includes both listed and emerging diseases.

In the third paragraph, the Commission agreed with comments that the obligation of the Competent Authority is to demonstrate that efforts have been made to make more than farmers aware of the signs of listed diseases and emerging diseases, and that this obligation also applies to reporting suspicions of disease. The Commission was of the opinion that these obligations would be applicable to more observers than farmers and fishers, and decided to add ‘aquatic animal health professionals, veterinarians and others’ after ‘farmers’ in the second sentence to emphasise the importance of reporting by these groups and replace ‘farmers with ‘relevant observers (e.g. farmers and fishers)’ in the third sentence and to include 'with an occupational role with aquatic animals’ after ‘others’ at the end of the same sentence. A relevant observer could include the owner of, or any person attending, aquatic animals; any person accompanying aquaculture animals during transport or any other person with an occupational relationship to aquatic animals.

In the third paragraph, the Commission did not agree with a comment to delete the second sentence as it considered that farmers are the key observers and that aquatic animal health professionals may be occasional observers.

In the last paragraph, the Commission clarified that the early detection system generates general knowledge (better described as information, rather than data which implies something empirical) generated through the awareness, readiness, and competence of the aquatic animal health infrastructure. Strong systems (combined with a pathogenic agent that manifests clinically) should, given enough time, detect disease if it was present. The Commission edited the paragraph to clarify that a quantitative assessment of the early detection system is generally not required and that a qualitative assessment would be sufficient for the self-declaration of freedom.

**Article 1.4.8. Requirements for passive surveillance**

In point 1 a), the Commission did not agree with a comment to replace ‘infection’ with ‘disease’ as it would appear tautological. The Commission did, however, agree to add ‘at least seasonally’ at the end of the sentence to clarify that conditions to not need to be continuously conducive to clinical expression of the disease.

In point 1 b), the Commission agreed to replace ‘reporting’ with ‘investigation and where appropriate, reporting to the Competent Authority’. This reflects that farmers, in many cases, would be the first to detect and report signs of disease to a private veterinarian or aquatic animal health professional who has the obligation to report to the Competent Authority, if they suspected a listed disease.

In point 1 c), the Commission agreed to delete ‘in all relevant production systems’ to clarify that passive surveillance requires sufficient observation of the animals such that the clinical signs would be observed if they were to occur – whether that be in production systems or other contexts (e.g. transport).

In point 1 d) i), the Commission did not agree with comments to delete ‘sufficient’ in front of ‘observation’ as observations need to be sufficient to achieve the outcomes of observation and reporting. The Commission agreed to delete the word ‘clinical’ in front of ‘signs of disease’ as it is redundant. The Commission deleted ‘clinical’ in front of ‘signs of disease’ throughout the chapter, for consistency.

In point 1 d) ii), the Commission agreed to amend the text to reduce wordiness and clarify that wild aquatic animals must be epidemiologically linked to farmed populations such that disease occurring in wild populations would also occur in farmed populations and be observed and reported.

In point 2, the Commission:

‒ agreed to add ‘veterinarians and others’ to the examples of observers in the first sentence as veterinarians in the private sector have a role to play in passive surveillance and should therefore be included together with aquatic animal health professionals;

‒ agreed to add ‘recognizing signs that are suspicious of a listed disease’ after the example in brackets, in the first sentence, to ensure consistency with the Glossary definition of ‘early detection system’;

‒ agreed to replace ‘are unlikely to be’ with ‘may not be’ to reflect the possible relevance of passive surveillance for wild populations;

‒ did not agree to delete ‘under most’ before ‘circumstances’ in the second sentence as it considered that this wording is accurate;

‒ agreed that the correct reference in the second sentence was 1 d) i) rather than 4 a);

‒ agreed in the last sentence to replace ‘provides appropriate sensitivity for’ with ‘will result in’ as the defined term “sensitivity” is not appropriate in this context.

In point 4 a), the Commission agreed to amend the text by specifying that the environmental conditions must be permissive for the development of clinical signs at least seasonally.

In point 4 b), the Commission did not agree with a comment to add ‘representative’ in front of ‘presence’ as this was not relevant for passive surveillance.

In point 5, the Commission agreed to restructure the sentence to avoid duplications and to improve clarity.

In point 6, the Commission agreed to amend the text to emphasise the importance of observations and initial investigations by farmers and private veterinarians or aquatic animal health professionals through passive surveillance to be rapidly reported to the Competent Authority for subsequent investigation.

**Article 1.4.9. Required periods for basic biosecurity conditions**

In point 1 a), the Commission agreed with a comment to amend the text to clarify that the application of this clause is to a specific pathogenic agent that is the subject of a declaration of freedom.

The Commission agreed with a comment to rephrase point 2 to clarify that the minimum periods that basic biosecurity conditions should be in place prior to a self-declaration of freedom from disease are defaults. These default periods are included in each disease-specific chapter, however, following consideration of the factors specified in this article longer periods may be deemed necessary for inclusion in the relevant chapter. The Commission confirmed that the factors in this article are used to set the requirements in each disease-specific chapter and are not provided for application by Competent Authorities.

In point 2 b), the Commission made amendments to clarify that for Pathway 2, the default minimum period of basic biosecurity conditions required prior to a self-declaration, for all listed diseases, is ten years.

In the same point, the Commission did not agree with a comment to allow for a shorter period to achieve 95% likelihood of freedom if the annual likelihood of detection can be demonstrated to substantially exceed 30%, noting that these are default minimum periods. The Commission noted that if a shorter period was to be included as an option, standards for quantitative assessment of passive surveillance sensitivity would be required and the standards would need to be updated to include guidance on the requirements for the quantitative assessment.

The Commission clarified that Pathway 2 would not be applicable for emerging diseases as it would not be possible to have basic biosecurity conditions in place for a disease if it had not been a known disease for at least 10 years.

In point 2 b) v), the Commission did not agree with a request to add ‘in susceptible species’ after ‘clinical expression’ as it considered this to be redundant because clinical expression would only occur in susceptible species.

In point 2 c), the Commission did not agree with a comment to allow for a default minimum period of basic biosecurity conditions of less than one year prior to commencement of targeted surveillance. The Commission had chosen a default one-year minimum period as it expected that this period will be sufficient under most circumstances for a disease to reach a prevalence sufficiently high to be detected by a survey designed in accordance with the recommendations of Chapter 1.4.

**Article 1.4.10. Required periods for targeted surveillance**

In the second paragraph, the Commission agreed to add a cross reference to ‘Article 3.1. Selection of populations and individual specimens, of relevant disease-specific chapters of the *Aquatic Manual*’, to clarify that this paragraph is about the sampling frame and not the populations that will be sampled. The Commission informed Members that the intention here was not to suggest every species or population be sampled, but rather that all populations of susceptible species be considered when designing surveys, and then the prioritised populations, based on likelihood of infection, would be sampled.

In the second paragraph, the Commission did not agree with a comment that surveys with relatively continuous sampling could accrue results within a six-month period without a three-month break between surveys. The Commission considered that there was a need to ensure there is a distinction between time-limited targeted surveys for the purpose of declaring freedom and routine sampling that is unlikely to be optimised for detection of the target pathogen. Targeted surveys should be designed to generate a 95% confidence of detection; however, sample size calculations and analysis of the results are considerably more complex when sampling a small number of animals on a frequent or continuous basis in comparison to at a limited number of sampling events at specified time points. This same rationale was applied to a comment in Article 1.4.12.

In the penultimate paragraph, the Commission agreed to amend the text to emphasise that if a different period for targeted surveillance is stipulated in the disease-specific chapter, the minimum required period would be more than one year.

In response to a comment, the Commission agreed to amend the last paragraph, to clarify that one survey in a compartment is required to ensure that basic biosecurity conditions are effective. The Commission also added text to clarify that the minimum period of targeted surveillance required prior to returning to free status will be specified in the relevant disease specific chapter of the *Aquatic Code*.

**Article 1.4.11. Pathway 1 – Absence of susceptible species**

In point 1, the Commission did not agree to delete ‘sound’ at the beginning of the sentence or to insert ‘in the country/zone/compartment’ in front ‘of susceptible species’ as the intent is that the pathway would not be applicable for diseases with an uncertain host range; for example, where the host range is broad and is expected to increase with exposure of hosts in new geographic areas. The pathway would not be available for some diseases with uncertainty regarding their host range and would not be included as an option in the relevant disease-specific chapter. This is explained in the penultimate paragraph of this article.

In point 2, the Commission agreed with a comment to delete ‘based on active surveillance’ and added ‘demonstrated by the following forms of evidence’ to indicate the forms of evidence that could be used to establish the absence of susceptible species. The Commission did not agree with a comment to add a definition for active surveillance as the above change meant the term would not be in use.

The Commission did not agree with a comment to add text in the last paragraph on intentional or non-accidental introduction of susceptible species that are not documented to be part of the country’s natural fauna and subsequent use of Pathway 1 for declaration of freedom. If susceptible species have been introduced, through intentional or accidental means prior to a self-declaration of freedom being made, targeted surveillance, through Pathway 3, would be required to have confidence in the disease free status.

**Article 1.4.12. Pathway 2 – Historically free**

The Commission amended the title to ‘historical freedom’ to harmonise with the use of terminology in the rest of the chapter.

The Commission did not agree with a comment to add information regarding annual sensitivity of the surveillance system and potential for changing pathways as it determined that the text was clear as written.

Requirements for passive surveillance

In the second paragraph, the Commission agreed with a comment to delete ‘(and ideally a quantitative assessment of sensitivity would be included)’, noting that a qualitative assessment is

considered to be sufficient in most circumstances. The Commission also note that a requirement for quantitative assessment of passive surveillance sensitivity would put a claim of historical freedom out of reach for most Members.

Need for targeted surveillance

The Commission agreed with a comment to rephrase the text to improve clarity, and noted that the intent of this sentence was to indicate that this pathway should only be used if passive surveillance information is the primary form of evidence that the disease is absent.

The Commission did not agree with a request that Pathway 2, could be applied for compartments.

The Commission did also not agree with a comment to allow for a shorter period to claim historic freedom and advised that Pathway 3 should be used in such cases.

**Article 1.4.13. Pathway 3 – Surveillance**

The Commission amended the title to ‘Targeted surveillance’ to harmonise with the use of terminology in the rest of the chapter.

The Commission agreed with a comment that information provided in point 1 is duplicated in the subsequent paragraph. It agreed to delete the paragraph entitled ‘Requirements for basic biosecurity conditions’ and insert additional information at the beginning of point 1 for clarity.

Requirements for targeted surveillance

In the first paragraph, the Commission agreed to delete the phrase ‘the rate’ as it was not needed.

In the third paragraph, the Commission did not agree with a comment, also received on Article 1.4.10., that surveys with relatively continuous sampling could accrue results within a six-month period without a three-month break between surveys. See Article 1.4.10. for the Commission’s explanation.

In the third paragraph, the Commission agreed to replace ‘an overall’ with ‘at least’, as 95% confidence is the minimum standard and is consistent with text in Article 1.4.14. The Commission also agreed to add ‘set to a maximum’ after ‘should be’ and delete ‘or lower’ after ‘2%’ as 2% is consistent with Article 1.4.14.

The Commission agreed to delete the last paragraph as this was covered in Article 1.4.15.

Other sources of data

The Commission agreed to replace ‘structured surveillance’ with ‘targeted surveillance’, as it was a more appropriate term.

**Article 1.4.14. Pathway 4 – Returning to freedom**

In the third paragraph, the Commission amended the text for improved clarity and to align with proposed amendments in Article 1.4.10.

In the fourth paragraph, the Commission agreed to add ‘and update’ after ‘review’ to ensure that if there was a breach of basic biosecurity conditions then these would also need to be updated.

1. Infected zone and protection zone

In the second paragraph, the Commission agreed with a comment to add text that consideration should also be given to the type of aquaculture production system (open or closed). Vectors was added in sentences 2 and 4 to ensure that movements of vectors are considered in addition to wild susceptible species.

2. Requirements for targeted surveillance in a country or zone

In point 2 b), the Commission agreed with a comment to replace ‘geographical’ with ‘hydrographical’ to reflect the fact that sites can be geographically close but not epidemiologically linked by water.

The Commission agreed with a request to add a sentence at the end of the last paragraph to clarify that if disease is detected in wild populations of susceptible species, and eradication is not possible, the country or zone remains infected. The Commission did not agree to add recommendations on further actions (e.g. establishing compartments) as this was not thought to be appropriate. Any further actions would be decided by the Competent Authority.

3. Requirements for targeted surveillance in a compartment

The Commission agreed with a comment to add ‘or at the maximum length of time allowed by production cycle of species’ after ‘6 months’ to clarify that the production cycle of some species is shorter than six months.

In response to a comment about the need to ensure a flexible approach to determining survey design within compartments, the Commission reminded Members that this was included in the discussion papers and that Members had indicated that at least one survey should be required. The Commission also reminded Members that the requirements for surveillance to maintain freedom would also have to be met.

**Article 1.4.15. Maintenance of disease free status**

The Commission agreed that the requirements to maintain freedom should be based on the level of confidence that a country, zone or compartment remains free, rather than the initial pathway utilised to achieve freedom. The Commission also considered that the information included in model Article X.X.8. for each listed disease was applicable to all diseases and better suited for inclusion in Article 1.4.15. The Commission noted that additional information regarding maintenance of freedom may be necessary in Article X.X.8. of disease-specific chapters based on the epidemiology of a disease.

The Commission revised Article 1.4.15. consistent with the above approach based on the guidance included in both model Article X.X.8. and Article 1.4.15. (also see Item 5.1.4.2.).

The Commission agreed with a comment that Competent Authorities should ensure prompt investigation of any health events or other information that may raise suspicion of the occurrence of a listed disease from which a country, zone or compartment that has been declared free. Text to this effect was added to the revised article.

**Article 1.4.16. Design of surveys to demonstrate freedom from disease**

In the first sentence of the first paragraph, the Commission agreed to add ‘and maintain freedom’ after ‘Article 1.4.14.’ as this article applies to the maintenance of a claim of freedom, as well as regaining freedom.

In the first paragraph, the Commission did not agree with a comment to remove ‘clinical’ in ‘clinical expression of disease’ as it considered that ‘clinical’ was appropriate in the context of ‘conditions conducive to clinical expression of disease’.

1. Population

In the second paragraph, the Commission agreed with a comment to add ‘within the selected population’ after ‘all individuals’ to avoid misunderstanding that all susceptible species may require sampling. Similarly to Article 1.4.10., the intention is not to suggest that every species or population be sampled, but rather that all populations be considered when designing surveys (i.e. within the sampling frame), and populations would then be prioritised for sampling based on the likelihood of infection.

In the fourth paragraph, the Commission agreed with a comment to add ‘Similarly, wild aquatic animal populations are not evenly distributed within a zone’, as it considered that this should be considered in the design of surveys as it could lead to clusters of infection.

In the fourth paragraph, the Commission agreed with a comment to delete ‘ponds’ as ponds may not be a good example of a first stage sampling group for a two-stage sampling survey.

In the last sentence of the fourth paragraph, the Commission agreed to replace ‘selected’ with ‘first stage sampling’ to make the text more explicit about two-stage sampling.

3. Statistical Methodology

In the second point b), the Commission agreed with a comment to add ‘that can remain sub-clinical’ because there is a difference between transient infection and subclinical infection. Transient disease is not detected effectively even at very low design prevalence (e.g. for infection with ISAV HPR0), whereas subclinical disease (e.g. for infection with KHV) is present at very low levels but can be detected at a low (1% or less) design prevalence.

4. Risk based sampling

In point a), the Commission agreed with a comment to amend the text to reflect the five transmission pathways that are outlined in Article 1.4.7. of Chapter 4.1. Biosecurity for aquaculture establishments.

In point b), the Commission agree with a comment to delete ‘quarantine facilities’ as this did not align with the definition for quarantine in the Glossary.

5. Test characteristics

In the second paragraph, the Commission did not agree to delete ‘not’ before ‘be pooled’ as it is not acceptable to pool samples for a declaration of freedom without evidence to support such an approach. The Commission also noted that the text includes a reference to the disease-specific chapters of the *Aquatic Manual* that provide guidance on pooling.

7. Multi-stage structured survey design

In the second sentence of paragraph 1, the Commission agreed with a comment to add ‘or discrete populations of wild susceptible species’ after ‘(or villages)’ and ‘or defined stocks within a wild population’ after (or village) to provide examples on how sampling levels can be applied to wild populations.

8. Discounting

In the first paragraph, the Commission agreed with a comment to add ‘of disease in a population’ after ‘clinical expression’ to ensure consistency of terminology within the chapter.

**Article 1.4.18. Diagnostic confirmation of a listed disease or an emerging disease**

In the fifth paragraph, the Commission agreed to include a cross reference to Chapter 1.1.1. of the *Aquatic* *Manual*.

In the final paragraph, the Commission did not agree to add an additional sentence regarding the implementation of disease control measures when the presence of a listed or emerging disease is suspected or confirmed as this is outside the scope of Article 1.4.18. and covered elsewhere in the chapter.

The revised Chapter 1.4. Aquatic Animal Health Surveillance, is presented as [**Annex 7**](#A7) for Member comments.

* + - 1. *Model Articles X.X.4. to X.X.8. for disease-specific chapters to address declaration of freedom from [Pathogen X]*

Comments were received from Canada, Japan, the UK and the EU.

*Background*

At its February 2020 meeting, the Aquatic Animals Commission considered comments received on the discussion paper ‘Approaches for determining periods required to demonstrate disease freedom’, and presented model Articles X.X.4., to X.X.8. for the disease-specific chapters of the *Aquatic Code* for comments.

At its February 2021 meeting the Commission considered comments on the model Articles X.X.4. to X.X.8. These articles were amended in conjunction with amendments to the draft revised Chapter 1.4. Aquatic Animal Health Surveillance. The Commission highlighted that relevant cross-references to articles of Chapter 1.4. have been included in the model articles.

**Previous Commission reports where this item was discussed:**

February 2020 report (Item 7.2.2., page 15); February 2021 report (Part B: Item 1.2.2., page 5).

**September 2021**

The Commission noted that time periods in these model articles will be determined by the Commission for each disease-specific chapter based on the criteria that are included the revised Chapter 1.4. For this reason, periods are shown as [X] to indicate that the period is yet to be determined for each specific disease. Assessment of the periods for each disease-specific chapter of the *Aquatic Code* will occur following adoption of the revised Chapter 1.4. and the model articles X.X.4 to X.X.8.

**Article X.X.5. Country free from infection with [PATHOGEN X]**

In point 2 a), the Commission did not agree with a comment to replace ‘conditions that are conducive to the clinical expression of infection with [PATHOGEN X], as described in the corresponding chapter of the *Aquatic Manual*’ with ‘passive surveillance was undertaken in accordance with the conditions outlined in Chapter 1.4., Articles 1.4.7. and 1.4.8.’. The Commission explained that this is not appropriate given that point 2 b) requires that basic biosecurity conditions have been continuously met, including that an early detection system be in place. The Commission also did not agree with the same comment on point 2 a) of Article X.X.6.

In point 1), the Commission agreed to amend the default minimum period from two years to six months to align with the revised Article 1.4.9.2. a) of Chapter 1.4. The same amendment was made to Article X.X.6. point 2 b).

In the first line of point 4 d), the Commission agreed with a comment to add ‘in wild and farmed susceptible species’ to make it explicit that targeted surveillance would be required in both wild and farmed susceptible species to facilitate a self-declaration of freedom when farms and wild populations are epidemiologically linked. Under these circumstances, at least two years of surveillance would be required.

In the sixth paragraph of point 4, the Commission reminded Members that these are model articles and once adopted, the relevant amendments, including time periods (presented in square brackets) will be applied to each of the disease-specific chapters. The default minimum periods will be applied unless consideration of the relevant factors in Chapter 1.4. indicates that a longer period would be required.

**Article X.X.6. Zone free from infection with [Pathogen X]**

In point 4 d), the Commission did not agree with a comment to add ‘using a suitable sample size, and under conditions including water temperature, which are conducive to the clinical expression of the disease’ as it considered that there are numerous considerations for targeted surveillance throughout Chapter 1.4. and ‘as described in Chapter 1.4.’ ensures that all considerations for targeted surveillance are considered.

**Article X.X.7. Compartment free from infection with [Pathogen X]**

In point 2 b) the Commission agreed that basic biosecurity conditions do not include a biosecurity plan and so it added ‘compartment’ to the first line. The Commission agreed to amend the definition of biosecurity plan to refer to Chapter 4.1. (also see Item 5.1.2.1.).

In point 2 c), the Commission did not agree to add ‘However, a different period (less than one year) may be stipulated if warranted by the epidemiology of the disease and the criteria described in Article 1.4.10. of Chapter 1.4.’ at the end of the point. The Commission noted that Article 1.4.10. describes the criteria for setting the period for targeted surveillance for each disease-specific chapter and that changes have been proposed to Article 1.4.10. for clarity (see Item 5.1.4.1.).

**Article X.X.8. Maintenance of free status**

The Commission agreed to amend model Article X.X.8. and Article 1.4.15. as described above (see Item 5.1.4.1.). Much of the information that had been included in this model article was moved to Article 1.4.15. as it was better suited there. A cross reference to Article 1.4.15. was provided and the commission noted that, based on the epidemiology of a specific disease, additional information regarding maintenance of freedom may sometimes be necessary in model Article X.X.8. of disease-specific chapters.

The revised model Articles X.X.4. to X.X.8. for disease-specific chapters to address declaration of freedom from [Pathogen X] are presented as [**Annex 8**](#A8) for Member comments.

* + 1. Safe Commodities – Articles X.X.3 for disease-specific chapters

*Background*

At its September 2020 meeting, the Aquatic Animals Commission reviewed Article X.X.3. of all disease-specific chapters to address comments that the recommended time and temperature treatments in these articles represented different levels of thermal treatment and that some were not commercially feasible as they would diminish product quality. The Commission noted that it was difficult to propose a uniform model Article X.X.3. because of differences in time/temperature treatments as well as products in Article X.X.3. between disease-specific chapters. Therefore, the Commission developed an example article, Article 9.8.3. Infection with white spot syndrome virus, to demonstrate the suggested approach for Member comments.

At its February 2021 meeting, the Commission considered comments and amended the example article and then applied these amendments to all of the disease-specific chapters in Section 9 of the *Aquatic Code*, Diseases of crustaceans. The time/temperature treatments provided in Articles 9.X.3. for all of the crustacean disease-specific chapters were adjusted in line with the information provided in the ‘[Safe commodity assessments for OIE listed aquatic animal diseases](https://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/Aquatic_Commission/Aquatic_Animal_Product_Assessment_FINAL_110416.pdf)’ published in 2016.

The Commission also proposed a specific time/temperature heat treatment for meal in Articles 9.X.3. As a result of this amendment, the Commission indicated that the use of the definition of ‘meal’ throughout the *Aquatic Code* would be discussed at the Commission’s September 2021 meeting to determine if the addition of a core time/temperature for meal in Article X.X.3. will require the Glossary definition be amended.

**September 2021**

The Commission reviewed the use of ‘meal’ throughout the *Aquatic Code* and agreed that the addition of a specific time/temperature heat treatment for meal included in Articles 9.X.3. did not impact the definition of meal in the Glossary. As a result, no amendments have been proposed for the definition of meal in the glossary.

The Commission noted that in some of the articles of the disease-specific chapters (e.g. Articles 9.X.7., 9.X.8., 9.X.9. and 9.X.10.) there is a cross-reference to ‘point 1 of Article X.X.3.’. Given the proposed amendments to point 1 of Article 9.X.3. and 10.X.3., the Commission agreed that the cross reference to ‘point 1’ should be deleted from the relevant articles once the proposed amendments to Articles 9.X.3. and 10.X.3. are adopted.

The Commission agreed to implement these revisions one section at a time and to circulate for comment the revised Articles 9.X.3.(crustacean diseases) and Articles 10.X.3. (fish diseases); revised Articles 8.X.3. (amphibian diseases) and Articles 11.X.3. (mollusc diseases) would be circulated for comment in its February 2022 report.

* + - 1. *Revised Articles 9.X.3. for crustacean disease-specific chapters*

Comments were received from the USA and the EU.

**Previous Commission reports where this item was discussed:**

September 2020 (Item 4.7., page 10), February 2021 (Part B: Item 1.4., page 8).

**September 2021 meeting**

**Article 9.X.3. of all crustacean disease-specific chapters**

The Commission agreed with a comment that when a time period is presented as a fraction of a minute that this may be difficult to interpret when translated into different languages. The Commission agreed to ensure that any fractions of minutes used in the *Aquatic Code* will be amended to appear as seconds. In addition, when the time/temperature heat treatment requires only one minute for inactivation this has been amended to read as sixty seconds. For time periods greater than one minute, the time will remain in minutes.

The Commission re-ordered the aquatic animal products listed in Articles X.X.3. so that all thermal treatments for inactivation of a specific pathogenic agent appear in the list before other products and treatment types; for example, meal was moved above oil.

**Article 9.1.3.1. Acute hepatopancreatic necrosis disease (AHPND)**

In point 1 a), the Commission did not agree with a comment to remove ‘sufficient to attain a core temperature of at least 100°C for at least one minute (or a time/temperature equivalent that has been demonstrated to inactivate VpAHPND)’, and noted that this information is based on the core temperatures required for the inactivation of AHPND as presented in the commodity assessments available at <https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/>.

The revised Articles 9.X.3. for crustacean disease-specific chapters are presented as [**Annex 9**](#A9) for Member comments.

* + - 1. *Revised Articles 10.X.3. for fish disease-specific chapters*

**September 2021 meeting**

The time/temperature treatments provided in Article 10.X.3. of all fish disease-specific chapters were amended in line with the information provided in the [2016 Safe commodity assessments for OIE listed aquatic animal diseases](https://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/Aquatic_Commission/Aquatic_Animal_Product_Assessment_FINAL_110416.pdf). These articles were also amended in line with the proposed changes in the crustacean disease-specific Articles 9.X.3. (see Item 4.1.5.1.).

**Article 10.3.3. – Infection with *Gyrodactylus salaris***

The Commission agreed to not apply the proposed time/temperature heat treatment for *G. salaris* given that *G. salaris* would not survive in a pasteurised or retorted product as the parasite would not survive in any heated product.

The revised Articles 10.X.3. for fish disease-specific chapters are presented as [**Annex 10**](#A10) for Member comments.

* + 1. Draft Chapter 9.X. Infection with decapod iridescent virus 1

*Background*

Following the adoption of infection with decapod iridescent virus 1 (DIV1) in Article 1.3.1. of Chapter 1.3. Diseases listed by the OIE, at the 88th General Session in May 2021, the Commission developed a draft Infection with DIV1 chapter for the *Aquatic Code*.

**September 2021**

The Commission developed a draft of Chapter 9.X. Infection with decapod iridescent virus 1, based on the article structure of other disease-specific chapters in Section 9. This new chapter includes proposed horizontal amendments to article structure, such as the model Articles X.X.4. to X.X.8. (see also Item 5.1.4.2.) and Articles 9.X.3. (see also Item 5.1.5.1.). The Commission noted that the proposed article structure for 9.X.3., and 9.X.4. to 9.X.8., is dependent on adoption of the model articles by Members.

The Commission noted that the susceptible species in Article 9.X.2. would be placed under study pending assessment against Chapter 1.5. Criteria for listing species as susceptible to infection with a specific pathogen. The aquatic animal products listed in Articles 9.X.3. and 9.X.14. would be placed under study pending assessment against Chapter 5.4. Criteria to assess the safety of aquatic animal commodities.

The Commission agreed that the default periods for basic biosecurity conditions and targeted surveillance presented in the revised Chapter 1.4. Aquatic Animal Disease Surveillance, would be appropriate for infection with DIV1. The Commission noted that following the adoption of the revised Chapter 1.4. an assessment of these periods would be required for all listed diseases, including infection with DIV1.

The new draft Chapter 9.X. Infection with decapod iridescent virus 1, is presented as [**Annex 11**](#A11) for Member comments.

* + 1. Article 10.1.2. of Chapter 10.1. Infection with epizootic haematopoietic necrosis virus

The Aquatic Animals Commission agreed to list fish species susceptible to infection with epizootic haematopoietic necrosis virus in a table format, in line with the convention to list susceptible species in table format if there are more than ten species susceptible. (see also Item 6.1.3.).

The revised Article 10.1.2. of Chapter 10.1. Infection with epizootic haematopoietic necrosis virus, is presented as [**Annex 12**](#A12) for Member comments.

* + 1. Article 10.10.2. of Chapter 10.10. Infection with koi herpesvirus

The Aquatic Animals Commission noted that common carp X crucian carp hybrids (*Cyprinus carpio x Carassius carassius)* had been omitted from Article 10.7.2. despite these hybrids having been found susceptible through the assessment of the ad hoc group of susceptibility of fish species. The Commission agreed to correct this omission (see also Item 6.1.5.).

The amended Article 10.7.2. of Chapter 10.7. Infection with koi herpesvirus, is presented as [**Annex 13**](#A13) for Member comments.

* + 1. Susceptible species- Section 11. Diseases of Molluscs
       1. Articles 11.1.1. and 11.1.2. of Chapter 11.1. Infection with abalone herpesvirus

The Commission considered the *ad hoc* Group report on Susceptibility of mollusc species to infection with OIE listed diseases and commended its members for their comprehensive work.

The *ad hoc* Group had applied the criteria for listing species as susceptible to infection with a abalone herpesvirus in accordance with Chapter 1.5. Criteria for listing species as susceptible to infection with a specific pathogen.

The Commission amended Article 11.1.1. to ensure consistency with other mollusc disease-specific chapters.

The Commission agreed to amend the list of susceptible species in Article 11.1.2. in line with recommendations of the *ad hoc* Group. It noted that the four species currently included in Article 11.1.2. meet the criteria for listing as susceptible to infection with abalone herpesvirus, i.e., small abalone (*Haliotis diversicolor*), greenlip abalone (*Haliotis laevigata*), blacklip abalone (*Haliotis rubra*) and hybrids of greenlip x blacklip abalone (*Haliotis laevigata x Haliotis rubra*) and were proposed for retention in Article 11.1.2. No new species were found to meet the criteria for listing as susceptible to infection with abalone herpesvirus.

Relevant sections of Chapter 2.4.1. Infection with abalone herpesvirus, in the *Aquatic Manual* were also amended in line with the recommendations of the *ad hoc* Group (see Item 6.2.).

The Commission encouraged Members to refer to the *ad hoc* Group’s June 2021 report available on the OIE Website (https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/), for details of the assessments conducted by the *ad hoc* Group.

The revised Articles 11.1.1. and 11.1.2. of Chapter 11.2. Infection with abalone herpesvirus, are presented as [**Annex 14**](#A14)for Member comments.

* + - 1. *Articles 11.2.1. and 11.2.2. of Chapter 11.2. Infection with Bonamia exitiosa*

Comments were received from Canada, China (People’s Rep. of) and the EU.

*Background*

At its February 2021 meeting, the Aquatic Animals Commission reviewed the December 2020 report of the *ad hoc* Group on Susceptibility of mollusc species to infection with OIE listed diseases. The *ad hoc* Group had applied the criteria for listing species as susceptible to infection with *Bonamia exitiosa* in accordance with Chapter 1.5. of the *Aquatic Code*.

The Commission had agreed to amend Article 11.2.1. to ensure consistency with other mollusc disease-specific chapters.

The Commission had agreed to amend the list of susceptible species in Article 11.2.2.*,* in line with the recommendations of the *ad hoc* Group.

**Previous Commission reports where this item was discussed:**

February 2021 report (Part B: Item 1.5., page 10).

**September 2021**

The Commission acknowledged a comment requesting additional information be provided in the assessment table of the *ad hoc* Group reports regarding the route of infection for Stage 1 and the method for pathogen identification for Stage 2. The Commission agreed that this information should be considered for inclusion in future *ad hoc* Group reports to support Members’ understanding of the assessments and to ensure consistency between the assessments completed for the different species groups.

The Articles 11.2.1. and 11.2.2. of Chapter 11.2. Infection with *Bonamia exitiosa,* are presented as [**Annex 15**](#A15) for Member comments.

* 1. Texts for Member information
     1. Emerging diseases
        1. *Infection with carp edema virus (CEV)*

Comments were received from Japan.

*Background*

At its February 2021 meeting, the Aquatic Animals Commission reviewed new scientific information on infection with carp edema virus (CEV) and reported that infection with CEV had spread from the Asia-Pacific region to many European countries and had caused mortalities in common carp and koi carp. The Commission noted that mortalities caused by infection with CEV in New Caledonia have demonstrated the virulence of CEV to koi carp, and the spread of infection and mortalities caused by CEV in koi carp farms in China (People’s Rep. of) have significant impacts. The Commission also noted that the decrease in mortality rates in some countries was likely to be the result of successful mitigation measures.

**Previous Commission reports where this item was discussed:**

February 2020 report (Item 7.3.3., page 17); September 2020 (Item 6.3., page 17); February 2021 (Part B: Item 2.2., page 11).

**September 2021**

The Commission reviewed the latest scientific evidence and noted that infection with CEV continues to be reported to impact production and cause mortality events in wild and farmed populations but the severity of the impacts is unclear.

The Commission did not agree with a comment that infection with CEV did not meet the definition of an emerging disease, and reiterated that detections of infection with CEV should be reported to the OIE as an emerging disease, in accordance with Article 1.1.4. of the *Aquatic Code*.

The Commission encouraged Members to investigate mortality and morbidity events in carp, emphasising that a better understanding of the virus is essential for efforts to control its possible spread and impacts on carp populations.

The Commission will continue to monitor the global situation for infection with CEV and seek further information from scientists working on the disease.

* + - 1. *Infection with Entercytozoon hepatopenaei*

The Aquatic Animals Commission reviewed the scientific evidence to determine whether infection with *Entercytozoon hepatopenaei* (EHP) meets the OIE definition of an emerging disease. The Commission noted that there have been reports of significant economic and production impacts related to the disease, particularly in Asia, that have been ongoing for some time, that there are available diagnostic methods and evidence that EHP can be spread through trade.

The Commission agreed that infection with EHP meets the definition of an emerging disease, but recognised that there is some uncertainty in regard to the spread and impacts of the disease outside of Asia.

The Commission agreed that any detections of infection with *EHP* should be reported to the OIE as an emerging disease, in accordance with Article 1.1.4. of the *Aquatic Code.*

The Commission encouraged Members to investigate morbidity and mortality events in shrimp and invited Members to provide further information on the disease, particularly from Members in Africa and South America.

* + 1. New draft Chapters 4.X. Emergency disease preparedness and 4.Y. Disease outbreak management

Comments were received from Chile, AU-IBAR and CVP.

*Background*

The Aquatic Animals Commission further developed the article structure of the new draft Chapters 4.X. Emergency disease preparedness, and 4.Y. Disease outbreak management. Given the importance of this work to support Members in these critical areas, the Commission agreed to circulate the article structure of the new draft chapters to Members for comments before starting work to draft the detailed text.

**Previous Commission reports where this item was discussed:**

February 2020 (Item 7.3.2., page 16), September 2020 (Item 6.1., page 16), February 2021 (Part B: Item 1.2.2., page 5).

**September 2021 meeting**

The Commission thanked Members for their constructive comments on the proposed article structure for the new two draft chapters and informed Members that these comments would be taken into consideration as the chapters are developed.

The Commission requested an *ad hoc* Group be convened to develop the text for the two new chapters and requested that *ad hoc* Group start work on the new draft Chapter 4.X. Emergency disease preparedness.

* + 1. Chapter 10.10. Infection with viral haemorrhagic septicaemia virus

*Background*

At its September 2020 meeting, the Aquatic Animals Commission confirmed its decision that genotypes should not be included in Article 10.10.2. of Chapter 10.10. Infection with viral haemorrhagic septicaemia (VHSV), as the Commission had not assessed whether VHSV genotypes can be differentiated for the purpose of distinguishing risk management measures for traded commodities.

At the Commission’s February 2021 meeting, in response to several requests by Members to initiate an assessment of VHSV genotypes with respect to strain differentiation as had been conducted for ISAV, the Commission agreed that further guidance on the principal of applying risk assessments to justify mitigation measures directed at specific genotypes would be useful. It noted that this issue could be addressed through the possible restructuring of articles of disease-specific chapters and that approaches in the *Terrestrial* *Code* should be considered. At that time, the Commission indicated that the next Commission would need to prioritise this activity against other items in its workplan.

**Previous Commission meeting reports where this item was discussed:**

February 2021 (Part A: Item 3.16., page 11).

**September 2021 meeting**

The Commission discussed the feasibility and benefits of differentiating VHSV genotypes for the purposes of trade.

The Commission noted that there is significant complexity associated with the different VHSV genotypes and gaps in knowledge. The Commission agreed that it would be difficult to develop standards to reflect strain differentiation of VHSV genotypes, in a way that could be adopted and easily managed by Members. The Commission also expected that VHSV strain differentiation would not result in a significant outcome for members in the terms of improved utility of the standards.

Following these considerations, the Commission agreed not to pursue strain differentiation for VHSV. However, the Commission reiterated that a Member may, based on a risk assessment and a claim of freedom from a specified VHSV genotype, take appropriate measures to protect its declared free status.

The Commission also discussed the considerations regarding a comment made in its September 2020 report requesting the Commission to reconsider the listing of Atlantic salmon (*Salmo salar*) as susceptible to all genotypes of VHSV in Section 2.2.1. of Chapter 2.3.10. of the *Aquatic Manual*, and specifically susceptibility to genotypes I, II and III. The Commission agreed that Atlantic salmon should remain listed in Article 10.10.2., as susceptibility to specific genotypes is not included in the *Aquatic Code*. However, the Commission agreed to refer the question of susceptibility of Atlantic salmon to genotypes I, II and III to the *ad hoc* Group for Susceptibility of fish species to infection with OIE listed diseases.

1. **OIE *MANUAL OF DIAGNOSTIC TESTS FOR AQUATIC ANIMALS***
   1. Texts for Members’ comment

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

A software-generated document that compares the adopted version of a chapter and the proposed new text will be created. This comparison document will not be included in the Commission’s report, but will be available upon request from the OIE Standards Department (AAC.Secretariat@oie.int).

* + 1. Guidance document on the use of environmental DNA methods for aquatic animal disease surveillance

Comments were received from Australia, Bangladesh, Canada, China (People’s Rep. of), the UK, the USA, AU-IBAR and the EU.

*Background*

The monitoring of aquatic systems using environmental DNA (eDNA) is a rapidly advancing research field that will provide opportunities for rapid, cost-effective, non-destructive methods to screen for pathogens, especially in wild aquatic populations where sampling may be difficult or removal of animals undesirable. The Aquatic Animals Commission is aware that eDNA methods exist for detecting pathogenic agents of several listed diseases, including infection with *Xenohaliotis californiensis*, infection with *Batrachochytrium dendrobatidis*, infection with *Aphanomyces astaci* and infection with *Gyrodactylus salaris*.

The Commission agreed that as these methods are available and currently in use, it would be advisable for guidance to be provided on appropriate application and potential limitations. The Commission noted that as accurate estimates of diagnostic performance are not available for designing surveillance programmes using eDNA assays, data obtained from eDNA methods may not be suitable to support declaration of freedom from listed diseases. The Commission also noted that confirmation of infection by listed diseases could not be made using eDNA methods; however, positive results could be appropriate criteria for a suspect case.

At its February 2021 meeting, the Commission developed a discussion document outlining the benefits and limitations of eDNA detection within a diagnostic or disease surveillance context. This document is intended to guide the appropriate purposes of use and assay performance reporting required for an eDNA assay to be considered for inclusion in the *Aquatic Manual*.

**Previous Commission reports where this item was discussed:**

February 2020 (Item 8.4.2, page 22), September 2020 (Item 6.4, page 17), February 2021 (Part B: Item 3.1, page 12).

**September 2021 meeting**

The Commission thanked Members for the thorough engagement and feedback received on the guidelines provided for the use of environmental DNA methods for the detection of OIE listed aquatic animal diseases that were circulated in its February 2021 Part B report. The Commission noted that the comments were generally positive and in support of the approaches presented in the discussion paper.

The Commission did not agree to broaden the scope of the definition to include host-derived materials, such as faeces and mucous which are usually shed into the environment. The Commission noted that these host-derived sample types present different considerations (e.g. sampling, processing, extraction)as opposed to environmenal samples (e.g. water or soil).

In point 9, the Commission did not agree to amend the Glossary definition of ‘case’ as it considered it important to retain the current nomenclature as it is consistent with that of Section 6 of each disease-specific chapter of the *Aquatic Manual*. The Commission reminded Members that a positive result obtained from an eDNA method recommended in the *Aquatic Manual* is not considered to provide appropriate evidence to confirm a case in apparently healthy animals, and would only be suitable as a criterion for a suspect case.

The Commission will consider the second round of comments at its February 2022 meeting, after which the guidelines will be published on the OIE website.

The revised guidance document on the use of environmental DNA methods for aquatic animal disease surveillance, is presented as [**Annex 16**](#A16) for Member comments.

* + 1. Chapter 2.3.0. General information (diseases of fish)

The Aquatic Animals Commission noted the need to add a sentence to Section 2.5. Use of molecular techniques for surveillance testing, confirmatory testing and diagnosis, of the general information chapter on the possibility of false-negative results (positive samples giving a negative result) occurring in PCR reactions due to the presence of a new variant that is not recognised by the PCR primer/probe set).

The revised Chapter 2.3.0. General information (diseases of fish), is presented as [**Annex 17**](#A17) for Member comments.

* + 1. Chapter 2.3.2. Infection with epizootic haematopoietic necrosis virus

The Aquatic Animals Commission reviewed Chapter 2.3.2*.* Infection with epizootic haematopoietic necrosis virus, which had been updated by the OIE Reference Laboratory experts and reformatted using the new disease chapter template.

The main amendments include:

‒ updated lists of susceptible host species and species with incomplete evidence for susceptibility, in accordance with the findings of the *ad hoc* Group on Susceptibility of fish species;

‒ updated information on the aetiological agent, its survival and stability outside the host and the sections on likelihood of infection by species, host life stage, population or sub-populations and aquatic animal reservoirs of infection;

‒ in the section on disease pattern updated information on modes of transmission and life cycle and on geographical distribution;

‒ updated information on specimen selection, sample collection, transportation and handling;

‒ updated the section on diagnostic methods including completing Table 4.1 OIE recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals*,* and revising the molecular diagnostic tests;

‒ revised definitions of suspect and confirmed case in apparently healthy and clinically affected animals.

The revised Chapter 2.3.2. Infection with epizootic haematopoietic necrosis virus, is presented as [**Annex 18**](#A18) for Member comments.

* + 1. Chapter 2.3.4. Infection with HPR-deleted or HPR0 infectious salmon anaemia virus

Comments were received from Armenia, Canada, China (People’s Rep. of), Cuba, Switzerland, Thailand, the UK, the EU and the USA.

*Background*

The Aquatic Animals Commission, at its September 2020 meeting, reviewed Chapter 2.3.5. Infection with HPR-deleted or HPR0 infectious salmon anaemia virus, which had been updated by the OIE Reference Laboratory experts and reformatted using the new disease chapter template.

**Previous Commission reports where this item was discussed:**

September 2020 (Item 5.4, Page 15).

**September 2021**

The Commission did not agree with a comment to jointly describe HPR-deleted ISAV and HPR0 ISAV rather than separately in the chapter. The Commission confirmed that the clinical expression of disease, epidemiology and control measures differ and justify leaving their descriptions separate.

In Section 1. Scope, the Commission did not agree with a proposal to replace ‘disease outbreaks’ with ‘HPR-deleted ISAV genotypes’ in a sentence on a suggested link between non-pathogenic HPR0 ISAV and pathogenic HPR-deleted ISAV as the change would alter the intended meaning of the sentence. The Commission noted that there is sufficient evidence in the cited references to support the statement to indicate the relationship between the presence of HPR deletion and the occurrence of clinical disease.

In Section 2.1.1. Aetiological agent, the Commission agreed to move a sentence on the properties of ISAV to the beginning of the section, but did not agree to delete the word ‘physicochemical’ as the sentence correctly indicates that the physicochemical characteristics of ISAV are consistent with those of the members of the Family *Orthomixoviridae*. The Commission also agreed to include a more detailed description of the virus and new references to this section. Finally, the Commission did not agree to replace ‘transient’ with ‘sometimes below the threshold of detection’ in a sentence on the seasonal nature of HRP0 ISAV: transient is the correct term and describes the natural behaviour of the pathogen while below the threshold of detection would mean that it cannot be detected.

In Section 2.1.3. Survival and stability outside the host, the Commission expanded the information on the infectivity of ISAV in seawater under different physical conditions and updated the references.

In Section 2.2.2. Species with incomplete evidence for susceptibility, the Commission agreed to insert ‘RT’ before PCR.

A number of Members had commented on Section 2.2.3. Non-susceptible species. The Commission reiterated that this section had been deleted from the template for disease-specific chapters in the *Aquatic Manual* (also see the Commission’s February 2021 meeting). The comments were therefore not considered.

In Section 2.2.4. Likelihood of infection by species, host life stage, population or sub-populations, the Commission deleted ‘only’ before ‘a few cases have been reported in the freshwater stage’ as disease outbreaks are increasing in freshwater.

In Section 2.2.5. Distribution of the pathogen in the host, the Commission agreed to add a reference to support the statement that clinical disease and macroscopic organ lesions appear foremost in severely anaemic Atlantic salmon in HPR-deleted ISAV. In the HPR0 ISAV paragraph, the Commission did not agree to mention ‘non-HPR0 specific’ as it is not the commonly used expression.

In Section 2.2.6. Aquatic animal reservoirs of infection, the Commission agreed to insert ‘HPR-deleted’ before ‘ISAV’ in the last sentence to improve clarity.

In Section 2.3.1. Mortality, morbidity and prevalence, the Commission agreed to add a new sentence at the start of the paragraph: ‘The disease pattern with HPR-deleted ISAV depends on many factors including the strain of the virus’, but did not support the inclusion of a second proposed sentence ‘Not all strains result in noticeable disease on the farm’ as the statement is not correct. The Commission agreed to insert a new reference to support the statement that morbidity and mortality may vary greatly between net pens and between farms during outbreaks of infection with HPR-deleted ISAV. The Commission deleted the last sentence in the paragraph as it was not relevant to the section.

In Section 2.3.4. Modes of transmission and life cycle, the Commission clarified that the first sentence on the main route of infection refers to horizontal transmission, and added a sentence and reference on vertical transmission. The Commission agreed that ISAV may be shed in skin and thus included it in the list, and deleted ‘but shedding from localised gill infection may be most important’ as there is no strong evidence to support this statement.

In Section 2.3.6. Geographical distribution, the Commission agreed to remove the second sentence on disease occurrence as this information can be found in the OIE-WAHIS interface.

In Section 2.4.1. Vaccination, the Commission did not agree to delete the information on the history of vaccination in certain countries believing that Members could find this text to be of interest. The Commission made some editorial changes in the section.

In Section 2.4.7. General husbandry, the Commission provided a reference to support the statement that good biosecurity and husbandry practices reduce the risk of outbreaks of infection with HPR deleted ISAV.

In Section 3.1. Selection of populations and individual specimens, the Commission detailed which fish should be sampled for virus detection methods and added cross references to Sections 2.3.2. Clinical signs*,* including behavioural changes, and 2.3.3. Gross pathology, for clarity. For consistency with the other updated fish disease chapters, the Commission added information on sampling for surveillance and for disease outbreak situations.

In Section 3.2.2. Detection of HPR0 ISAV, the Commission kept the first part of the sentence ‘Gill tissue is recommended’ and deleted the rest as the detection of HPR0 in organs other than gills is controversial.

In Section 3.4. Non-lethal sampling, the Commission clarified that blood is preferred for non-lethal sampling for HPR-deleted ISAV.

In Section 3.5.1. Samples for pathogen isolation, the Commission agreed to delete the reference to bioassay as it is not recommended in Table 4.1.

In Section, 3.5.2. Preservation of samples for molecular detection, the Commission corrected the PCR to ‘real-time RT-PCR’ and agreed to delete mention of commercial products name.

In Section 3.6. Pooling of samples, the Commission added the standard text clarifying that pooling of samples from more than one individual animal for a given purpose should only be recommended where robust supporting data on diagnostic sensitivity and diagnostic specificity have been evaluated and found to be suitable. Regarding small life stages, the Commission agreed to delete ‘up to 0.5 g’ from the pooling recommendation because 0.5 g of tissue is the minimum amount needed to perform virus isolation, but not necessarily the other test methods referenced in this chapter.

In Table 4.1, the Commission corrected some of the terminology used in the methods column to conform to the template. The Commission also modified footnote 2 (also see Item 8.2.).

In Section 4.3. Cell culture for isolation, the Commission added more details on cell culture procedures to provide more fulfilling information in this section.

Sections 4.4.1. Real-time PCR and 4.4.2. Conventional PCR*,* the Commission agree to replace ‘PCR’ with ‘RT-PCR’. In Section 4.4.2., the Commission did not agree to replace the words ‘if necessary’ with ‘if the laboratory has no access to real-time methodology’ in a sentence stating that primers for segment 7 and 8 may also be used for conventional RT-PCR as it considered the change not necessary. The Commission did agree to delete the last three paragraphs from the section as they are already in Section 4.4.1.

In Section 4.7. Immunohistochemistry (IHC), the Commission agreed to create a new subsection 4.7.1. IHC on paraffin sections from formalin-fixed tissue,and to clarify that Section 4.7.2. is for the indirect fluorescent antibody test on tissue imprints and blood smears. The Commission agreed to delete the word ‘polyclonal’ from the start of the first paragraph of Section 4.7.1. as the text refers to both monoclonal and polyclonal antibodies. And finally in Section 4.7.1. ii) *Staining procedure for IHC*, the Commission removed reference to the monospecific rabbit antibody against ISAV nucleoprotein as other suitable antibodies could be used, and placed reference to goat anti-rabbit IgG with a reference to species specific IgG.

In Section 6. Corroborative diagnostic criteria, the Commission did not agree with a general comment not to separate the case definitions into ‘apparently healthy’ and ‘clinically affected’ animals. The Commission reminded Members that they had opportunities to comment on the disease chapter template when it was appended to the report of the February 2018 meeting before it was implemented from February 2019. The template has been consistently applied to all the fish disease chapters, and the case definitions are consistent with the purposes of the diagnostic tests given in Table 4.1 (also see Item 4.1. of the Commission’s February 2021 report). The Commission did not agree with a comment to mention the fact that having an established link with a confirmed case can also create a suspect case, as this information is already mentioned in the below the first paragraph of Section 6.1.

In Section 6.1. Apparently healthy animals or animals of unknown health status, the Commission did not agree to add text stating that healthy populations are sampled ‘for early detection of disease’ as this purpose is not addressed in Section 5.

In Section 6.1.1. Definition of suspect case in apparently healthy animals, the Commission agree to delete criteria i) ISAV typical CPE in cell cultures (HPR deleted only) as this is not recommended in Table 4.1. For consistency with the terminology used throughout the fish disease chapters, the conventional RT-PCR was replaced with RT-PCR.

In Section 6.1.2. Definition of confirmed case in apparently healthy animals, under ‘*Definition of confirmed case of infection with HPR-deleted ISAV* and Section 6.2.2. Definition of confirmed case in clinicallyaffected animals, the Commission clarified that the PCR methods are of segment 6 of the gene, and replaced ‘HE gene’ with ‘amplicon’. In Section 6.1.2., Commission reduced the number of criteria from six criteria to three to simplify the definitions. Under *‘Definition of confirmed case of infection with HPR0 ISAV*, the Commission revised criterion i) by adding real-time RT-PCR for detection of ISAV in tissue preparations and clarified that sequencing of the amplicon is to verify HPR0-deletion.

In Section 6.2.1. Definition of suspect case in clinically affected animals, the Commission did not agree to amend the first sentence before the list of criteria as the text is from the template and is standard throughout the chapters.

In Section 6.2.2. Definition of confirmed case in clinically affected animals, the Commission did not agree to add ‘in addition to the criteria in Section 6.2.1.’ to the first sentence before the list of criteria as they considered it clear as written. The Commission agreed to delete the existing criteria i) as HPR0 does not grow in cell culture and there is no need to sequence, and replaced it with a new criterion i) on virus isolation in cell culture and virus identification. The Commission reduced the number of criteria from six criteria to three to simplify the definitions.

The revised Chapter 2.3.4. Infection with HPR-deleted or HPR0 infectious salmon anaemia virus, is presented in [**Annex 19**](#A19) for Member comment.

* + 1. Chapter 2.3.6. Infection with koi herpesvirus

Comments were received from Armenia, Canada, China (People’s Rep. of), Cuba, Japan, Switzerland, the UK the EU and the USA.

*Background*

At its September 2020 meeting, the Aquatic Animals Commission reviewed Chapter 2.3.7. Infection with koi herpesvirus (KHV), which had been updated by the OIE Reference Laboratory experts and reformatted using the new disease chapter template.

The Commission agreed that the disease name ‘infection with koi herpesvirus’ should be retained and used in the *Aquatic* *Code* and *Aquatic* *Manual* for reasons of continuity and familiarity. CyHV-3, the virus name recognised by the ICTV is, however, referred to in Section 1 of the chapter. This is a similar approach used for other listed diseases where the official pathogen name may be relatively unfamiliar.

**Previous Commission reports where this item was discussed:**

September 2020 (Item 5.5, page 15).

**September 2021**

The Commission reiterated its decision to refer to the pathogenic agent throughout the chapter as KHV rather than CyHV-3 for continuity (also see the Commission’s September 2020 report).

In reply to a request to recommend the most suitable detection methods for KHV, the Commission informed Members that such guidance is available in the chapter in Table 4.1 OIE recommended diagnostic methods and their level of validation for surveillance of healthy animals and investigation of clinically affected animals, and on Section 6 Corroborative diagnostic criteria.

The Commission did not agree to delete ‘all genotypes of’ [the pathogenic agent] from Section 1 Scope, because the pathogenic agent does include all genotypes of the virus and this is substantiated by the references provided.

In Section 2.1.1. Aetiological agent, the Commission agreed to expand the description of the aetiological agent and to include new references.

In response to a comment to delete the last sentence of Section 2.1.3. Survival and stability outside the host, on the infective period of the virus in sterilised environmental water samples, the Commission agreed to maintain the sentence and to add a reference to support the statement.

In Section 2.2.1. Susceptible host species,the Commission agreed to add ‘and subspecies’ [of common carp] after ‘all varieties’, to delete ‘/goldfish’ before ‘hybrids’ and to add ‘*Cyprinus carpio × Carassius Carassius*’ all of which is in line with the recommendations made by the *ad hoc* Group on Susceptibility of fish species to infection with OIE listed diseases (also see Item 5.1.8.).

In Section 2.2.2. Species with incomplete evidence for susceptibility, the Commission agreed to delete the rainbow trout (*Oncorhynchus mykiss*) in accordance with the recommendations of the *ad hoc* Group on Susceptibility of fish species.

A number of Members had commented on Section 2.2.3. Non-susceptible species. The Commission reiterated that this section had been deleted from the template for disease-specific chapters in the *Aquatic Manual* (also see the Commission’s February 2021 report). The comments were therefore not considered.

In Section 2.2.3. Likelihood of infection by species, host life stage, population or sub-population, the Commission inserted a new sentence to provide guidance on the three life stages used in Table 4.1.

In Section 2.2.7. Vectors, the Commission reduced the existing text to the most relevant information. Also, consistent with the definition of vector in the *Aquatic Code*, a new sentence was included to state that no species of vector have been demonstrated to transmit KHV to susceptible species.

In Section 2.3.4. Modes of transmission and life cycle, the Commission rejected a suggestion to add intestine along with gills as the major portal of virus entry into carp, as the publication provided to support this comment and the references already cited do not indicate intestine as port of entry.

In Section 2.4.1. Vaccination, the Commission agreed to update the information by adding text that reflects developments in research on vaccine candidates against KHV.

In Section 2.4.5. Inactivation methods, the Commission included other methods of inactivation of the virus and a reference that had been mistakenly omitted from the draft chapter.

In Section 2.4.6. Disinfection of eggs and larvae, the Commission clarified that disinfection is of the surface of the eggs.

In Section 2.4.7. General husbandry, the Commission did not agree with the proposal to add that fish can be held ‘at permissive temperatures for development of clinical signs’ as other factors influence development of clinical signs; the change would imply that two thresholds have been established which is not the case.

In Section 3.1. Selection of populations and individual specimens, the Commission added information on sampling for surveillance and for disease outbreak situations to be consistent with the other updated fish disease chapters.

In Section 3.4. Non-lethal sampling, the Commission did not agree with a proposal to include ‘However, serology may be useful to document exposure to KHV if the virus is latent’ as serology is not sufficiently validated and not rated in Table 4.1.

In Section 3.5.2. Preservation of samples for molecular detection, the Commission agreed to add a line that repeated freezing and thawing should be avoided.

Section 3.5.3. Samples for histopathology, immunohistochemistry or in-situ hybridisation, the Commission deleted the existing text and replaced it with a cross reference to Chapter 2.3.0. (also see Item 6.2.1.2.).

In Section 3.5.5. Samples for other tests, the Commission deleted the existing texts as reference to blood sampling is not relevant and inserted ‘Not applicable’.

For Section 3.6. Pooling of samples, the Commission added the standard text clarifying that pooling of samples from more than one individual animal for a given purpose should only be recommended where robust supporting data on diagnostic sensitivity and diagnostic specificity have been evaluated and found to be suitable. Regarding small life stages, the Commission agreed to delete ‘or specimens up to 0.5 g’ from the pooling recommendation because 0.5 g of tissue is the minimum amount needed to perform virus isolation, but not necessarily the other test methods referenced in this chapter.

In Table 4.1, the Commission agreed to remove serology (ELISA) from the table as it is not used for KHV. For the real-time PCR, the Commission also agreed to increase the ratings for all categories in purposes A *Surveillance of apparently healthy animals* and B *Presumptive diagnosis of clinically affected animals* to ‘+++’ and the level of validation to ‘3’. The Commission did not agree to score the conventional PCR for purpose A *Surveillance of apparently healthy animals* because the sensitivity is considered too low. Finally the Commission agreed to modify footnote 2 (also see Item 6.2.1.1.).

In Section 4.3. Cell culture for virus isolation, the Commission deleted ‘KFC’ from the recommended cell line as it is not preferred for virus isolation. The remaining cell lines (CCB and KF-1) were reordered according to their usefulness. In the subsection ‘Confirmatory identification’, a few edits were made including correcting a reference and organising all the references to place it at the end of the paragraph.

In Section 4.4. Nucleic acid amplification, the Commission placed all the information on controls in a paragraph at the beginning of the section as they are common to both real-time and conventional PCR.

In Section 4.4.2. Real-time PCR, the Commission agreed to delete a sentence at the end of the first paragraph stating that positive results obtained by real-time PCR should be confirmed by conventional PCR and sequence analysis as this information is more suited to and given in the case definitions in Section 6. Finally, the Commission agreed to add a footnote to Table 4.4.2.1 clarifying that the Gilad *et al.* (2004) assay had been modified by Clouthier *et al*. (2017) by increasing the probe quantity.

In Section 4.4.3. Conventional PCR, the Commission agreed to add a footnote to Table 4.4.3.1. clarifying that the Bercovier *et al*. (2005) assay performed using different cycling conditions has been validated by Clouthier *et al*. (2017). The cycling conditions given for the Bercovier *et al*. assay were also corrected.

In Section 4.4.4. Other nucleic acid amplification methods, the Commission did not agree to a proposal to include a protocol for the LAMP method noting that the cited reference included sufficient details for users to undertake the method.

In Section 4.10. Other methods, the existing text on the ELISA was deleted as serology is not relevant in this chapter. The text was replaced with the words ‘none published or validated’.

In response to various comments received on Section 5 Tests recommended for surveillance to demonstrate disease freedom in apparently healthy populations, the Commission clarified that real-time PCR assays are recommended for surveillance in apparently healthy animals but may not detect the KHV variants that were described by Englesma *et al.* (2013). In areas where these variants may be present, the conventional nested PCR assay published by Engelsma *et al.* (2013) should be considered.

In Section 6 Corroborative diagnostic criteria, the Commission did not agree with a general comment not to separate the case definitions into ‘apparently healthy’ and ‘clinically affected’ animals. The Commission reminded Members that this approach in the disease chapter template was first provided to Members for comment in the report of the February 2018 meeting before being implemented from February 2019. The template has been consistently applied to all the fish disease-specific chapters, and the case definitions are consistent with the purposes of the diagnostic tests given in Table 4.1 (also see Item 4.1. of the Commission’s February 2021 report).

In Section 6.1. Apparently healthy animals or animals of unknown health status, the Commission did not agree to add text stating that healthy populations are sampled ‘for early detection of disease’ as this purpose is not addressed in Section 5.

In Sections 6.1.1., 6.1.2. and 6.2.2., the Commission edited existing criteria and included new criteria as needed. The Commission did not agree with a comment to delete several criteria from Section 6.2.2. as it is deviating from the harmonised approach adopted in all chapters.

For the Table in Section 6.3.2. For surveillance of apparently healthy animals, the Commission added a footnote to clarify that the diagnostic accuracy study did not include samples that were known to be positive for KHV variants.

The revised Chapter 2.3.6. Infection with koi herpesvirus, is presented in [**Annex 20**](#A20)for Member comments.

* + 1. Chapter 2.3.7. Infection with red sea bream iridoviral disease

The Aquatic Animals Commission reviewed Chapter 2.3.7. Infection with red sea bream iridovirus*,* which had been updated by the OIE Reference Laboratory experts and reformatted using the new disease chapter template.

The main amendments include:

‒ updated the scope of the chapter;

‒ updated information on the aetiological agent;

‒ updated sections on disease pattern, biosecurity and disease control strategies, and on specimen selection, sample collection, transportation and handling;

‒ updated the section on diagnostic methods including completing Table 4.1 and revising the molecular tests, the indirect fluorescent antibody test and immunocytochemistry; and

‒ revised definitions of suspect and confirmed case in apparently healthy and clinically affected animals.

The Commission is aware that other viruses in the Genus *Megalocytivirus*, for example, infectious spleen and kidney necrosis virus (ISKNV) and turbot reddish body iridovirus (TRBIV), may also cause disease of fish. These viruses are not currently listed by the OIE and are not included within the scope of the infection with red sea bream iridovirus (RSIV) chapter. If ISKNV, TRBIV or other megalocytiviruses were to be listed, the viruses would need to be assessed against the listing criteria in Chapter 1.2. of the *Aquatic Code*. If they were found to fulfil the listing criteria, they could be proposed for listing to the OIE General Assembly. In the meantime, this chapter remains focused on infection with RSIV.

The revised Chapter 2.3.7. Infection with red sea bream iridovirus, is presented as [**Annex 21**](#A21) for Member comments.

* + 1. Susceptible species of Section 2.4. Diseases of molluscs
       1. *Sections 2.2.1. and 2.2.2. of Chapter 2.4.1. Infection with abalone herpesvirus (susceptibility of species)*

The Aquatic Animals Commission amended Sections 2.2.1. and 2.2.2. of Chapter 2.4. Infection with abalone herpesvirus, in line with the recommendations of the *ad hoc* Group on Susceptibility of mollusc species to infection with OIE listed diseases (also see Item 5.1.9.1.).

The Commission encouraged Members to refer to the *ad hoc* Group’s June 2021 report available on the OIE Website (Link to add), for details of the assessments conducted by the *ad hoc* Group.

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.3. Infection with abalone herpesvirus, are presented as [**Annex 22**](#A22)for Member comments.

* + - 1. *Sections 2.2.1. and 2.2.2. of Chapter 2.4.2. Infection with Bonamia exitiosa (susceptible species)*

Comments were received from the EU.

*Background*

At its February 2021 meeting, the Aquatic Animals Commission reviewed the December 2020 report of the *ad hoc* Group on Susceptibility of mollusc species to infection with OIE listed diseases. The *ad hoc* Group had applied the criteria for listing species as susceptible to infection with a specific pathogenic agent in accordance with Chapter 1.5. of the *Aquatic Code* for infection with *Bonamia exitiosa*.

The Commission had agreed to amend Sections 2.2.1. and 2.2.2. of Chapter 2.4.2. Infection with *Bonamia exitiosa* in line with the recommendations made by the ad hoc Group (report available at: <https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/>).

**Previous Commission reports where this item was discussed:**

February 2021 (Part B: Item 3.2., page 13).

**September 2021**

Members agreed with the proposed modifications.

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.2. Infection with *Bonamia exitiosa* are presented as [**Annex 23**](#A23) for Member comments.

* + - 1. *Table 4.1. OIE recommended diagnostic methods and their level of validation for surveillance of apparently health animals and investigation of clinically affected animals*

Table 4.1 of the new *Aquatic Manual* chapter template includes a column for the level of validation of each test method (from 1 to 4 in accordance with Chapter 1.1.2. Principles and methods of validation of diagnostic assays for infectious diseases) in addition to rating each test against its purpose of use. Having two different scoring systems for two different components of diagnostic test use and interpretation has led to some confusion. Questions about divergence between the two scores have often arisen (e.g. low level of validation but high rating for purpose of use or vice versa).

To address this issue, the Commission revised the explanatory text for Table 4.1 in the disease chapter template: the key and ratings against purposes of use of each test has been clarified, and a note linking the validation stage to Chapter 1.1.2. has been included. The new key and explanatory text would be sent to the OIE References Laboratories for feedback before it is included in the chapter template. Should be feedback be positive, the new key could be applied to the chapters presented for adoption in May 2022.

The new key and explanatory text in Table 4.1. OIE recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals, are presented as [**Annex 24**](#A24) for Member comments.

* 1. Texts for Members’ information
     1. Disease Chapter Template
        1. *Horizontal amendments*

The Commission agreed to amend footnote 2 of Table 4.1 *OIE recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals* from ‘Early and juvenile life stages have been defined in Section 2.2.3.’ to ‘Susceptibility of early and juvenile life stages is described in Section 2.2.3.’ and to amend Section 2.2.3. Likelihood of infection by species, host life stage, population or sub-populations, where necessary.

* + - 1. *Section 3.5.3. Samples for histopathology, immunohistochemistry or in-situ hybridisation*

A Member had noted inconsistencies in the information provided in Section 3.5.3. Samples for histopathology, immunohistochemistry or in-situ hybridisation, of the *Aquatic Manual* disease-specific chapters, with some chapters providing many details, while other chapters only providing a reference to Chapter 2.3.0. To address this issue, the Commission agreed that the following standard text would be applied to the section in all the disease chapters:

‘Standard sample collection, preservation and processing methods for histological techniques can be found in Section 2.2. of Chapter 2.3.0. General information (diseases of fish).’

Where additional disease-specific information is required, this would be included on a case by case basis.

The text has been added to the template.

* + 1. Chapter 2.3.1. Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)

The Aquatic Animals Commission reviewed the first draft of Chapter 2.3.1. Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome), which had been reformatted using the new disease chapter template. The chapter had been reviewed by laboratory experts and a member of the Commission, but the task was challenging because of the absence of an OIE Reference Laboratory for this disease. The Commission agreed to work further on the revision, in particular on Section 4. Diagnostic methods including Table 4.1. OIE recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals, and on Section 6. Corroborative diagnostic criteria. The further revised chapter would be reviewed again at the next meeting in February 2022.

* + 1. Chapter 2.3.9. Infection with spring viraemia of carp virus

A Member had submitted published references on the validation of real-time RT-PCRs for the detection of spring viraemia of carp virus (SVCV). The Commission reviewed the publications and related literature and noted that considerable efforts had been made to validate the assays by the research teams. However, despite the high analytical sensitivity and good specificity, the validation did not fully cover all the SVCV genotypes known to exist, a mismatch of the primers and probes was found by multiple alignment of the related viral fragments, and poor sensitivity was shown when testing some tissue homogenate samples. Therefore the expert advised that the tests cannot be recommended for inclusion in the *Aquatic Manual* until the assays have been further evaluated.

* + 1. Establishment of the order for review of the *Aquatic Manual* chapters

The Aquatic Animals Commission noted that all the disease chapters in Section 2.3. Diseases of fish, had now been updated and reformatted using the new disease chapter template. The Commission agreed to next address the chapters in Section 2.2. Diseases of crustaceans, and identified the following four chapters to which the template will now be applied:

* Chapter 2.2.1. Acute hepatopancreatic necrosis disease
* Chapter 2.2.2. Infection with *Aphanomyces astaci* (crayfish plague)
* Chapter 2.2.3. Infection with *Hepatobacter penaei* (necrotising hepatopancreatitis)
* Chapter 2.2.4. Infection with infectious hypodermal and haematopoietic necrosis virus.

The OIE Reference Laboratory experts will be asked to assist in the task of updating the texts.

* + 1. Diseases of Crustaceans: Chapter 2.2.0. General Information

Following the decision to update and reformat the disease chapters in Section 2.2. of the *Aquatic Manual*, the Commission identified the need to update Chapter 2.2.0. General Information. As previously done for Chapter 2.3.0., the Commission will request the assistance of all OIE Reference Laboratory experts for crustacean diseases in this revision.

1. *AD HOC* GROUPS
   1. *Ad hoc* Group on Tilapia lake virus

The electronic *ad hoc* Group on Tilapia lake virus (TiLV) was established in November 2017 to assess TiLV diagnostics and validation. The *ad hoc* Group worked from November 2017 to September 2021 to:

* evaluate published and unpublished methods for detection of TiLV;
* describe the level of validation of each method and determine additional validation requirements;
* recommend any additional assays that may need to be developed; and
* facilitate the sourcing and distribution of well-characterised positive control material for method evaluation, implementation and two inter-laboratory comparability studies.

The first round of the OIE Inter-laboratory comparability panel for Tilapia lake virus PCR was carried out in 2019 and the second round was carried out in 2021. The *ad hoc* Group recommended that all four tests evaluated would allow criterion 3 of Chapter 1.2. to be fulfilled (see Item 5.1.3.).

The report of the *ad hoc* Group on Tilapia lake virus can be found at (https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/)

* 1. *Ad hoc* Group on Susceptibility of mollusc species to infection with OIE listed diseases report (June 2021)

The *ad hoc* Group on Susceptibility of mollusc species to infection with OIE listed diseases met during June 2021 to conduct assessments for susceptibility of mollusc species to infection with abalone herpes virus (see Item 5.1.9.1.).

The Commission was informed that the *ad hoc* Group is planning to meet in November in 2021 to progress its work assessing species susceptible to listed OIE mollusc diseases.

The report of the *ad hoc* Group on Susceptibility of mollusc species to infection with OIE listed diseases (June 2021) can be found at (https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/).

* 1. *Ad hoc* Group on Susceptibility of fish species to infection with OIE listed diseases

The Commission agreed to request that the *ad hoc* Group on Susceptibility of fish species to infection with OIE listed diseases be reconvened to complete its work on the applying the criteria of Chapter 1.5., for listing species as susceptible to infection with a specific pathogen to OIE listed diseases, for the remaining two diseases: infection with red seabream iridovirus and infection with *Aphanomyces invadans*.

* 1. *Ad hoc* Group on new draft Chapters 4.X. Emergency disease preparedness and 4.Y. Disease outbreak management

The Commission requested that an *ad hoc* Group be convened to develop the text of the two new chapters and requested that the *ad hoc* Group start work on the new draft Chapter 4.X. Emergency disease preparedness (also see Item 5.2.2.).

1. **OIE REFERENCE CENTRES OR CHANGE OF EXPERTS**
   1. Further develop SOPs to include provisions for suspending laboratories and for handling laboratories that temporarily have no designated expert

The *Procedures for the designation of OIE Reference Laboratories* (SOPs) were adopted in 2017 and have been implemented by this Commission and the Biological Standards Commissions since then. More recently, it has become apparent that parts of the SOPs need to be updated, for example the time line for the achievement of accreditation to a quality management system can be deleted from the SOPs as the final deadline of 31 December 2019 is past. Implementation of the SOPs has also revealed the need for a procedure for temporary suspension of OIE Reference Laboratory status, for example because of temporary lack of diagnostic ability due to construction or restructuring of the laboratory’s facilities. The need was also identified for a procedure to be followed when the nomination for a replacement expert is not endorsed by the Specialist Commission leaving a laboratory without a designated expert for a short period of time. The Aquatic Animal Commission reviewed and approved text proposed by the Secretariat to address these issues. The SOPs had been approved by the Biological Standards Commissions in February 2021. They would now be presented to the Director General for endorsement. If endorsed, the amended SOPs would be appended to the report of the February 2022 meeting of the Biological Standards Commission and uploaded to the web page.

* 1. Follow-up on the Biological Standards Commission’s consultation with the Council

The Aquatic Animals Commission was updated on a consultation that had taken place between the OIE Council and the Biological Standards Commission on the appointment of OIE Reference Laboratory experts, applications from private companies for Reference Centre status, and lack of testing of international samples by OIE Reference Laboratories (see report of the meeting of the OIE Biological Standards Commission, February 2021 Part B, agenda Item 4.5.).

* 1. Evaluation of applications for OIE Reference Centres for aquatic animal health issues or change of experts

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

*OIE Collaborating Centre for Antimicrobial Stewardship in Aquaculture*

Laboratory of Veterinary Pharmacology (FARMAVET) and Laboratory of Food Safety (LIA) and Center for Research and Innovation in Aquaculture (CRIA), University of Chile, Faculty of Veterinary and Animal Sciences, Santa Rosa 1735, La Pintana, Region Metropolitana, CHILE   
Tel.: (+56-2) 29.78.55.80 / 29.78.03.52  
E-mail: [bsmartin@uchile.cl](mailto:bsmartin@uchile.cl); jcornejo@uchile.cl Website: http://www.veterinaria.uchile.cl   
Contact Point: Dr Betty San Martin Nunez.

* 1. Explore candidates as Reference Laboratory for Infection with decapod iridescent virus 1

The Aquatic Animals Commission noted the need to designate an OIE Reference Laboratory for infection with decapod iridescent virus 1 following its listing in May 2021. The Commission considered OIE Members that could potentially host an OIE Reference Laboratory for this disease. The Commission proposed that the Delegates of the Members concerned be asked to consider supporting an application from suitable institutes in their countries. The Commission also invites applications from any Member with expertise in this disease.