*Original: English*

*January and February 2022*

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

**Virtual meeting, 24 and 27 January, and from 16–23 February 2022**

**PART A – Texts to be proposed for adoption at the OIE 89th General Session in May 2022**

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The OIE Aquatic Animal Health Standards Commission (the Aquatic Animals Commission) held its meeting electronically on the 24 and 27 January and from 16 to 23 February 2022. The list of participants is attached as [**Annex 1**](#A1).

Considering the ongoing COVID-19 pandemic, the 89th Annual General Session will be held in a semi-hybrid format from Monday 23 to Thursday 26 May 2022. During the 89th General Session new and revised chapters of the OIE International standards (the *Aquatic Animal Health Code*, the *Terrestrial Animal Health Code*, the *Manual of Diagnostic Tests for Aquatic Animals* and the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*) will be proposed for adoption.

To facilitate this process, the February 2022 meeting report of the Aquatic Animals Commission will be distributed in two parts: Part A (herewith) provides information about the new and revised texts for the *Aquatic Code* and the *Aquatic Manual* that will be proposed for adoption at the 89th General Session; and Part B (to be published in April 2022) will provide information about other topics discussed at the Commission’s February 2022 meeting including texts circulated for comment and information.

In preparation for the 89th General Session, the OIE will once again organise pre-General Session information webinars to ensure that Members are aware of the background and key aspects of the standards being presented for adoption. Attendance to these webinars will be by invitation only. Please note that Delegates will soon receive detailed information about the 89th General Session, and in particular the process for the adoption of standards.

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 the Commission’s September 2021 report: Australia, Canada, Chile, China (People’s Rep. of), Chinese Taipei, Colombia, Japan, Korea (Rep. of), New Caledonia, New Zealand, Norway, Switzerland, Thailand, United Kingdom (the UK), United States of America (the USA), the Member States of the European Union (the EU) and the African Union Inter-African Bureau for Animal Resources (AU-IBAR) on behalf of the African Members of the OIE. 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 prior to the deadline 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 to distinguish them from those made previously. Due to the large number of comments, the Commission was not able to provide a detailed explanation of 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 reminded Members that *ad hoc* Group reports can be found on the OIE Website: <https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/>. 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 below includes the agenda items addressed by the Aquatic Animals Commission at this meeting and includes links to relevant items within this report. Members should note that the texts in **Annexes 2, 3, 4, 7, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21 and 22**  will be proposed for adoption at the 89th General Session in May 2022. **Annexes 5, 6, 8 and 17** are provided for Members information.

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1. **WELCOME FROM THE DEPUTY DIRECTOR GENERAL INTERNATIONAL STANDARDS AND SCIENCE**

Dr Montserrat Arroyo, the OIE Deputy Director General, International Standards and Science, welcomed members of the Aquatic Animals Commission and thanked them for their ongoing contributions to this work, noting the significant challenges posed by the ongoing COVID-19 pandemic, such as virtual meetings. Dr Arroyo commended the Commission for its ambitious agenda and on consistently providing high quality information in its reports. She extended her appreciation to the members’ employing institutions and national governments.

Dr Arroyo briefed the members on preparations for the semi-hybrid 2022 OIE General Session, including pre-General Session webinars that will be conducted by each of the OIE Specialist Commissions to inform Members about the revised and new standards that will be proposed for adoption. She also informed the Commission that the Technical Item would be on the OIE and Veterinary Services engagement in global, regional and national Emergency Management Systems. Dr Arroyo provided a summary of ongoing work on the OIE standards development and review system, including the development and planning for digital tools. Finally, she informed the Commission of an ‘after-action review’ conducted by the OIE in response to the COVID-19 pandemic.

Dr Arroyo and the members of the Aquatic Animals Commission discussed the importance of ensuring Member’s involvement in the OIE Standards setting process, and how to best support them to engage in this process. Dr Arroyo informed the Aquatic Animals Commission of the launch of a survey by the OIE Observatory to investigate the barriers to the implementation of aquatic animal health and welfare standards as part of the implementation of the Aquatic Animal Health Strategy. She also thanked the members of the Commission for participating in a pilot phase to test an online commenting system.

The members of the Aquatic Animals Commission thanked Dr Arroyo for the excellent support provided by the OIE Secretariat.

1. **MEETING WITH THE DIRECTOR GENERAL**

Dr Monique Eloit, the OIE Director General, met the Aquatic Animals Commission on 23 February 2022 and thanked its members for their support and commitment to achieving OIE objectives. She recognised the Commission’s efforts and adaptability to develop new ways of working despite the challenges imposed by the COVID-19 pandemic. Dr Eloit provided an update on the 89th OIE General Session preparation and informed the Commission of a new initiative to review the OIE Science system.

Dr Eloit informed the Commission of the budgetary situation of the Organisation and noted that due to the continued increase of activities, the current regular budget would not be sufficient to ensure the sustainable delivery of some core OIE activities. Dr Eloit highlighted that this situation might impact how the Commission and its Secretariat undertake some of their work. Dr Eloit acknowledged the work already being done by the Commission and the OIE Secretariat in prioritisation of its work and ensuring alignment with the priorities of the OIE Aquatic Animal Health Strategy.

The Commission welcomed the initiative to review the OIE Science system and noted that this work should also take into consideration how this system interacts with the OIE Standard setting process.

The Aquatic Animals Commission thanked Dr Eloit for making time to meet with its members and commended the excellent work of the Secretariat for meeting preparations and its work during the meeting especially given the challenges of virtual meetings.

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 4.1.2.2.).

1. **THE OIE *AQUATIC ANIMAL HEALTH CODE***
   1. Texts to be proposed for adoption in May 2022

The Aquatic Animals Commission thanked Members for highlighting translation issues in some of the Annexes circulated for comments in the French and Spanish versions of the September 2021 Aquatic Animals Commission report, and noted that these have been reviewed and corrected.

* + 1. User’s Guide

Comments were received from Colombia, New Caledonia, Switzerland and the EU.

*Background*

At its September 2021 meeting, the Aquatic Animals Commission proposed amendments to the User’s Guide to improve readability and ensure that it reflected key amendments made in the 2021 edition of the *Aquatic Code*.

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

September 2021 report (Item 5.1.1., page 6).

**February 2022 meeting**

In point 1 of Section A. Introduction, the Commission acknowledged a general comment requesting that an emphasis be placed on the importance of welfare for aquatic animals in general rather than focusing only on farmed aquatic animals. The Commission did not agree and reminded Members that the *Aquatic Code* currently only addresses welfare standards related to farmed fish.

In the second sentence of point 6 in Section B. *Aquatic Code* content, the Commission agreed with a comment that ‘disposal of aquatic animal waste’ would be complemented by the addition of ‘handling, and treatment’ to align with the title of Chapter 4.8. Handling, disposal and treatment of aquatic animal waste, and amended the text accordingly.

The revised User’s Guide is presented as [**Annex 2**](#A2)and will be proposed for adoption at the 89th General Session in May 2022.

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

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

*Background*

At its February 2021 meeting, the Aquatic Animals Commission proposed amendments to the Glossary definitions for ‘Basic biosecurity conditions’, ‘Early detection system’ and proposed a new Glossary definition for ‘Passive surveillance’. These amendments were to ensure alignment with the proposed amendments to Chapter 1.4. Aquatic Animal Health Surveillance. The revised definitions were circulated for comment in the Commission’s February 2021 report.

At its September 2021 meeting, the Commission considered comments received and amended the definitions as appropriate. The Commission also proposed to amend the definition of ‘Biosecurity plan’, which had not previously been circulated for comment, to include a reference to Chapter 4.1. Biosecurity for aquaculture establishments. The revised definitions were circulated for comment in the Commission’s September 2021 report.

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

February 2021 (Part B: Item 1.1., page 3); September 2021 (Item 5.1.2.1., page 6).

**February 2022 meeting**

**Basic biosecurity conditions**

The Commission noted Member’s support for the proposed definition.

**Biosecurity plan**

The Commission did not agree with a comment to delete ‘to zone and compartment’ as Article 5.3.7. Sequence of steps to be taken in establishing a zone or compartment and having it recognised for international trade purposes, indicates the requirement of a ‘biosecurity plan’ for aquaculture establishments and for recognition of a zone or compartment for the purposes of international trade.

The Commission also did not agree with a comment that the measures applied to mitigate the identified risk in the biosecurity plan should only be in accordance with the recommendations in Article 4.1.7. as it considered that the recommendations for a biosecurity plan are broader than the recommendations in Article 4.1.7. However, the Commission agreed that the context for the use of the term ‘biosecurity plan’ is broader than Chapter 4.1. and agreed to delete the reference to ‘Chapter 4.1.’ and revert to the current text ‘*Aquatic Code’*. Consequently, there are no proposed amendments to the Glossary definition of ‘biosecurity plan’.

**Early detection system**

The Commission did not agree to add ‘including an attempt for disease diagnosis’ after ‘investigation’ as it considered that this was clear as written and that this point is addressed in the proposed new Article 1.4.18. Diagnostic confirmation of a listed disease or an emerging disease.

The Commission did not agree with a comment to harmonise this definition with that in the *Terrestrial Code.* Members were reminded that the definition of ‘Early detection system’, like all Glossary definitions, is for the purposes of the *Aquatic Code* and that it had been modified in conjunction with the amendments made to Chapter 1.4. The *Terrestrial Code* definition of an ‘Early detection system’ does not align with the proposed amendments to Chapter 1.4.

The Commission did not agree to add ‘control or eradication’ after ‘investigation’ as it considered that the definition should not include all steps within a disease response, but rather that an ‘early detection system’ would contribute to an initial disease investigation.

**Passive surveillance**

The Commission noted some divergent views on the definition but reminded Members that the definitions in the Glossary are for the purposes of the *Aquatic Code*, as indicated at the top of the Glossary.

The Commission agreed with a comment to provide more guidance and clarity on the types and sources of information that would be part of a passive surveillance system and amended the definition accordingly.

The revised Glossary definitions for ‘Basic biosecurity conditions’, ‘Early detection system’ and ‘Passive surveillance’ are presented as [**Annex 3**](#A3) and will be proposed for adoption at the 89th General Session in May 2022.

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

Comments were received from Australia, Canada, China (People’s Rep. of), Colombia, New Caledonia, Switzerland and the EU.

*Background*

At its September 2018 meeting, 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. The revised definitions were circulated for comment in the Code Commission’s September 2018 report. The *ad hoc* Group on Veterinary Services considered the comments submitted and proposed revised definitions.

At their respective September 2020 meetings, the Code Commission and the Aquatic Animals Commission discussed the importance of ensuring alignment of these definitions in the two Codes except where differences could be justified and agreed to circulate 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* for comment in the September 2020 report of the Code Commission and the Aquatic Animals Commission, respectively. Neither Commission addressed comments received during their respective February 2021 meetings due to time constraints.

In preparation for the September 2021 meetings, the Presidents of the two Commissions met to review all comments previously received. 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 respective September 2021 Commission reports, as well as some more detailed information on the use of these terms in each Code.

At its September 2021 meeting, the Aquatic Animals Commission considered the comments received on its September 2020 report, as well as the feedback from the Presidents discussions, and the outcome of the Code Commission’s discussions at its September 2021 meeting. The Aquatic Animals Commission made one additional amendment to the definition for ‘Veterinary Authority’ that was not included in the Code Commission proposal but otherwise the definitions were aligned. The revised definitions were circulated for comment in the Aquatic Animals Commission September 2021 report.

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

September 2020 (Item 4.5.3., page 9); September 2021 (Item 5.1.2.2., page 7).

**February 2022 meeting**

The Commission noted that most comments submitted were in support of the proposed definitions.

In response to a general comment requesting clarification regarding the responsibilities and interactions between the different organisations who fulfil the roles of ‘Aquatic Animal Health Services’, ‘Competent Authority’ and ‘Veterinary Authority’ the Commission reminded Members that a detailed explanation was provided in the Commission’s September 2021 report. The Commission reiterated that 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 Aquatic Animal Health Services.

In response to a comment to clarify the meaning of the term ‘standards’, the Commission agreed with the suggestion to revise the paragraph on the SPS agreement in the foreword of the *Aquatic Code* to clarify that ‘standards’ refers to all chapters and articles of the *Aquatic Code*. The Commission will also consider amendments elsewhere in the *Aquatic Code* where appropriate. The Commission informed Members that when undertaking this work that it would ensure that any changes are aligned in the *Terrestrial Code*, where relevant.

The revised Glossary definitions for ‘Competent Authority’, ‘Veterinary Authority’ and ‘Aquatic Animal Health Services’, are presented as [**Annex 3**](#A3) and will be proposed for adoption at the 89th General Session in May 2022.

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

Comments were received from Australia, Chinese Taipei, Colombia, New Caledonia, Switzerland, Thailand and the EU.

*Background*

At its September 2017 meeting, 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.

The *ad hoc* Group on Infection with tilapia lake virus conducted its work electronically between November 2017 and September 2021.

At its September 2021 meeting, the Commission considered the *ad hoc* Group’s final report and noted its conclusion that there are reliable diagnostic methods for TiLV. The Commission reviewed its previous assessment of infection with TiLV against the criteria in Article 1.2.2. It agreed that Criteria 1, 2, 3, 4b and 4c were met and therefore infection with TiLV should be proposed for listing in Article 1.3.1. of Chapter 1.3. Diseases listed by the OIE. The Commission circulated the revised Article 1.3.1. for comment in its September 2021 report.

The Assessment for listing infection with tilapia lake virus was provided for Member information in the September 2021 Report of the Commission (<https://www.oie.int/en/what-we-do/standards/standards-setting-process/aquatic-animals-commission/#ui-id-3>).

**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 (Item 5.1.3., page 11).

**February 2022 meeting**

The Commission noted the general support of Members for the listing of infection with tilapia lake virus in Chapter 1.3. Diseases listed by the OIE, and updated the assessment against the listing criteria to reflect recently published scientific information.

The Commission agreed with a comment requesting the OIE to apply the same approach for future emerging disease events as was applied to infection with TiLV. The Commission informed Members that this approach would be formalised through future work of the Commission.

The Commission did not agree with a comment that infection with TiLV does not meet Criteria No. 4b and No. 4c of Article 1.2.2. (i.e. affect the health of cultured and wild animals respectively) and therefore should not be proposed for listing. The Commission noted that different strains of TiLV have shown different virulence between susceptible species and that those strains that are highly virulent pose a threat to farmed and wild tilapia populations. The Commission agreed that the study (Piamsomboon *et al*., 2021), which was provided as support for infection with TiLV not meeting all the criteria for listing, did not provide any evidence on the absence of pathogenicity. Of most significance within the study was the detection of PCR positives in Asian sea bass (*Lates calcarifer*). The Commission reiterated that a finding of subclinical infection in one circumstance cannot be extrapolated to absence of pathogenicity in all circumstances.

Reference:

Piamsomboon, P.& Wongtavatchai, J. (2021). Detection of Tilapia Lake Virus (TiLV) in healthy fish from the pre-existing disease environment using different RT-PCR methods. *Turkish Journal of Fisheries and Aquatic Sciences*, **21**, 205-209. http://doi.org/10.4194/1303-2712-v21\_4\_05

The Commission agreed with a comment that if listing of infection with tilapia lake virus in Chapter 1.3. Diseases listed by the OIE, is adopted in May 2022, an OIE Reference Laboratory for infection with tilapia lake virus will need to be designated.

The revised and updated ‘Assessment of infection with tilapia lake virus (TiLV) for listing in Chapter 1.3. of the *Aquatic Code’*, is presented as [**Annex 5**](#A5)for Member information.

The revised Article 1.3.1. of Chapter 1.3. Diseases listed by the OIE is presented as [**Annex 4**](#A4) and will be proposed for adoption at the 89th General Session in May 2022.

* + 1. Approaches to demonstrate disease freedom

*Background*

At its September 2018 meeting, the Aquatic Animals Commission developed a discussion paper on approaches for determining periods required to demonstrate disease freedom, which was circulated for comments. At its September 2019 meeting, the Commission considered comments received and circulated a revised paper for comments. At its February 2020 meeting, the Commission developed model Articles X.X.4.–X.X.8. to replace the existing articles in the disease-specific chapters of the *Aquatic Code.* The model articles were circulated for comments in the Commission’s February 2020 report.

At its September 2020 meeting, the Commission considered all comments received and agreed that Chapter 1.4. Aquatic animal health surveillance, needed to be revised to better complement the proposed model articles. The revised Chapter 1.4. and the model Articles X.X.4. to X.X.8. for disease-specific chapters to address declaration of freedom from [Pathogen X], were circulated for comment in the Commission’s February 2021 report. At its September 2021 meeting, the Commission considered all comments received and amended the texts as appropriate, and circulated the revised Chapter 1.4. and the model Articles X.X.4. to X.X.8. for disease-specific chapters to address declaration of freedom from [Pathogen X] for another round of comments.

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

September 2018 (Item 2.10., page 11); September 2019 (Item 6.6., page 9); February 2020 (Item 7.2.2., page 15); September 2020 (Item 6.2., page 16); February 2021 (Part B: Item 1.2., page 4); September 2021 (Item 5.1.4., page 12).

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

Comments were received from Australia, Canada, Chile, China (People’s Rep. of), Colombia, New Caledonia, Norway, Switzerland, the UK, the USA and the EU.

**February 2022 meeting**

**General Comments**

The Commission thanked Members for their comprehensive comments and noted the general support for the proposed chapter.

The Commission agreed with a comment to further develop the application procedures for OIE publication of self-declarations of freedom and for possible mechanisms to encourage Members to submit applications. The Commission agreed that it would discuss this issue further and also investigate proposal to require annual updates to confirm that the requirements for maintenance of freedom in Chapter 1.4 are being met.

The Commission agreed that ‘Competent Authorities’, ‘the Competent Authority’ and ‘a Competent Authority’ had been applied inconsistently throughout the proposed chapter. It noted that there may be more than one Competent Authority involved in a self-declaration of freedom and so replaced ‘the Competent Authority’ with ‘a Competent Authority’ or ‘Competent Authorities’, where relevant.

In response to a comment requesting the publication of scientific assessments for the default minimum periods for basic biosecurity conditions included within the disease-specific chapters, the Commission informed Members that detailed information on the proposed default minimum periods has been provided in previous reports of the Commission. The Commission encouraged Members to refer to its previous reports.

The Commission did not agree with a comment requesting a delay in proposing the amended Chapter 1.4. for adoption. It noted that the development of this chapter has been thoroughly consulted since 2018 and Members’ have expressed overall support for the proposed amended chapter, which the Commission considered to be a vast improvement on the current chapter. The Commission emphasised that it is important to provide guidance to Members on the requirements for surveillance to support the proposed changes in the disease-specific chapters regarding self-declaration of freedom, and agreed to propose the revised chapter for adoption. The Commission reminded Members that it will be possible to continue to improve the chapter, if necessary, after adoption.

**Article 1.4.1.**

The Commission did not agree with a comment to add ‘a specific’ after ‘self-declaration of freedom from’ as ‘self-declaration of freedom from disease’ is a defined term in the Glossary that includes a reference to a specific disease.

**Article 1.4.2.**

Minor editorial changes were made to this article as described in the general comments above.

**Article 1.4.3.**

In response to a comment to add a point on shared water bodies in Article 1.4.12., the Commission agreed that this was an important point that had been captured in the disease-specific chapters of the *Aquatic Code,* but not in Chapter 1.4. The Commission agreed that it would be more appropriate to add it to the first paragraph of Article 1.4.3., to emphasise that the evidence used to support a claim of freedom must account for shared water bodies.

In point 1, the Commission did not agree to add a new pathway for shared water bodies as the proposed pathways consider the situations at the country and zone levels, both of which may include shared water bodies. The Commission also added wording in the introductory text to clarify that all pathways must account for shared water bodies.

In point 1, the Commission did not agree to add ‘(excluding species with incomplete or no evidence of susceptibility)’ as it considered the glossary definition of ‘susceptible species’ to provide sufficient clarity.

The Commission did not agree with a comment to change ‘passive surveillance information’ to ‘passive surveillance data’ as passive surveillance may provide more qualitative information than just data, which implied empirical evidence. Similar replacements had previously been made throughout the chapter at the September 2021 meeting.

In point 2, the Commission agreed with a comment to add ‘at the country or zone level’ to align with Table 1.1. The Commission also agreed to add the levels of application for the other pathways within the respective points for consistency.

The Commission did not agree with a comment to add ‘when historical freedom can not be demonstrated’ to the title of pathway 3 as the capacity to claim freedom using any pathway would not be restricted based on the inability to demonstrate freedom through any other pathway. The choice of which pathway to use for a self-declaration of freedom depends on the specific circumstances of the situation. To remove any ambiguity, the Commission deleted part of the first sentence.

In the final sentence of pathway 3, the Commission did not agree with a comment that supplementary passive surveillance information must be quantitative and agreed it would need to be judged on its merits, not on whether it is qualitative or quantitative.

In the final sentence of pathway 3, the Commission did not agree to replace ‘information may also be used in this pathway’ with ‘may also contribute evidence to this pathway’ as it was not considered an improvement.

The Commission agreed with a comment that a flowchart providing a visual representation of the pathways of freedom, in theory, may be of assistance to Members but did not want to delay proposing the new chapter for adoption in order to incorporate such a flowchart.

In pathway 1 of Table 1.1., the Commission did not agree with a comment to add compartment as a level of application for pathway 1, as it considered that targeted surveillance is always required to demonstrate that biosecurity measures are effective to establish a free status for a compartment. However, the Commission agreed that additional guidance on compartmentalisation is required and noted that this would be a logical progression of work following adoption of Chapter 4.1 on Biosecurity for Aquaculture Establishments and the new guidance on declaration of freedom. The commission agreed to prioritise revision of Chapter 4.2. Zoning and Compartmentalisation, within it’s work plan to ensure additional guidance and clarity on compartmentalisation is provided to Members.

In pathway 3 of Table 1.1., the Commission did not agree to replace ‘population’ with the defined term ‘study population’ under ‘Secondary evidence to claim freedom’ as it considered that the use of ‘population’ within this context is more appropriate than the Glossary definition of ‘study population’.

In Table 1.1., the Commission did not agree that there was no difference between pathways 3 and 4. The Commission agreed that while the two pathways were similar, the context of applying them is different and that the proposed chapter provides guidance when declaring freedom using those pathways.

**Article 1.4.4.**

In point 2, the Commission agreed with a comment to replace ‘confirm’ with ‘verify’ as this was a more suitable word.

In the first sentence of the final paragraph, the Commission deleted ‘Except when otherwise provided for in the disease-specific chapter’ to remove inconsistencies with Article 1.4.16. which indicates that ‘Apparent disease at any level in a target population automatically invalidates any freedom from disease claim.’. The Commission also noted that the *Aquatic Code* disease-specific chapters do not allow for Members to maintain a claim of freedom when an outbreak has occurred.

**Article 1.4.5.**

The Commission did not agree with a comment to reconcile Article 1.4.5. with Chapter 4.1. Biosecurity for aquaculture establishments, as Article 1.4.5. provides guidance on the biosecurity and surveillance that is applied at the national level while Chapter 4.1. provides guidance on biosecurity applied at the establishment level.

The Commission agreed with a comment to remove point 3 as an early detection system is included within the requirements of Article 1.4.6. Basic biosecurity conditions. However, to ensure that the requirement for an early detection system was emphasised, the Commission added ‘(which include an early detection system)’ to point 2 after ‘basic biosecurity conditions’.

**Article 1.4.6.**

In point 1, the Commission did not agree with a comment to revert to the previous text and include a requirement for ‘compulsory requirement for notification of a specific disease, or suspicion of the disease to a Competent Authority’. The Commission considered that it was unnecessary as point 1 in Article 1.4.6. refers to Article 1.4.7. which includes a legal obligation to report listed diseases. However, the Commission added ‘emerging diseases’ to point 2 of Article 1.4.7. as it considered that recognition and reporting of emerging diseases is of significance to the performance of the early detection system.

In point 2, the Commission did not agree with a comment to add ‘anthropogenic’ after ‘measures to prevent the’ as the scope of basic biosecurity conditions is for a country, zone or compartment. While some pathways relating to the movement of wild animals may not be manageable at some levels, at others they can be; for example, compartments may erect barriers to prevent the entry of wild aquatic animals (as recommended in Article 4.1.7. point 1 j).

**Article 1.4.7.**

In the first paragraph, the Commission agreed with a comment to clarify that the objective of an early detection system extended beyond the collection of information for a declaration of freedom. As such the Commission amended the wording to ‘The early detection system of the Competent Authority is important to generate evidence for claims of disease freedom and to provide assurance that a change in disease status would be rapidly discovered’.

In point 3, the Commission did not agree with a comment to add ‘Veterinary Authority or designated Competent Authority’ and delete ‘Aquatic Animal Health Services’ as Aquatic Animal Health Services is the appropriate term to use because a disease investigation may not always be completed by a government authority.

In point 3, the Commission agreed with a comment to add ‘led by a Competent Authority’ at the end of the sentence as a Competent Authority should lead emergency aquatic animal disease response activities.

In point 4, the Commission did not agree with a comment to delete ‘Aquatic Animal Health Services’ and add ‘Competent Authority’ as laboratory services are not always within the Competent Authority of Member Countries and could be contracted by the private sector or other countries.

In point 5, the Commission did not agree with a comment to delete ‘with an occupational role with aquatic animals’ as aquatic animal health professionals are authorised by the Competent Authority and ‘others’ indicates a broad public responsibility. The Commission noted that Members had previously requested other possible occupational roles be included within point 5 and proposed adding ‘with an occupational role with aquatic animals’ to broaden the scope of the point to address those comments.

The Commission did not agree to add a point 6 requiring listing of specific notifiable diseases within Member Country legislation as it considered that the inclusion of ‘listed diseases and emerging diseases’ within point 5 already addressed this concern. However in order to emphasise this, the Commission amended point 5 to ‘..suspicion of the occurrence of listed diseases or emerging diseases…’.

The Commission did not agree to add a point 6 requiring ‘enhanced awareness of the status of susceptible species populations through time’ as the proposed point is an outcome measure while the list within Article 1.4.7. includes input measures.

In the first sentence of the eighth paragraph, the Commission did not agree to add ‘in a timely manner’ after ‘detected’ as it could be confusing considering that sensitivity for passive surveillance is estimated as a default annual basis of 30% which accumulates over a 10-year period to 95%. In the second sentence, the Commission also did not agree to add ‘or investigation’ as investigation is covered in the definitions of passive surveillance and an early detection system.

In the second sentence of the last paragraph, the Commission did not agree to delete ‘diagnostic’ before ‘assays’ as it was considered that the use of ‘diagnostic assays’ assists with understanding and is consistent with the Glossary definitions for disease and diagnosis.

In the last paragraph, the Commission did not agree with a comment to delete ‘can be quantified, for example, by use of a scenario tree model, however, in most circumstances a qualitative assessment will be sufficient’ and to add text on reporting that is repeated elsewhere, as the proposed changes would remove unique guidance on measuring sensitivity and did not improve the existing text.

**Article 1.4.8.**

In point 1 a), the Commission agreed that there was repetitive information to that provided in point 4. The Commission agreed to delete point 4 as it did not provide any additional information.

In point 1 a), the Commission did not agree with a comment to add ‘in that species’ after ‘disease’ as it was not considered an improvement.

In point 1 b), the Commission agreed that there was some repetition between point 1 and 5 in Article 1.4.7. and point 1b) of Article 1.4.8. Therefore, the Commission deleted ‘there should be sufficient awareness by potential observers of the study population, such that’ to remove any repetition while maintaining the unique information regarding investigation.

In point 1 d), the Commission did not agree to add ‘(or proxy or sentinel populations)’ after ‘they’ as it considered the current text more explicit.

In point 1 d ii), the Commission did not agree to:

– add ‘the Competent Authority can demonstrate that’ as the Commission considered that may be difficult to obtain evidence that can demonstrate an epidemiological link;

– remove the point as it was considered necessary guidance for Members and that disease occurrence in an adjacent farmed population would be part of the early detection system and passive surveillance;

* add ‘epidemiologically linked’ before ‘farmed populations’ as the concept is already embedded at the beginning of the sentence.

In point 2, the Commission did not agree to delete the point as it was considered necessary guidance for Members.

In the second sentence of point 2, the Commission agreed to amend the reference to ‘points 1a), b and d) may not be’ to clarify that for wild populations, some aspects stated under point d ii) should be met for passive surveillance.

In the second sentence of point 3, the Commission did not agree to delete ‘and surveys (e.g. of wild populations)’ but agreed that to clarify the purpose of the surveys a different example should be provided ‘(e.g. fisheries and aquatic fauna surveys)’.

**Article 1.4.9.**

In point 1 the Commission agreed with a comment to add ‘or’ after point 1a) and replace the ‘and’ after point 1b) with an ‘or’ as the different pathways would not all apply in one situation.

In the second sentence of point 2 and in point 2b), the Commission did not agree to add an option and guidance for a shorter default minimum periods as the consensus from the consultation process with Members was that the 10 year default minimum should be retained. 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. However, the Commission does not intend to develop such standards and if a faster pathway for a self- declaration of freedom was desired, pathway 3-Targeted surveillance, could be used.

At the end of point 2 b), the Commission agreed to add ‘recommended in the disease-specific chapters’ as it is important to clarify that these are criteria for disease-specific chapter determinations and not intended for country-specific evaluation.

In point 2 b) iv), the Commission agreed to delete ‘and therefore the likelihood of detection’ as all listed factors (i-vi) are intended to inform the likelihood of annual detection and is a repetition from 2 b) above.

In point 2 b v), the Commission agreed to amend the wording to ‘(i.e., periods of the year when prevalence and intensity of infection is highest and most conducive to detection) to ensure consistency with point 2 c) and Article 1.4.10.

In point 2 c), the Commission did not agree to add the possibility of having a shorter requirement for basic biosecurity conditions as it was considered that basic biosecurity conditions are controls implemented at a national level and not related to production cycle within a premises.

Within sentences 2 and 3 in point 2d), the Commission agreed to add wording to ensure that it is explicit that the introduction route for the disease occurrence must be identified and mitigated before pathway 4 can be completed.

**Article 1.4.10.**

In the fourth sentence of the sixth paragraph, the Commission agreed with a comment that wild populations should be considered for sampling as there may be different species in the wild that may be more likely to show signs of disease than those being farmed. The Commission also agreed to delete ‘at the farm level’ to clarify that any population (farmed or wild) could be sampled.

In the sixth paragraph, the Commission did not agree that continuous sampling could be used as there is 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 pathogenic agent. However, the Commission recognised that obtaining a three month interval between surveys might be challenging in some circumstances, however, it was considered to be better placed in the third paragraph of ‘Requirements for targeted surveillance’ in Article 1.4.13. The Commission agreed to amend the text to include flexibility for these specific situations by adding: ‘In situations where seasonal conditions do not permit a gap of at least three months between surveys, the maximum possible time gap should be allowed to elapse between one survey and the next.’

In the last paragraph, the Commission did not agree to add ‘effective in accordance with the *Aquatic Code* for a specific pathogen’ to address detection of possible lingering infection. According to the requirements in disease-specific chapters, all aquatic animals are required to have been destroyed and then restocked. Depopulation is the first step in establishing that the pathogenic agent has been eliminated; only through a stepwise process including depopulation, cleaning, disinfection and fallowing followed by targeted testing can elimination of a pathogenic agent be confirmed.

**Article 1.4.11.**

At the end of the first paragraph, the Commission did not agree to add ‘Absence of susceptible species is not a pathway to prove freedom for compartments’ as the application of the pathways is outlined in Table 1.1. and declaration of freedom at a compartment level would not be required for trade in species that are not considered susceptible.

The Commission reiterated that it did not agree with comments also made on other articles to add compartments 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.

The Commission did not agree to remove the second paragraph as it is a requirement to ensure that no susceptible species have been introduced for the pathway to be utilised and basic biosecurity conditions must be maintained to ensure consistency with Article 1.4.9.

In point 2 a), the Commission agreed to add ‘reports which provide evidence regarding’ as it added clarity.

In the penultimate paragraph, the Commission did not agree to delete ‘pathogenic agent’ and add ‘susceptible species’ as it was not considered an improvement.

The Commission reminded Members that each pathway is intended to support a claim of freedom independent of other pathways. The Commission considered that Article 1.4.3. and this article emphasise that pathway 1 would only be applicable for commencing production of a new species, that is listed as susceptible in Article X.X.2. of the disease-specific chapters, in a country or zone where it has been demonstrated that no susceptible species were previously present. Once a new species has been introduced, further declarations of freedom would require the use of pathway 3-Targeted surveillance. The use of pathway 1 would be chosen depending on the circumstances of the specific situation.

**Article 1.4.12.**

In the first sentence of the first paragraph and in point 2, the Commission did not agree with a comment to add compartment as an applicable level of application for pathway 2 – Historical freedom. The Commission considered that while historical health records may support a self-declaration of freedom, targeted surveillance is required to demonstrate that biosecurity measures are effective. Targeted surveillance is a fundamental requirement to establish free status of a compartment.

In point 1, the Commission agreed with a comment to add ‘or zone’ and to add cross-references to Articles 1.4.6. and 1.4.7. to ensure consistency within the Chapter.

In the first paragraph of ‘Requirements for passive surveillance’, the Commission did not agree to add guidance on how 95% confidence could be quantified and found equivalent to other pathways. Instead, the Commission agreed to delete the paragraph as it was considered that the information was found in Article 1.4.9.

In the second sentence of the second paragraph of ‘Requirements for passive surveillance’, the Commission agreed to delete ‘cover’ and add ‘represent’ to emphasise that the Early Detection Systems should be representative of the populations of susceptible species in the country or zone.

In the section, ‘Need for targeted surveillance’, the Commission did not agree to add ‘(i.e. population under sufficient surveillance, species susceptible to show clinical signs, environmental conditions conducive to clinical expression)’, as it was considered to not be an improvement and created unnecessary repetition within the chapter.

**Article 1.4.13.**

The Commission did not agree to change the title of pathway 3 to ‘Surveillance when Historical freedom cannot be demonstrated’ as all four pathways are available and the most suitable would be chosen by a competent authority depending on the circumstances.

In the third paragraph of ‘Requirements for targeted surveillance’, the Commission did not agree to remove the second sentence, as it would remove the guidance on the duration of the survey required to obtain freedom. The Commission noted that there was consensus for the 2-year duration for surveys from the extensive consultation completed.

With the addition of the new sentence as a result of comments on Article 1.4.10., the Commission split the third paragraph of ‘Requirements for targeted surveillance’ into two paragraphs for readability.

In the first sentence of the new fourth paragraph of ‘Requirements for targeted surveillance’, the Commission agreed with a comment to:

– delete ‘or greater’ after ‘95% confidence’ and to add ‘would be detected if present at or above’ after ‘pathogenic agent’ to clarify that the surveillance sensitivity (confidence) calculates the probability of detecting a pathogenic agent if present;

– add ‘Over the period of targeted surveillance, the combined’ and ‘in the country, zone or compartment’ after ‘design prevalence’ as it was considered to provide additional clarity and guidance.

In the new fourth paragraph of ‘Requirements for targeted surveillance’, the Commission agreed with a comment to add a cross-reference Article 1.4.16. for establishing the design prevalence. However, the Commission did not agree to refer to the relevant disease-specific chapter of the *Aquatic Manual* as design prevalence is not presented in the *Aquatic Manual* and would always need to be determined based on the circumstances of the survey, in addition to disease-specific factors.

In ‘Other sources of data’, the Commission did not agree with a comment to add a requirement for quantification of the passive surveillance system as it was considered to not be an improvement and too complex for most Members to implement. The Commission also considered that the ‘other sources of data’ should not be the core evidence to support the claim of freedom. It is up to the Competent Authority to demonstrate that the information used to support the claim of freedom is sufficiently rigorous and the Commission considered that there was sufficient guidance in the proposed chapter to support Members to do this.

**Article 1.4.14.**

In the first sentence in the first paragraph of point 2, in 2a) and in the first sentence of point 3, the Commission did not agree with a comment to remove the requirement for depopulation of infected populations and to add a requirement for pathogen eradication or containment as this pathway concerns the return to freedom after a disease outbreak. The Commission considered that a return to freedom could not be achieved without depopulation either by slaughter or moving the animals to an infected area outside the zone or compartment. Depopulation is the first step in establishing that the pathogenic agent has been eliminated; only through a stepwise process including depopulation, cleaning, disinfection and fallowing followed by targeted testing can elimination of a pathogenic agent be confirmed.

In point 2 b), the Commission did not agree with a comment to add ‘vessels’, or ‘staff’ as it considered that the point did not need to be inclusive of all possible pathways of exposure.

In the fourth sentence of the last paragraph of point 2, the Commission agreed with a comment to delete ‘is not present’ and add ‘would not be detected if present at’ as the surveillance sensitivity (confidence) calculates the probability the pathogen would be detected if present. Similarly in the final sentence of point 3, the Commission also agreed to delete ‘is not present above’ and add ‘would be detected above’.

**Article 1.4.15.**

In point 2, the Commission did not agree with a comment to delete points a) and b), as it agreed that targeted surveillance is required at the zone or compartment level except when they occur within a country that is declared free. The Commission noted that there are several reasons why a compartment may be established within a free country such as to prevent the introduction of other diseases for which the country is not free, to obtain a higher level of assurance of disease freedom, in preparation for possible future disease outbreaks within the country or for valuable broodstock populations.

**Article 1.4.16.**

In the second sentence of the second paragraph of point 1, the Commission agreed with a comment to delete ‘Exotic’ as the defined term ‘disease’ was more appropriate.

In the third paragraph, the Commission agreed with a comment to delete ‘risk of infection’ and add ‘likelihood of exposure’ as this will determine whether clustering might occur and whether a multi-stage survey is required.

In the third paragraph, the Commission agreed to delete ‘is relatively small, and’ as the size of population is not a factor for choosing a single vs multi-stage surveys. The main factor is homogeneity of the likelihood of exposure.

In the fifth paragraph of point 3, the Commission agreed with a comment to delete ‘below’ and add ‘above’ to correct an error.

In the same paragraph, the Commission did not agree to

– delete ‘infection’ and add ‘disease’ as it considered that infection was the most appropriate term to be used;

* rephrase the paragraph as the proposed changes did not improve clarity.

The Commission did not agree to delete the sixth paragraph of point 3, as it considered that the text was useful and the terminology used appropriate.

In the third sentence of point 3b), the Commission agreed with a comment to delete ‘that can remain sub-clinical’ and add ‘less contagious’ as it is not because an infection is sub-clinical that it is less contagious (i.e. lower prevalence).

In point 3 b) i), the Commission did not agree with a comment to remove the point, as it considered that a default value needed to be provided and that a higher design prevalence could be used, if appropriately justified.

In point 4, the Commission agreed with a comment that the list of risk factors for disease introduction, exposure and establishment could be expanded and added ‘exposure to recent stressors’ to point c) and added a new point e) ‘evidence of morbidity or mortality’ as these are additional factors that could identify high risk populations.

In the second paragraph of point 5, the Commission did not agree with a comment to require validation of test methods prior to initiation of targeted surveillance as it was considered too restrictive for implementation by all Members. The Commission also informed Members that guidance on validation of diagnostic assays and approaches for diagnostic sensitivity and specificity should be included in the *Aquatic Manual* only.

In the first paragraph of point 6, the Commission agreed with a comment to expand the introductory wording of the paragraph for clarity. However, the Commission did not agree with a comment to remove Table 1.2. as Members have found it useful. Nor did it agree to make generalised recommendations for acceptable diagnostic test sensitivity and specificity by type of assay as there are many factors involved.

In the eighth paragraph of point 6, the Commission did not agree to insert the formula and an example of software that could be used by Members for sample size calculations as it considered that it would not be appropriate to recommend specific resources in the *Aquatic Code*. The Commission recommended Members seek advice or support from one of the two Epidemiology and Risk Assessment of Aquatic Animal Diseases Collaborating Centres. The Contact information for the Collaborating centres can be found on the OIE website (<https://www.oie.int/en/what-we-offer/expertise-network/collaborating-centres/#ui-id-3>) .

In the fifth sentence of the eighth paragraph of point 6, the Commission did not agree to add ‘pathogenic agent would be detected if present at a’ prior to ‘*prevalence*’ as it considered it would change the meaning of the information provided.

In point 7, the Commission did not agree with a comment to:

– delete ‘discrete populations of wild susceptible species’ and delete ‘defined stocks within a population’ as it was not considered to be an improvement;

* add ‘or stocks’ after ‘discrete populations’, delete ‘defined within a wild population stocks’ and add ‘individual animals within a defined wild population stock’ as stocks and population were considered to be the same.

In point 7, the Commission agreed to delete ‘discrete’ before ‘populations’ as it was not clear how these words represent different sampling stages and that it could be confusing to Members to have wild populations described as both ‘discrete populations’ and ‘defined stocks’. In response to comments on point 8, the Commission agreed to delete the point on Discounting as the paragraph was considered not relevant to the chapter.

**Article 1.4.17.**

In the first paragraph, the Commission added ‘and may be supplemented with targeted surveillance if necessary (as described in Article 1.4.12.).’ to align with the types of primary and secondary surveillance information described in Table 1.1. for each pathway for self-declaration of freedom from disease.

In the final paragraph, the Commission agreed with a comment that there are various approaches to surveillance sensitivity estimation and combination and that scenario tree modeling is just one approach. The Commission rephrased the paragraph to indicate scenario tree modeling is just an example of how multiple sources of information can be combined.

**Article 1.4.18.**

In the third sentence of the third paragraph, the Commission did not agree to delete ‘lower’ and add ‘different’ as it considered a higher standard of evidence may interfere with notification requirements.

The Commission noted that due to the extensive number of amendments being proposed compared to the current text in the *Aquatic Code*, the revised Chapter 1.4. would be proposed for adoption as clean text. However, the Commission agreed to also provide a version of Chapter 1.4., for Member information only, that shows the changes made to the draft revised chapter during this meeting. This marked version is presented in [**Annex 6**](#A6)**.**

The revised version of Chapter 1.4. Aquatic Animal Health Surveillance is presented as [**Annex 7**](#A7) and will be proposed for adoption at the 89th General Session in May 2022.

* + - 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, Chile, Chinese Taipei, Colombia, New Caledonia, New Zealand, Switzerland, the USA, and the EU.

**February 2022 meeting**

The Commission reminded Members that if the model Articles X.X.4. to X.X.8. for disease-specific chapters to address declaration of freedom from [Pathogen X], are adopted at the 89th General Session in May 2022, these amendments will be applied to all disease-specific chapters in the 2022 edition of the *Aquatic Code*.

In response to a general comment and to comments on Article X.X.7., the Commission did not agree to add compartment as an applicable level of application for pathway 1, as it considered that targeted surveillance is required to demonstrate that biosecurity measures are effective and that it is a fundamental element to establish a free status for a compartment (see Item 4.1.4.1.).

**Article X.X.5.**

In response to a comment requesting a definition of ‘shared water body’, the Commission did not agree as it considered that it would not be an improvement. The Commission considered that the reference to ‘shared water bodies’ in Article X.X.5. refers to natural epidemiological linkages that could not be broken through implementation of basic biosecurity conditions that apply to trade, movement of product etc, and that this concept is generally understood.

In the second paragraph, the Commission agreed with a comment to add ‘if it can demonstrate that’ at the end of the sentence as it would be expected that in a declaration Members would demonstrate how the requirements for freedom have been met. This change has also been proposed for Articles X.X.6. and X.X.7. and within the draft Chapter 9.X.

In point 4 b), the Commission did not agree to remove the requirement for depopulation and add a requirement for pathogen eradication as this point concerns the return to freedom after a disease outbreak. The Commission considered that a return to freedom could not be achieved without depopulation either by slaughter or moving the animals to an infected area outside the zone or compartment. The Commission also did not agree with a comment to make this change in Article X.X.6. point 4 b) and X.X.7. point 2 a) and in Chapter 1.4. (see Item 4.1.4.1.).

In point 4 d) ii), the Commission did not agree to delete ‘affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*’ and to add ‘wild susceptible species were not linked to the disease event that occurred’ as it was not considered to be an improvement.

**Article X.X.7.**

In point 2 b), the Commission added ‘aquatic’ prior to ‘animal’ to align with an amendment to draft Chapter 9.X. (see Item 4.1.6.).

The Commission noted that due to the extensive number of amendments being proposed compared to the current text in the *Aquatic Code*, the revised model Articles X.X.4. to X.X.8. for disease-specific chapters to address declaration of freedom from [Pathogen X] would be proposed for adoption as clean text. However, the Commission agreed to also provide a version of the revised model Articles, for Member information only, that shows the changes made to the draft revised model Articles during this meeting. This marked version is presented in [**Annex 8**](#A8)**.**

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 9**](#A9) and will be proposed for adoption at the 89th General Session in May 2022.

* + 1. Safe Commodities – Articles X.X.3 of 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/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 agreed to begin with a review of Section 9. and developed an example article, Article 9.8.3. Infection with white spot syndrome virus, to demonstrate the suggested approach, noting that it was difficult to propose a uniform model Article X.X.3. because of differences in time/temperature treatments as well as products listed in Article X.X.3. between disease-specific chapters. The Commission circulated the example article, Article 9.8.3., for comment in its September 2020 report.

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

Comments were received from Colombia, New Caledonia, Switzerland, Thailand, the UK, the EU and AU-IBAR.

*Background*

At its February 2021 meeting, the Aquatic Animals Commission considered comments on the example Article 9.8.3. and applied these amendments to Article 9.X.3. for 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. were amended 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. The revised Articles 9.X.3. were circulated for comment in the Commission’s February 2021 report.

At its September 2021 meeting, the Commission reviewed comments and revised the proposed Articles 9.X.3. to improve clarity including re-ordering the aquatic animal products. The Commission also reviewed the use of ‘meal’ throughout the *Aquatic Code* and agreed that the addition of a specific time/temperature heat treatment for meal proposed in Articles 9.X.3. did not impact the definition of meal in the Glossary. The revised Articles 9.X.3. were circulated for comments in the Commission’s September 2021 report.

**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 (Item 5.1.5., page 24).

**February 2022 meeting**

The Commission noted that the convention for the inclusion of numbers within the *Aquatic Code* is based on the Oxford dictionary, i.e. to write in full numbers from one to ten and for numbers above ten to use a numerical format, e.g. 100.

The Commission wished to inform Members that it has included work to review the safe commodity assessments for all listed diseases on its work plan. This will ensure that the thermal treatments for inactivation of listed pathogens are based on current scientific evidence (see February 2022 Aquatic Animals Commission report Part B).

The Commission reiterated that the proposed amendments have been made to specify the time/temperature treatments required to inactivate the pathogenic agent. The Commission noted that this is a change from the current commodity-based approach and was made in response to Member comments that some of the levels of thermal treatment in the current text were inconsistent or not commercially feasible as they would diminish product quality.

The Commission agreed with a comment that some of the proposed time/temperatures could be challenging to practically implement and reminded Members that equivalent time/temperature combinations could be used (e.g. longer times at lower temperatures or shorter times at higher temperatures) where supported by evidence. The Commission also agreed that there is limited scientific information on the inactivation of many aquatic animal pathogenic agents and it encourages research by Members on inactivation of OIE listed pathogenic agents.

In point 1 of Article 9.X.3., the Commission agreed with a comment not to specify any product types such as cooked, pasteurised or retorted, noting that these were only examples and that any aquatic animal product should be considered safe if it has undergone the time/temperature treatment, as specified. The Commission noted that this approach will be applied to all the other revised Articles X.X.3.

In point 1 of Article 9.1.3. of Chapter 9.1, Acute hepatopancreatic necrosis disease (AHPND), the Commission did not agree with a comment that the reference to the specific strain of *Vibrio parahaemolyticus* (Vp) should be deleted. The Commission agreed that this would be in contradiction to Article 9.1.1. which indicates the causative agent for AHPND. However, the Commission noted that there is scientific literature which indicates that other *Vibrio* species may cause AHPND and it will request that the AHPND reference laboratories provide a recommendation on this issue for the Commission’s September meeting.

In response to a comment on point 1 of Article 9.5.3. requesting the use of the current time/temperature published in the *Aquatic Code* for inactivation of infection with IMNV, the Commission noted that the inactivation time/temperature previously adopted (and current in the 2021 version of the *Aquatic Code*) was an error as it did not reflect the information presented 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 investigated if there was any additional scientific information on inactivation of IMNV to support an alternative time/temperature combination, however, there is none and the commission agreed that there was no evidence to support an alternative at this time.

The revised Articles 9.X.3. for crustacean disease-specific chapters are presented as [**Annex 10**](#A10)and will be proposed for adoption at the 89th General Session in May 2022.

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

Comments were received from Australia, Canada, Colombia, New Caledonia, Switzerland, Thailand, the UK and the EU.

*Background*

At its September 2021 meeting, the Aquatic Animals Commission reviewed and amended, as appropriate, Articles 10.X.3. of the disease-specific chapters of Section 10. Diseases of fish, of the *Aquatic Code* while ensuring alignment with proposed amendments to Articles 9.X.3. (see Item 4.1.5.1.).

The time/temperature treatments provided in Articles 10.X.3. of all fish disease-specific chapters were amended 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 agreed not to include time/temperature heat treatments for *Gyrodactylus salaris* given that *G. salaris* would not survive in heat treated products such as pasteurised or retorted products because the parasite would be inactivated. The revised Articles 10.X.3. were circulated for comment in the Commission’s September 2021 report.

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

September 2021 (Item 5.1.5.2., page 25).

**February 2022 meeting**

As described for item 4.1.5.1, the Commission wished to inform Members that it has included work to review the safe commodity assessments for all listed diseases on its work plan to ensure that the time/temperatures for inactivation of listed pathogens is based on current scientific evidence (see February 2022 Aquatic Animals Commission report Part B).

In response to a general comment, the Commission agreed in principle that the articles relating to safe commodities (Articles X.X.3. and X.X.12.) in the disease-specific chapters should be sequential within the disease-specific chapters. The Commission noted that while the current order of articles is not ideal, a rearrangement of articles would have to be addressed through a broader review of the article structure of disease-specific chapters. This could be completed pending prioritisation of that work against other items within the Commission’s workplan.

The Commission did not agree with a general comment to combine Articles X.X.3. and X.X.12., and noted that each article has a different scope. Article X.X.3. lists aquatic animal products that are considered safe for importation for any purpose regardless of the specified disease status of the exporting country, zone or compartment. Article X.X.12. lists aquatic animal products that are considered safe for retail trade for human consumption regardless of the specified disease status of the exporting country, zone or compartment. The assessments for products listed in Article X.X.3 and X.X.12 against the criteria in Chapter 5.4. Criteria to assess the safety of aquatic animal commodities, are available on the OIE website: ‘[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 applied any relevant changes made in Article 9.X.3. to ensure harmonisation across all Articles X.X.3, as appropriate.

In point 1 of Article 10.3.3. of Chapter 10.3, Infection with *Gyrodactylus salaris,* in response to a comment, the Commission deleted ‘pasteurised or retorted’ to align with proposed changes in other 10.X.3 articles and added ‘that have been heat treated and are hermetically sealed’. The Commission agreed that a specific time/temperature treatment was not required because, as an ectoparasitic helminth with a direct lifecycle, live birth and no resistant life stages, *G. salaris* would not survive in any heat treated, hermetically sealed product.

In points 6 and 7 of Article 10.3.3., the Commission did not agree to add a requirement for eviscerated fish, fillets and steaks to originate from fish held for 14 days in 25 parts per thousand (ppt) seawater prior to harvest and processing. The Commission noted that a 14 day holding period to inactivate *G. salaris* was not specified in the safe commodity assessment for this product ([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)). The Commission explained that the 14-day period indicated in Article 10.3.10. Infection with *Gyrodactylus salaris* is for trade of live fish, not for chilled eviscerated fish.

On point 1 of Article 10.5.3., Infection with salmonid alphavirus, a comment was made requesting that the proposed time/temperature for inactivation be reverted to the current text in the *Aquatic Code* as it was more practical for implementation. The Commission reiterated that this article was updated to be consistent with the information presented 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 reminded Members that equivalent time/temperature combinations can be used where supported by evidence.

The revised Articles 10.X.3. for fish disease-specific chapters are presented as [**Annex 11**](#A11)and will be proposed for adoption at the 89th General Session in May 2022.

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

Comments were received from Australia, Canada, Chinese Taipei, Colombia, Korea (Rep. of), New Caledonia, Switzerland and the EU.

*Background*

Following the listing of infection with decapod iridescent virus 1 (DIV1) in Article 1.3.1. of Chapter 1.3. Diseases listed by the OIE, adopted in May 2021, the Aquatic Animals Commission developed a draft Chapter 9.X. Infection with decapod iridescent virus 1.

The format of the draft Chapter 9.X. was based on the article structure of other disease-specific chapters in Section 9 and included proposed horizontal amendments such as the model Articles X.X.4. to X.X.8. and Articles 9.X.3. The Commission noted that the proposed article structure for Article 9.X.3., and Articles 9.X.4. to 9.X.8., is based on model articles that will be proposed for adoption in May 2022.

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 also 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 Health Surveillance, would be appropriate for infection with DIV1. The Commission noted that if the revised Chapter 1.4. is adopted in May 2022, an assessment of these periods would be required for all listed diseases, including infection with DIV1. The draft Chapter 9.X. was circulated for comment in the Commission’s September 2021 report.

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

September 2021 report (Item 5.1.6., page 25).

**February 2022 meeting**

In point 1 of Article 9.X.3. the Commission applied relevant changes made in Article 9.X.3. to ensure harmonisation across all Articles X.X.3, as appropriate (see Item 4.1.5.1.).

In line 4 of Article 9.X.5. the Commission applied relevant changes to ensure harmonisation model Article X.X.4 to X.X.8 (see Item 4.1.4.2.).

In point 2 a) of Article 9.X.7. the Commission did not agree to replace ‘aquatic animals’ with ‘susceptible aquatic animals with DIV1’. The Commission noted that point 2 is for the specific situation of regaining self-declaration of freedom after a disease incursion and that that all aquatic animals within the compartment would have to be killed and disposed of to achieve the outcome of re-gaining a self-declaration of freedom.

In point 2 b) of Article 9.X.7. the Commission agreed to add ‘aquatic’ before ‘animal’ for clarity. This amendment was also applied to the model articles for application to all disease-specific chapters (see Item 4.1.4.2.).

In the title of Article 9.X.12., the Commission did not agree to add ‘bait’ after ‘animal feed’ as the definition of feed in the Glossary would include bait.

The new draft Chapter 9.X. Infection with decapod iridescent virus 1, is presented as [**Annex 12**](#A12) and will be proposed for adoption at the 89th General Session in May 2022.

* + 1. Susceptible species – Section 10. Diseases of Fish
       1. *Article 10.1.2. of Chapter 10.1. Infection with epizootic haematopoietic necrosis virus*

Comments were received from Colombia, Switzerland and the EU.

*Background*

At its September 2021 meeting, the Aquatic Animals Commission agreed to present the list of susceptible species in Article 10.1.2. in a table format, in line with the agreed convention to list susceptible species in a table format if there are more than ten susceptible species. The revised Article 10.1.2. was circulated for comment in the Commission’s September 2021 report.

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

September 2021 (Item 5.1.7., page 26).

**February 2022 meeting**

The Commission reviewed comments received and did not propose any amendments, noting that Members were supportive of the proposed changes.

The revised Article 10.1.2. of Chapter 10.1. Infection with epizootic haematopoietic necrosis virus, is presented as [**Annex 13**](#A13) and will be proposed for adoption at the 89th General Session in May 2022.

* + - 1. *Article 10.7.2. of Chapter 10.7. Infection with koi herpesvirus*

Comments were received from Colombia, Switzerland and the EU.

*Background*

At its September 2021 meeting, 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 assessed as susceptible by the *ad hoc* Group of Susceptibility of fish species (<https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/#ui-id-3>). The Commission proposed to add common carp X crucian carp hybrids (*Cyprinus carpio x Carassius carassius)* to Article 10.7.2. and circulated this proposal for comment.

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

September 2021 (Item 5.1.8., page 26).

**February 2022 meeting**

The Commission reviewed comments received and did not propose any amendments noting that Members were supportive of the proposed changes.

The revised Article 10.7.2. of Chapter 10.7. Infection with koi herpesvirus, is presented as [**Annex 14**](#A14) and will be proposed for adoption at the 89thGeneral Session in May 2022.

* + 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*

Comments were received from Chinese Taipei, Colombia, Switzerland and the EU.

*Background*

At its September 2021 meeting, the Aquatic Animal Commission considered the June 2021 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 abalone herpesvirus in accordance with Chapter 1.5. Criteria for listing species as susceptible to infection with a specific pathogen. The *ad hoc* Group report can be found on the OIE website at <https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/#ui-id-3>.

The Commission agreed to amend the list of susceptible species in Article 11.1.2. in line with recommendations of the *ad hoc* Group. They also agreed to amend Article 11.1.1. to ensure consistency with other mollusc disease-specific chapters with respect to the inclusion of the name and taxonomy of the pathogenic agent. Articles 11.1.1. and 11.1.2. were circulated for comment in the Commission’s September 2021 report.

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

September 2021 (Item 5.1.9.1., page 26).

**February 2022 meeting**

The Commission reviewed comments received and did not propose any amendments noting that Members were supportive of the proposed changes.

The revised Articles 11.1.1. and 11.1.2. of Chapter 11.1. Infection with abalone herpesvirus, are presented as [**Annex 15**](#A15)and will be proposed for adoption at the 89th General Session in May 2022.

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

Comments were received from Chinese Taipei, Colombia, Switzerland, the USA and the EU.

*Background*

At its February 2021 meeting, the Aquatic Animals Commission considered 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. Criteria for listing species as susceptible to infection with a specific pathogen. The *ad hoc* Group report can be found on the OIE website at <https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/#ui-id-3>.

The Commission agreed to amend the list of susceptible species in Article 11.2.2. in line with the recommendations of the *ad hoc* Group. They also agreed to amend Article 11.2.1. to ensure consistency with other mollusc disease-specific chapters with respect to the inclusion of the name and taxonomy of the pathogenic agent. Articles 11.2.1. and 11.2.2. were circulated for comment in the Commission’s February 2021 report.

At its September 2021 meeting, the Commission noted Member’s support on the proposed amendments. No further amendments were made to Articles 11.2.1. and 11.2.2. that were circulated for comment in the Commission’s September 2021 report.

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

February 2021 (Part B: Item 1.5., page 10); September 2021 (Item 5.1.9.2., page 27).

**February 2022 meeting**

The Commission did not agree with a comment to reorder the species in Article 11.2.2. alphabetically by scientific name so that the *Ostrea* species and *Crassostrea* species are grouped together, as the convention is to order susceptible species alphabetically by English common names. Changing this approach would require horizontal changes in all disease-specific chapters of the *Aquatic Code* and in corresponding disease-specific chapters of the *Aquatic Manual*. The Commission noted that it will look further into the issue within the context of other items prioritised on its workplan.

In response to a comment to include *Ostrea equestris* in Article 11.2.2. of Chapter 11.2. Infection with *Bonamia exitiosa*, the Commission consulted the *ad hoc* Group on Susceptibility of mollusc species to OIE listed diseases. The *ad hoc* Group applied the criteria outlined in their November December 2020 report (<https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/#ui-id-3>) for the susceptibility of mollusc species to infection with *Bonamia exitiosa*.

The Commission noted that the *ad hoc* *Group* had considered scientific evidence that supported that *O. equestris* and *Ostrea stentina* are distinct species and the ramifications for the susceptible species assessments. The Commission agreed with the recommendations of the *ad hoc* Group to include *O. equestris* in Article 11.2. and delete *O. stentina* as it no longer met the criteria for listing as susceptible to infection with *Bonamia exitiosa*. Relevant sections of Chapter 2.4.2., Infection with *Bonamia exitiosa* were also amended in line with the recommendations of the *ad hoc* Group (see Item 5.1.4.2.)

The *ad hoc* Group assessment of *O. equestris* and reassessment of *O. stentina* for listing as susceptible to infection with *Bonamia exitiosa* can be found in [**Annex 17**](#A17).

The revised Articles 11.2.1. and 11.2.2. of Chapter 11.2. Infection with *Bonamia exitiosa,* are presented as [**Annex 16**](#A16) and will be proposed for adoption at the 89th General Session in May 2022.

1. **OIE *MANUAL OF DIAGNOSTIC TESTS FOR AQUATIC ANIMALS***
   1. Texts proposed for adoption in May 2022

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](mailto:AAC.Secretariat@oie.int)).

At the last meeting in September 2021, the Commission had proposed amendments to the explanatory text in Section 4. Diagnostic methods, introducing Table 4.1. *OIE recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals.* The Commission reviewed comments received from Members and Reference Laboratory experts, and finalised the text. All chapters proposed for adoption would include the new explanatory text.

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

Comments were received from Colombia, Switzerland, and the EU.

*Background*

At its September 2021 meeting, 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 Section 2.5. was circulated for comment in the Commission’s February 2021 report.

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

September 2021 (Item 6.1.2., page 31).

**February 2022 meeting**

The Commission agreed to include a new sentence on the need to further investigate negative molecular results when clinical signs indicate the presence of a specific disease or when other positive test results indicate that a false negative result may have been obtained.

The revised Chapter 2.3.0. General information (diseases of fish), is presented as [**Annex 18**](#A18) and will be proposed for adoption at the 89th General Session in May 2022.

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

Comments were received from Australia, Canada, Chile, China (People’s Rep. of), Colombia, Norway, Switzerland, Thailand, the UK and the EU.

*Background*

At its September 2020 meeting, the Aquatic Animals Commission reviewed Chapter 2.3.4. 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. The revised chapter was circulated for comment in the Commission’s September 2020 report.

At its September 2021 meeting, the Commission amended the proposed chapter after considering Member comments. The Commission did not agree to jointly describe infection with HPR-deleted ISAV and HPR0 ISAV rather than consider them separately in the chapter. The Commission confirmed that the clinical expression of disease, epidemiology and control measures differ which justified leaving their descriptions separate. The revised chapter was circulated for comment in the Commission’s September 2021 report.

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

September 2020 (Item 5.4., Page 15); September 2021 (Item 6.1.4., page 32).

**February 2022 meeting**

A Member had submitted a recently published short communication on the first report of successful isolation of a HPR0-like variant of ISAV using cell culture and asked that the chapter be reviewed in the light of this finding. The Commission carefully reviewed the publication, which is an experimental study and noted that the finding, which is significant, requires further investigation. The Commission made reference to this finding at appropriate places within the chapter.

Another Member commented that since HPR-deleted and HPR0 variants of ISAV were listed in 2013, new scientific experience and information on these variants has been gathered and published. The Member asked that the Commission consider reviewing the assessment of these variants against the listing criteria, particularly the HPR0 variant. The Commission advised Members that it will consider the assessment of ISAV in its broader work plan in the future, however, noted that it is important that any changes to the listing are considered carefully to ensure stability of reporting requirements and trade standards. Members are encouraged to provide any relevant information for its consideration.

In Section 2.1.1. Aetiological agent, the Commission agreed that the differences between the North American clade and European clade are not only limited to segment 6 and included a reference to this finding. The Commission also agreed to include a sentence and a reference stating that deleted ISAV variants have been found without virulence marker on segment 5. A Member proposed including a sentence in this section on the newly isolated and cultured HPR0-like variant. The Commission agreed that the sentence would fit better in Section 4.3. Cell culture for isolation.

In Section 2.1.3. Survival and stability outside the host, the Commission supported a proposal to include a sentence on the difficulty of estimating how long the virus remains infectious in the natural environment.

Given the publication on the isolation and cultivation of HPR0-like ISAV mentioned above, the Commission agreed to delete a sentence stating that HPRO ISAV has not been isolated in cell culture from Section 2.2.4. Distribution of the pathogen in the host. However, a new sentence mentioning this single report was included in Section 4.3. Cell culture, clarifying that experimental studies in fish for this variant have not yet been published.

In Section 2.3.1. Mortality, morbidity and prevalence, the Commission did not agree to delete a statement that HPR0 ISAV has not been associated with clinical disease in Atlantic salmon based on the recent publication as this single report of an experimental study needs more investigation and *in-vivo* validation.

In Section 2.3.3. Gross pathology, the Commission agreed to remove from the list of findings that have been described to be consistent with infection with HPR-deleted ISAV the point i) yellowish or blood-tinged fluid in peritoneal and pericardial cavities. These findings are from a single study on Coho salmon conducted in 2001, it has not been possible to verify the findings, and Coho salmon are not considered a susceptible species.

In Section 2.3.4. Modes of transmission and life cycle, the Commission clarified that except for a single report, HPR0 ISAV has not been isolated in cell culture.

In Section 2.3.6. Geographical distribution, the Commission did not accept a suggestion to reinstate a statement that the HPR0 ISAV variant has been reported in all countries where infection with HPR-deleted ISAV has occurred as this is not confirmed. Information on disease occurrence can be found in the OIE-WAHIS.

In Section 3.1. Selection of populations and individual specimens, a Member proposed to separate the surveillance activities from the sampling of specimens. The Commission felt that the existing information is clear as written and did not agree to the change.

In Section 3.2.1. Detection of HPR-deleted ISAV, the Commission agreed to remove ‘gill’ from the list or organs or tissues to be sampled as only internal organs should be used for diagnostic testing for HPR-deleted ISAV.

In Section 3.4. Non-lethal sampling, the Commission agreed to insert a sentence and a reference stating that gill swabs are recommended for non-lethal sampling for HPR0.

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 to be consistent with amendment to the template agreed at the meeting in September 2021.

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, purpose ‘C Confirmatory diagnosis of a suspect result from surveillance or presumptive diagnosis’, the Commission agreed to change the rating of cell culture from’+++’ to ‘++’ for all life stages, the rating of the reverse-transcription PCR from ‘+’ to ‘++’ for early life stages and juveniles, and from’++’ to ‘+’ for adults, to add the rating ‘++’ to all life stages for the real-time PCR, and to give the level of validation of these three tests as ‘1’. The ratings are consistent with the case definitions given in Section 6. Corroborative diagnostic criteria. The Commission also agreed to change the level of validation of the real-time RT-PCR from ‘3’ to ‘1’ for the purpose B. Presumptive diagnosis of clinically affected animals, to be consistent with the method recommended in Section 4.4.1. of the chapter and to change the level of validation from NA (not available) to ‘1’ for immunohistochemistry and IFAT for purpose C.

In Section 4.3. Cell culture for isolation, based on earlier comments (see Section 2.1.1 and Section 2.2.4), text and a reference were added on the recent publication of the isolation of a HPR0-like variant of the ISAV using cell culture, but clarifying that experimental studies in fish for this variant have not yet been published.

In Section 6. Corroborative diagnostic criteria, the Commission did not accept to alter the introductory paragraph as the text is standard approved text from the template.

In Section 6.1.2. Definition of confirmed case in apparently healthy animals, the Commission did not agree to include cell culture in the criteria because it is not recommended in Table 4.1 for apparently healthy animals. In Section 6.3. Diagnostic sensitivity and specificity for diagnostic tests, a Member had proposed to include data from a published real-time RT-PCR. As the method is different from the one recommended in Section 4.4.1. of the chapter, the Commission did not agree to include it.

Finally, as none of the test methods are validated to at least level 2, the Commission deleted the data in Tables 6.3.1. For presumptive diagnosis of clinically affected animals and 6.3.2. For surveillance of apparently healthy animals.

The revised Chapter 2.3.4. Infection with HPR-deleted or HPR0 infectious salmon anaemia virus, is presented as [**Annex 19**](#A19) and will be proposed for adoption at the 89th General Session in May 2022.

* + 1. Chapter 2.3.6. Infection with koi herpesvirus

Comments were received from Australia, China (People’s Rep. of), Chinese Taipei, Colombia, Japan, Switzerland, Thailand, the UK, the USA and the EU.

*Background*

At its September 2020 meeting, the Aquatic Animals Commission reviewed Chapter 2.3.6. Infection with koi herpesvirus (KHV), which had been updated by the OIE Reference Laboratory experts and reformatted using the new disease chapter template. The revised chapter was circulated for comment in the Commission’s September 2020 report.

At its September 2021 meeting, the Commission reiterated 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. The revised chapter was circulated for comment in the Commission’s September 2021 report.

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

September 2020 (Item 5.5., page 15); September 2021 (Item 6.1.5., page 35).

**February 2022 meeting**

The Commission noted that several of the comments received and issues raised by Members are based on a paper by Engelsma *et al*. (2013). To address these comments, the Commission agreed to stress throughout the chapter that the strains detected by Engelsma *et al.* were novel strains of cyprinid herpesvirus closely related to KHV. The Commission also agreed to use the same terminology in the chapter that is used in the paper, for example to refer to KHV ‘strains’ rather than ‘genotypes’.

In Section 1. Scope, the Commission agreed to delete reference to ‘all genotypes’ of the pathogenic agent. The Commission also agreed to remove the references from this section following the style of the *Aquatic Manual*, and to delete the sentence on the use of the abbreviation ‘KHV’ as it is stated in the first sentence of the scope.

In Section 2.1.1. Aetiological agent, the Commission agreed to clarify that Engelsma *et al.* (2013) detected novel strains of cyprinid herpesvirus closely related to KHV. These strains may represent low or non-pathogenic variants of CyHV-3, but further investigation is required to establish the true genetic relationship between these strains and KHV. The Commission also agreed to update the description of the KHV genome, which has now been fully determined.

In Section 2.2.6. Vectors, the Commission agreed to include species of migratory wild duck as species in which KHV has been detected by PCR in areas where fish and ducks coexist, along with a reference supporting this finding.

In Section 2.3.4. Modes of transmission and life cycle, the Commission included the intestine as one of the portals of virus entry in carp, along with a supporting reference.

In Section 2.4.1. Vaccination, the Commission agreed to add the reference to the original publication of studies in Japan showing that oral administration of a liposome-based vaccine containing inactivated KHV was effective in protecting carp against clinical disease.

A Member commented that a sentence in Section 3.2 Selection of organs or tissues, stating that KHV DNA was detected with high probability from the encephalon of the surviving fish at 120 days post-infection was incorrect as the researchers had used material from a number of organs. The Commission reviewed the reference and confirmed that the virus was detected with the highest probability from the brain of surviving fish at 120 days post infection. The comment was thus rejected.

A Member questioned the ratings of the conventional nested PCR 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, which is based on Engelsma *et al.* (2013). The Commission, in consultation with the OIE Reference Laboratory experts, agreed to change the ratings from ‘++’ to ‘+’ for the purposes ‘A Surveillance of apparently healthy animals’ and ‘C Confirmatory diagnosis of a suspect result from surveillance or presumptive diagnosis’, and the ratings from ‘+++’ to ‘++’ for the purpose ‘B. Presumptive diagnosis of clinically affected animals’. The Commission also decided to change the level of validation from ‘1’ to ‘NA’ (not available) for all three purposes as no validation data are published.

For the conventional PCR, the Commission agreed to change the level of validation from ‘1’ to ‘3’ for the purposes ‘B. Presumptive diagnosis of clinically affected animals’ and ‘C Confirmatory diagnosis of a suspect result from surveillance or presumptive diagnosis’ and to include a footnote indicating the references supporting the change and clarifying that other conventional PCR assays are validated to level 1.

In Section 4.4.2. Real-time PCR, clarified the finding of Engelsma *et al.* (2013) that real-time PCR methods for the detection of KHV DNA in fresh tissue samples do not detect novel strains of cyprinid herpesvirus closely related to KHV.

In Section 4.4.3. Conventional PCR, and in line with the changes proposed to Table 4.1., the Commission agreed to remove text specifically recommending the Engelsma *et al.* (2013) method. The method remains listed in Table 4.4.2.1. Primer and probe sequences and cycling conditions for the KHV real-time PCR, as it is still listed in Table 4.1.

The Commission did not agree to include an antibody ELISA in Section 4.10. Other methods, as antibody tests are unreliable for this disease, and consequently the Commission does not recommend them for use.

In Section 5. Test(s) recommended for surveillance to demonstrate disease freedom in apparently healthy populations, the Commission agreed to refer to ‘novel strains of cyprinid herpesvirus closely related to KHV’ rather than to ‘KHV variants’ in accordance with the decision to use the findings as described in Englesma *et al.* (2013). Following the decision to no longer specifically recommend the conventional nested PCR published by Englesma *et al*. (2013), the Commission also agreed to delete the sentence referring to it.

In Section 6.2.2. Definition of confirmed case in clinically affected animals, the Commission did not agree to a proposal to delete all the criteria apart from a ‘positive result by conventional PCR or conventional nested PCR and sequencing of the amplicon‎’. The current text is consistent with the tests and their ratings in Table 4.1.

Finally, the Commission amended Table 6.3.1. For surveillance of clinically affected/apparently healthy animals by clarifying the published references on which the data is based. Table 6.3.2. Surveillance of apparently healthy animals was deleted as no information is currently available.

Reference:

Engelsma M.Y., Way K., Dodge M.J., Voorbergen-Laarman M., Panzarin V., Abbadi M., El-Matbouli M., Frank Skall H. Kahns S. & Stone D.M (2013). Detection of novel strains of Cyprinid herpesvirus closely related to koi herpesvirus. *Dis. Aquat. Org*., **107**, 113–120.

The revised Chapter 2.3.6. Infection with koi herpesvirus, is presented as [**Annex 20**](#A20)and will be proposed for adoption at the 89th General Session in May 2022.

* + 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* (*susceptible species*)

Comments were received from Chinese Taipei, Colombia, Switzerland and the EU.

*Background*

At its September 2021 meeting, the Aquatic Animals Commission reviewed the June 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 abalone herpesvirus.

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 (see also Item 4.1.8.1.). Articles 11.1.1. and 11.1.2. were circulated for comment in the Commission’s September 2021 report.

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

September 2021 (Item 6.1.7.1., page 39).

**February 2022 meeting**

The Commission reviewed comments received and did not propose any amendments noting that Members were supportive of the proposed changes.

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.3. Infection with abalone herpesvirus, are presented as [**Annex 21**](#A21) and will be proposed for adoption at the 89th General Session in May 2022.

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

Comments were received from Colombia, Switzerland, the USA 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 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 on Susceptibility of mollusc species to infection with OIE listed diseases.

At its September 2021 meeting, the Commission noted Member’s support on the proposed amendments. No further amendments were made to Section 2.2.1. and 2.2.2. that were circulated for comment in the Commission’s February 2021 report.

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

February 2021 (Part B: Item 3.2., page 13); September 2021 (Item 6.1.7.2., page 39).

**February 2022 meeting**

In response to a comment to include *Ostrea equestris* in Section 2.2.1. of Chapter 2.4.2. Infection with *Bonamia exitiosa*, the Commission consulted the *ad hoc* Group on Susceptibility of mollusc species to OIE listed diseases. The *ad hoc* Group applied the criteria outlined in their November December 2020 report (<https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/#ui-id-3>) for the susceptibility of mollusc species to infection with *Bonamia exitiosa*.

The commission noted that the *ad hoc* *Group* had considered scientific evidence that support that *O. equestris* and *Ostrea stentina* are distinct species and the ramifications for the susceptible species assessments. The Commission agreed with the recommendations of the *ad hoc* Group to include *Ostrea equestris* and delete *Ostrea stentina* from Section 2.2.1*.*Susceptible host species as *Ostrea stentina* no longer met the criteria for listing as susceptible to infection with *Bonamia exitiosa*. The Commission agreed to add *Ostrea stentina* to Section 2.2.2. Species with incomplete evidence for susceptibility. Article 11.2.2. of Chapter 11.2. Infection with *Bonamia exitiosa*, were also amended in line with the recommendations of the ad hoc Group (see Item 4.1.8.2.).

The *ad hoc* Group assessment of *Ostrea equestris* and reassessment of *Ostrea stentina* for listing as susceptible to infection with *Bonamia exitiosa* can be found in [**Annex 17**](#A17).

The revised Sections 2.2.1. and 2.2.2. of Chapter 2.4.2. Infection with *Bonamia exitiosa* are presented as [**Annex 22**](#A22) and will be proposed for adoption at the 89th General Session in May 2022.

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…/Annexes

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

**Virtual meeting, 24 & 27 January, 16-23 February 2022**

**\_\_\_\_\_\_\_\_**

**List of participants**

|  |  |  |
| --- | --- | --- |
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|  |  |  |

**Assessment for listing infection with Tilapia lake virus (TiLV)  
in the *Aquatic Code***

**Overall assessment**

The OIE Aquatic Animal Health Standards Commission assessed infection with tilapia lake virus (TiLV) against the criteria for listing aquatic animal diseases in Article 1.2.2. of the *Aquatic Code* (see Table 1 below).

**Table 1.** Summary of assessment of infection with TiLV

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Listing criteria | | | | | | Conclusion |
| 1 | 2 | 3 | 4a | 4b | 4c |  |
| Infection with TiLV | + | + | + | NA | + | + | The disease meets the criteria for listing |

NA = not applicable.

The criteria for the inclusion of a [disease](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_maladie) in the OIE list are as follows:

1. International spread of the [pathogenic agent](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_agent_pathogene) (via [aquatic animals](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_animaux_aquatiques), [aquatic animal products](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_produits_d_animaux_aquatiques), [vectors](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_vecteur) or fomites) is likely.

AND

2. At least one country may demonstrate country or [zone](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) freedom from the [disease](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_maladie) in susceptible [aquatic animals](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_animaux_aquatiques), based on provisions of Chapter [1.4.](https://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance)

AND

3. A precise [case definition](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_definition_d_un_cas) is available and a reliable means of detection and [diagnosis](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_diagnostic) exists.

AND

4a. Natural transmission to humans has been proven, and human infection is associated with severe consequences.

OR

4b. The [disease](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_maladie) has been shown to affect the health of cultured [aquatic animals](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_animaux_aquatiques) at the level of a country or a [zone](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) resulting in significant consequences e.g. production losses, morbidity or mortality at a [zone](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) or country level.

OR

4c. The [disease](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_maladie) has been shown to, or scientific evidence indicates that it would, affect the health of wild aquatic animals resulting in significant consequences e.g. morbidity or mortality at a population level, reduced productivity or ecological impacts.

**Background**

A novel orthomyxo-like virus, named as tilapia lake virus (TiLV), has been identified as the cause of mass die-offs of tilapia (Eyngor *et al.*, 2014) in both farms and the wild environment. The virus has been classified in the family *Amnoonviridae*, Genus *Tilapinevirus* and given the species name *Tilapia tilapinevirus* (ICTV, 2018). The host range is not well known but several species of tilapines are known to be susceptible (Eyngor *et al.,* 2014; Waiyamitra *et al.*, 2021) and the giant gourami (*Osphronemus goramy*) has shown evidence of susceptibility (Jaemwimol *et al*., 2018). TiLV has also been detected in other species, however without clinical signs (Piamsomboom *et al.*, 2021). Tilapia is the second most important group of farmed fish after carps. Global production of tilapia, predominantly *Oreochromis niloticus*, is estimated at 4.5 million metric tonnes (FAO data). Farming occurs primarily in tropical and subtropical countries though some production in recirculation systems has started in other regions. *O. niloticus* was first introduced to developing countries to support subsistence farming. However, larger scale commercial production is now important and frozen fillets and other tilapia products are traded globally. There are no treatments for infection with tilapia lake virus however there are vaccines under development (Zeng *et al*., 2021; Mai *et al.*, 2022).

**Assessment of TiLV using the new criteria for listing aquatic animal diseases in Chapter 1.2. of the *Aquatic* *Code***

**Criterion No. 1 International spread of the pathogenic agent (via aquatic animals, aquatic animal products, vectors or fomites) is likely.**

*Assessment*

TiLV has been reported in Bangladesh, Chinese Taipei, Colombia, Ecuador, Egypt, India, Indonesia, Israel, Malaysia, Mexico, Peru, Philippines, Tanzania, Thailand, Uganda and the United States of America (Ahasan *et al*., 2020, Amal *et* *al*., 2018, Bacharach *et al.*, 2016; Behera *et al*., 2018; Chaput *et al*., 2020; Castañeda *et al*., 2020; Contreras *et al*., 2021; Dong *et al.*, 2017; Fathi *et al.*, 2017, Ferguson *et al.*, 2014; Koesharyani *et al*., 2018, Mugimba., 2018, OIE, 2018a, OIE, 2018b; OIE, 2018c; Tsofack *et al.*, 2016). The Network of Aquaculture Centres in Asia–Pacific (NACA) also have notification requirements for infection with TiLV and this data shows a similar distribution of the disease for that region, as reported to the OIE. Despite geographic separation, strains were highly homologous, suggesting an epidemiological link and international spread. Historically, live tilapia have been traded internationally to establish populations for production in new regions, and extensive trade in live tilapia continues. The current driver for international trade is the dissemination of improved genetic strains (although the current pattern and volume of trade has not been determined for this assessment). Tilapia products are traded internationally and while a risk of transmission with some product types should be expected, product-specific risks have not been considered in this assessment (Castañeda *et al*., 2020).

Given the evidence of spread and the broad distribution of tilapia (Asia, Africa and South America), international spread is likely.

*Conclusion*

The criterion is met.

**Criterion No. 2 At least one country may demonstrate country or zone freedom from the disease in susceptible aquatic animals, based on provisions of Chapter 1.4.**

TiLV has been reported in Bangladesh, Chinese Taipei, Colombia, Ecuador, Egypt, India, Indonesia, Israel, Malaysia, Mexico, Peru, Philippines, Tanzania, Thailand, Uganda and the United States of America (Ahasan *et al*., 2020; Amal *et al*., 2018; Bacharach *et al*., 2016; Behera *et al*., 2018; Chaput *et al*., 2020; Castañeda *et al*., 2020; Contreras *et al*., 2021; Dong *et al*., 2017; Fathi *et al*., 2017; Ferguson *et al*., 2014; Koesharyani *et al*., 2018; Mugimba *et al*., 2018; OIE, 2018a; OIE, 2018b; OIE, 2018c; Tsofack *et al*., 2016). The Network of Aquaculture Centres in Asia–Pacific (NACA) also have notification requirements for infection with TiLV and this data shows a similar distribution of the disease for that region, as reported to the OIE. Additional countries in Africa have expressed a wish to declare freedom from infection with TiLV, but report that there is a lack of diagnostic capacity to support such self-declarations.

The distribution of the virus may be wider (mortality may not have been investigated in other regions); however, due to the broad distribution of tilapia (Asia, Africa and South America), virulence of the virus and the extensive trade in tilapia, it is likely that many countries are currently free. The information provided to the OIE and NACA on the disease status of Members for infection with TiLV through immediate notifications, six-monthly reports and annual reports provides support that countries are likely to be free of the disease.

**Table 2.** Outbreaks of infection with TiLV by country and commencement year notified to the OIE through the OIE-WAHIS.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Region or Country** | **2017** | **2018** | **2019** | **2020** | **2021\*** |
| **Americas** |  |  |  |  |  |
| Colombia |  |  |  | 1 |  |
| Mexico |  | 20 | 1 |  |  |
| Peru |  | 5 | 2 | 1 |  |
| USA |  |  | 3 |  |  |
| **Asia** |  |  |  |  |  |
| Chinese Taipei | 9 |  |  |  |  |
| India |  |  | 3 |  |  |
| Malaysia | 2 | 2 |  |  |  |
| Philippines | 1 |  | 1 |  |  |
| Thailand | 1 |  |  |  |  |
| **Europe** |  |  |  |  |  |
| Israel | 16 (Tilapia syncytial hepatitis) |  |  |  |  |
| **Total** | 29 | 27 | 10 | 2 |  |

\*No notifications have been notified to the OIE in 2021 to date.

*Conclusion*

The criterion is met.

**Criterion No. 3 A precise case definition is available and a reliable means of detection and diagnosis exists.**

An *ad hoc* Group was convened in 2017 on request from the Commission with the objective to assess TiLV diagnostics and validation, and specifically:

‒ 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 inter-laboratory comparability studies.

The *ad hoc* Group undertook TiLV inter-laboratory panel testing in two stages. Round 1 involved two laboratories and four molecular assays and Round 2 involved seven laboratories and four molecular assays. The *ad hoc* Group provided recommendations based on results of testing for both rounds.

The *ad hoc* Group evaluated three real-time PCR assays and one conventional nested PCR for their ability to reliably detect TiLV in an inter-laboratory comparison using a panel of 30 samples. All assays performed as expected and could reliably detect TiLV. Based on the recommendations of the *ad hoc* Group, the Commission considered all four tests evaluated would allow criterion 3, a precise case definition is available and a reliable means of detection and diagnosis exist, of Chapter 1.2. of the *Aquatic Code*, to be fulfilled.

*Conclusion*

The criterion is met.

**Criterion No. 4a Natural transmission to humans has been proven, and human infection is associated with severe consequences.**

*Assessment*

There is no evidence of transmission to humans.

*Conclusion*

Criterion not applicable.

**Criterion No. 4b The disease has been shown to affect the health of cultured aquatic animals at the level of a country or a zone resulting in significant consequences e.g. production losses, morbidity or mortality at a zone or country level.**

*Assessment*

Very high levels of mortality (>80%) have been observed in affected populations (both farmed and wild) (Bacharach *et al*., 2016; Behera *et al*., 2018; Ferguson *et al*., 2014; Gophen *et al*., 2015). Dong *et al*. (2017) reported approximately 90% mortality in red tilapia fingerlings within one month of stocking into cages. Since 2009 episodic losses of tilapia (*Oreochromis niloticus*) were recorded in fish farms all over Israel (Eyngor *et al*., 2014; Skornik *et al*., 2021). Mortality in farmed *O. niloticus* in Ecuador have also been attributed to TiLV (Ferguson *et al*., 2014). Losses are significant regionally and at a national level.

*Conclusion*

The criterion is met.

**Criterion No. 4c The disease has been shown to, or scientific evidence indicates that it would, affect the health of wild aquatic animals resulting in significant consequences e.g. morbidity or mortality at a population level, reduced productivity or ecological impacts.**

*Assessment*

Very high levels of mortality (>80%) have been observed in affected populations (both farmed and wild) (Bacharach *et al*., 2016; Ferguson *et al*., 2014; Gophen *et al*., 2015; Kabuusu *et al.*, 2017). Decreases of catch of tilapines, specifically *Sarotherodon* (Tilapia) *galilaeus*, from the Sea of Galilee have been observed since 2007. In 2017, a mortality event in wild tilapia in Malaysia was reported with an estimated 50% mortality (OIE, 2018c).

*Conclusion*

The criterion is met.

**Conclusion**

Infection with TiLV clearly meets the criteria for listing (1, 2, 3, 4b and 4c) and is proposed for inclusion in Chapter 1.3. Diseases listed by the OIE.

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CHAPTER 1.4.  
  
**AQUATIC ANIMAL DISEASE SURVEILLANCE**

Article 1.4.1.

**Purpose**

This chapter provides guidance on the *surveillance* approaches to be used by a *Competent Authority* to make and maintain a *self-declaration of freedom from disease* or to confirm the occurrence of a *listed disease* or an *emerging disease*.

Article 1.4.2.

**Introduction and scope**

This chapter supports ~~the~~a *Competent Authority* to meet the requirements for *self-declaration of freedom from disease* at the level of a country, *zone* or *compartment*, and for maintenance of freedom, that are presented in each disease-specific chapter. It also provides ~~the~~a *Competent Authority* with guidance to meet the requirements of *notification* of a *listed* *disease* or an *emerging disease* in accordance with Chapter 1.1.

This chapter is not intended to provide detailed technical guidance on *surveillance* design or analysis. ~~The~~ *Competent ~~Authority~~Authorities* ~~is~~ are encouraged to consult published literature and seek appropriate expertise to design and analyse *surveillance* programmes that meet the requirements of the *Aquatic Code*.

1) The general requirements of a *surveillance* system necessary to support a *self-declaration of freedom from* *disease* are specified in Articles 1.4.5. to ~~Article~~ 1.4.8.

2) The criteria that have been used to set the periods specified in each disease-specific chapter for *basic* *biosecurity conditions* to be in place, or for *targeted surveillance* that should be undertaken, prior to claiming freedom, are included in Articles 1.4.9. and 1.4.10.

3) The requirements for each of the four pathways for claiming freedom, and for maintaining freedom, are introduced in Article 1.4.3. and ~~are~~ described in detail in Articles 1.4.11. to ~~Article~~ 1.4.15.

4) Guidance on the design of surveys to demonstrate freedom from *disease*, and for combining multiple sources of *surveillance* information are provided in Articles 1.4.16. and Article 1.4.17., respectively.

5) Article 1.4.18. provides guidance on diagnostic confirmation of *listed* *diseases* or an *emerging disease.*

~~The~~*Competent ~~Authority~~Authorities* should refer to the relevant disease-specific chapter of the *Aquatic Manual* for recommendations on sample collection and appropriate diagnostic methods for *surveillance* and diagnosis of *listed diseases*. The relevant disease-specific chapter of the *Aquatic Manual* should also be consulted for the necessary information on epidemiology and diagnostic performance of assays required for *surveillance* programme design.

Article 1.4.3.

**Pathways for demonstrating freedom from disease**

~~The~~ *Competent ~~Authority~~Authorities* may use one of four pathways to make a *self-declaration of freedom from* *disease*. Each pathway outlines the *aquatic animal* health circumstances and requirements that should be met for a self-declarationto be made. Any one of these four pathways may be utilised; however, ~~the~~a *Competent Authority* should provide evidence that all relevant requirements to demonstrate *disease* freedom have been met as described in this chapter and the relevant disease-specific chapter of the *Aquatic Code* including when water bodies are shared with other countries or are under the control of different *Competent Authorities*. The four pathways are:

1. Absence of susceptible species

This pathway may be utilised if, as described in Article 1.4.11., it can be demonstrated that no *susceptible species* are present at the country or *zone*.

2. Historical freedom

This pathway may be utilised if, as described in Article 1.4.12., there is evidence of historical absence of a *disease* at the country or *zone* level, that is supported primarily by *passive surveillance* ~~data~~ information generated by a country’s *early detection system*. *Targeted surveillance* data may also be used in this pathway, where appropriate.

3. Targeted surveillance

This pathway may be utilised at the country, *zone* or *compartment* level. ~~if the requirements of pathway 1 (absence of~~ *~~susceptible species~~*~~) or pathway 2 (historical freedom) cannot be met.~~ The pathway primarily uses *targeted surveillance* data, but other sources of evidence may be utilised as described in Article 1.4.13. *Passive surveillance* information may also be used in this pathway, where appropriate.

4. Returning to freedom

This pathway may be utilised, as described in Article 1.4.14., in circumstances where a self-declaration had been made, but free status was subsequently lost due to detection of the *disease* for a country, *zone* or *compartment*.

Table 1.1. A summary of the four pathways for *self-declaration of freedom from* *disease*, including the types of primary and secondary *surveillance* information, and the applicable level of application for either a country, *zone* or *compartment*.

|  |  |  |  |
| --- | --- | --- | --- |
| **Pathway** | **Primary surveillance evidence to claim *disease* freedom** | **~~Proposed~~ ~~s~~Secondary evidence to claim freedom (if required)** | **Applicable level of application** |
| 1. Absence of *susceptible species* | *~~Active~~* ~~surveillance~~Surveys, historical data, import records, environmental information | None | Country, *zone* |
| 1. Historical freedom | *Passive* *surveillance* | *Targeted surveillance* (in populations where *passive* *surveillance* is not appropriate) | Country, *zone* |
| 1. *Targeted surveillance* | *Targeted surveillance* | *Passive* *surveillance* (in appropriate populations) | Country, *zone*, *compartment* |
| 1. Returning to freedom | *Targeted surveillance* | *Passive* *surveillance* (in appropriate populations) | Country, *zone*, *compartment* |

Article 1.4.4.

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

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

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

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

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

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

4) the *surveillance* analysis and results;

5) the measures implemented to maintain freedom.

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

~~Except when otherwise provided for in the disease-specific chapter, an~~ An *outbreak* in a Member Country, a *zone* or a *compartment* having a self-declared free status results in the loss of the self-declared free status. The notification of an *outbreak* in a country, *zone* or *compartment* for which a *self-declaration of freedom* has been made, will result in an update of the OIE website concerning the original declaration. A Member Country wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this chapter.

Article 1.4.5.

**Biosecurity and surveillance system requirements**

The following *biosecurity* and *surveillance* system requirements should be met for any *self-declaration of freedom* *from disease* in the given *~~compartment, zone~~* ~~or~~ country, *zone* or *compartment*:

1) the quality of *Aquatic Animal Health Services* can be substantiated to meet the requirements of Chapter 3.1.:

2) *basic biosecurity conditions* (which include an *early detection system*) as described in Article 1.4.6. are in place;

~~3)~~ ~~an~~ *~~early detection system~~* ~~as described in Article 1.4.7. is in place;~~

~~4~~3) there has been no vaccination of *susceptible aquatic animals* for the specific *disease* ~~for at least~~from the ~~period that~~ implementation of the *basic biosecurity conditions* ~~have been applied~~ prior to self-declaration;

~~5~~4) the *Aquatic Animal Health Services* have sufficient capacity and expertise to investigate and report *disease* events to ~~the~~a *Competent Authority*;

~~6~~5) ~~the~~a *Competent Authority* has access to appropriate diagnostic capability (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed diseases* and *emerging diseases* in accordance with Article 1.4.18.

Article 1.4.6.

**Basic biosecurity conditions**

*Basic biosecurity conditions* include requirements for preventing the introduction and spread of ~~aone~~a specific *disease* and for detection of the *disease* should it occur. The requirements for *basic biosecurity conditions* include:

1. ~~a compulsory requirement for~~ *~~notification~~* ~~of a specific~~ *~~disease~~*~~, or suspicion of the~~ *~~disease~~*~~, to the~~ *~~Competent Authority~~*~~;~~

~~2~~1) an *early detection system* (as described in Article 1.4.7.);

~~3~~2) measures to prevent the introduction of the *pathogenic agent* into a country, *zone* or *compartment*, or the spread within or from *infected zones* and *protection zones*, in accordance with the relevant disease-specific chapter.

In making aself-declaration of freedom froma specific *disease* for a country, *zone* or *compartment,* ~~the~~a C*ompetent Authority* should describe how all of the requirements for ~~the~~ *basic biosecurity conditions* relevant to its declaration, ~~and ensure all requirements for~~ *~~basic biosecurity conditions~~* ~~described in this chapter~~ are continuously met.

Article 1.4.7.

**Early detection system**

The *early detection system* of ~~the~~a *Competent Authority* ~~underpins~~ is important to generate evidence for claims of disease freedom and to provide assurance that a change in disease status would be rapidly discovered.~~anycollect~~ *~~passive surveillance~~* ~~data information utilised by a~~ *~~Competent Authority~~* ~~to make a~~ *~~self-declaration of freedom from disease~~*~~.~~

A *self-declaration of freedom from disease* needs to document that the *early detection system* fulfils each of the~~five characteristics~~ requirements below:

1) ~~broad awareness, e.g. among~~ observers (e.g. the personnel ~~employed at~~of *aquaculture establishments,* ~~or involved in processing~~processors, transportation services) have broad awareness of the characteristic signs of *listed diseases* and *emerging diseases*;

2) *veterinarians* and *aquatic animal health professionals* are trained in recognising and reporting suspicion of *listed disease* and *emerging disease* occurrence;

3) the *Aquatic Animal Health Services* have capacity to undertake rapid and effective *disease* investigation based on a national chain of command led by a *Competent Authority*;

4) the *Aquatic Animal Health Services* have access to sufficient diagnostic capability (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed* *diseases* and the capacity and expertise to investigate *emerging* *diseases* as described in Article 1.4.18.;

5) *veterinarians,* ~~and~~ *aquatic animal health professionals* and others with an occupational role with *aquatic animals* have a legal obligation to report suspicion~~s~~ of the occurrence of *listed* *diseases* or *emerging* *diseases* ~~occurrence~~to ~~the~~a *Competent Authority*.

The sensitivity of an *early detection system* is the likelihood that the *disease* will be detected if present. Of fundamental importance is *disease* reporting by farmers, *aquatic animal health professionals,* ~~and~~*veterinarians* and others to initiate the necessary steps of *passive surveillance*. Specifically, ~~the~~a *Competent Authority* should be able to demonstrate that efforts have been made to make ~~farmers~~ relevant observers (e.g. farmers and fishers) aware of signs of *listed diseases* and *emerging diseases*, and secondly the obligation of farmers, *aquatic animal health professionals,* *veterinarians* and others with an occupational role with *aquatic animals* to report suspicion. The underpinning legal instruments should be cited.

The capacity of the *Aquatic Animal Health Services* to respond to suspicion of a *listed diseas*e can be evidenced by response plans, and a descriptive chain of command that will result in an official declaration that the *pathogenic agent* has been detected. Standard operating procedures for diagnostic assays for *listed diseases* and accreditation to internationally recognised laboratory standards can demonstrate the capacity of the *Aquatic Animal Health Services* to detect *listed diseases*. In addition, the effective functioning of the *early detection system* is best illustrated through examples of investigations in response to reported suspicion of *disease*. ~~Ideally, t~~The sensitivity of an *early detection system* (i.e. the likelihood of *pathogenic agent* detection following introduction) ~~should~~can be quantified, for example, by use of a scenario tree model; however, in most circumstances a qualitative assessment will be sufficient.

Article 1.4.8.

**Requirements for passive surveillance**

~~1)~~ In addition to the characteristics of an *early detection system* described in Article 1.4.7., the conditions described in this article should be met for *passive surveillance* ~~data~~ information to be utilised for a *self-declaration of freedom from* *disease.*

1) The conditions, which apply to each defined *study population* of *susceptible species* of a specific *disease*, are that:

a) conditions (biotic and abiotic) are conducive to clinical expression of the *infection*, such that if the *pathogenic agent* were present within the population of *susceptible species*, it would produce ~~clinical~~ signs of the *disease* at least seasonally;

b) ~~there should be sufficient awareness by potential observers of the~~ *~~study population~~*~~, such that~~ observation of ~~clinical~~ signs of the *disease*, which may include increased mortality, would lead to ~~reporting~~ investigation and where appropriate, reporting to ~~the~~a *Competent Authority*;

c) populations of susceptible farmed *aquatic animals* should be under sufficient observation ~~in all relevant production systems~~, such that, if ~~clinical~~ signs of the *disease* were to occur, they would be observed;

d) for populations of susceptible wild *aquatic animals*, they should:

i) be under sufficient observation, such that if ~~clinical~~ signs of the *disease* were to occur, they would be observed and reported, or

ii) be epidemiologically linked to farmed populations, such that if the *disease* were to occur in wild *aquatic animal* populations ~~would occur and~~ it would be observed and reported in adjacent farmed populations ~~if it were to occur in adjacent wild~~ *~~aquatic animal~~* ~~populations~~.

2) *Passive surveillance* depends primarily on observers (e.g. farmers, *aquatic animal health professionals,* *veterinarians* andothers)recognizing signs of *disease* that are suspicious of a *listed disease*  ~~reporting suspicion of~~ *~~disease~~*or unexplained increased mortality and reporting them to ~~the~~a *Competent Authority*. For wild populations, the requirements of points 1a), b) and ~~4 a) 1~~ d) ~~i) above are unlikely to be~~ may not be met under most circumstances and, therefore, *passive* *surveillance* will be insufficiently sensitive. If a *Competent Authority* utilises *passive surveillance* ~~data~~ information for defined populations of wild *aquatic animals*, it should demonstrate that the conditions of this article have been met, and that the *early detection system* ~~provides appropriate~~ *~~sensitivity~~* ~~for~~will result in detection of the *disease* should it occur.

3) Awareness of ~~clinical~~ signs of *disease* and the necessary level of observation is best demonstrated through examples of reporting by farmers, *aquatic animal health professionals, veterinarians* and others to ~~the~~a *Competent Authority*. In addition to reporting, information for *passive surveillance* may originate from inspections at processing plants, routine visits by government officials and surveys (e.g. ~~of wild populations~~fisheries and aquatic fauna surveys), submissions to laboratories, *aquaculture establishment* records (e.g. mortality, medicine use, etc.).

~~4)~~ *~~Passive surveillance~~* ~~is only effective if conditions are conducive to clinical expressions of~~ *~~disease~~*~~, which include:~~

~~a)~~ ~~environmental conditions (e.g. water temperatures) being permissive for the development of clinical signs, at least seasonallyduring at least a period of the year; and~~

~~b)~~ ~~the presence of~~ *~~susceptible species~~* ~~in which~~ *~~infection~~* ~~results in clinical signs.~~

~~5~~4) Evidence from published literature will generally be sufficient to demonstrate the environmental conditions in ~~over~~which ~~clinical signs appear, and in which~~ *infection* of *susceptible species* will result in clinical signs. This information should be supplemented with data on the environmental conditions for the *target populations*.

~~6~~5) *Passive surveillance* only contributes to the *early detection system* if observations and investigations that lead to suspicion of *listed diseases* or *emerging diseases* are rapidly reported, to allow ~~by~~ ~~the~~a *Competent Authority* ~~follow reports of~~ *~~disease~~*to undertake their own investigation.

Article 1.4.9.

**Required periods for basic biosecurity conditions**

1) Prior to a Member Country making a *self-declaration of freedom from disease*, *basic biosecurity conditions* should be in place for a ~~defined period.~~ *~~Basic biosecurity conditions~~* ~~should be applied for~~ sufficient duration ~~prior to a self-declaration~~*,* so that, by the end of the period, should the *disease* have been introduced before the *basic biosecurity conditions* began:

a) ~~no~~ the specific *pathogenic agent* would not remain present in the environment (see pathway 1 – absence of *susceptible species*) or;~~,~~

b) the *disease* would manifest clinically and be detected by the country’s *early detection system* (see pathway 2 – historical freedom);~~, and~~or

c) by the time *targeted surveillance* commenced (see pathway 3 – *Targeted surveillance*), *infection* levels would have reached the minimum *prevalence* estimate (i.e. the design *prevalence*) used in the survey design to calculate the sample sizes (e.g. number of *aquaculture establishments* and *aquatic animals* needed to demonstrate freedom).

2) Each disease-specific chapter of the *Aquatic Code* includes minimum periods that *basic biosecurity conditions* should be in place prior to a *self-declaration of freedom from* *disease*.These periods ~~are determined~~~~based on the factors described below.~~ reference a default minimum period or a longer period if determinednecessarybased on the factors described below:

a) For pathway 1, the default minimum period ~~that~~ of *basic biosecurity conditions* required ~~should be in place~~prior to a self-declaration, for all *listed diseases, ~~of freedom from disease~~* is six months. It is expected that this period will be sufficient for most *diseases* to ensure that no viable *pathogenic agent* introduced via *aquatic animal* commodities has remained present in the environment, and the *early detection system* was well established and demonstrated to be functioning. The required period that *basic biosecurity conditions* should be in place prior to making a self-declaration*,* using this pathway, is determined for each *~~pathogenic agent~~listed disease* based on its epidemiology (e.g. agent stability in the environment, presence of resistant life stages, *vectors*), and ~~is~~ a period longer than the default minimum may be specified in the relevant disease-specific chapter of the *Aquatic Code*.

b) For pathway 2, the default minimum period ~~that~~of *basic biosecurity conditions* required ~~should be in place~~prior to a self-declaration, for all *listed diseases,* is ten years. This period is the minimum required to achieve 95% likelihood of freedom, if the annual likelihood of detection is approximately 30%. However, if the average annual likelihood of detection ~~by a country’s~~ *~~early detection system~~* is considered to be less than 30% ~~in the period preceding declaration~~ (following consideration of the factors below), the minimum period required for *basic biosecurity conditions* defined in the relevant disease-specific chapter of the *Aquatic Code* will be set to a period ~~greater~~ longer than ten years, as appropriate. An evaluation of the following factors will determine whether a period longer than ten years is ~~required~~recommended in the disease-specific chapters:

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

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

iii) the variation in predilection to clinical *disease* among *susceptible species*;

iv) the expected severity and duration of clinical signs in the *susceptible species* ~~(and therefore the likelihood of detection)~~;

v) environmental conditions that influence levels of *infection* and clinical expression, including seasonality of the *disease* (i.e. periods of the year when *prevalence* and intensity of *infection* are highest and most conducive to detection ~~clinical~~ *~~disease~~* ~~occurs, e.g. when water temperatures are permissive~~);

vi) factors specific to the *pathogenic agent* (e.g. production of spores);

vii) production systems and management practices that would affect observation of clinical signs if they were to occur;

viii) any other relevant factors that may influence presentation of clinical signs and observation of the *disease* should it be present.

c) For pathway 3, the default minimum period ~~that~~ of *basic biosecurity conditions* ~~should be in place~~ required prior to commencement of *targeted surveillance* will ~~generally~~be one year. It is 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 this chapter. However, ~~different recommendations are provided in the disease-specific chapters of the~~ *~~Aquatic Code~~* ~~for some~~ *~~diseases~~* ~~where~~ the epidemiology of a *disease* and nature of production systems ~~would~~ may ~~affect~~ limit the ~~expected transmission, and thus~~ increase in *prevalence* and intensity of *infection* in the *susceptible species* following introduction of the *disease*. In these instances, the minimum period required for *basic biosecurity conditions* defined in the relevant disease-specific chapter of the *Aquatic Code* will be set to a period longer than one year, as appropriate. An evaluation of the following factors will determine whether a period longer than one year is required:

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

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

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

iv) production systems and management practices that would affect occurrence of *infection*;

v) any other relevant factors that may influence the expected rate of increase in *prevalence* and intensity of *infection* in *susceptible species* following introduction of the *disease*.

d) Pathway 4 is only applicable following the loss of *disease* freedom due to a *disease* *outbreak*. This circumstance implies a failure of *basic biosecurity conditions* to prevent the introduction of the *disease*. The pathway of *disease* introduction should be investigated and *basic biosecurity conditions* should be reviewed and modified as necessary to reduce the likelihood of *disease* introduction by the same or similar routes. Mitigation measures should be implemented following eradication of the *disease*, and prior to commencement of any *targeted surveillance* that will be utilised as evidence for a subsequent self-declaration.

Article 1.4.10.

**Required periods for targeted surveillance**

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

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

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

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

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

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

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

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

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

Article 1.4.11.

**Pathway 1** – **Absence of susceptible species**

Unless otherwise specified in the relevant disease-specific chapter of the *Aquatic Code*, a self-declaration of freedom from a specific *disease* may be made for a country or *zone* without applying *targeted surveillance* if there are no *susceptible species* (as listed in Article X.X.2. of the relevant disease-specific chapter of the *Aquatic Code*) present in that country or *zone*.

*Basic biosecurity conditions* should be in place for a period of time prior to a *self-declaration of freedom from* *disease*.

This pathway relies on confidence that *susceptible species* are in fact absent from a country or *zone*. To be confident that *susceptible species* are absent there should be:

1) sound knowledge of the range of *susceptible species* of a *pathogenic agent;* and

2) sufficient knowledge, ~~based on active~~ *~~surveillance~~*~~,~~ of the local *aquatic animal* fauna (including wild populations) demonstrated by the following forms of evidence:~~.~~

~~The forms of evidence that may be required to demonstrate absence of~~ *~~susceptible species~~* ~~include:~~

~~1~~a) reports which provide evidence regarding the absence ~~of reports of the existence~~ of the *susceptible species* in the country or *zone* from structured surveys (e.g. of fisheries and aquatic fauna surveys, historical fisheries data);

~~2~~b) documentation from the relevant *Competent Authority* showing that those *susceptible species* have not been imported into the country or *zone*;

~~3~~c) provision of documentation which sets out scientific evidence indicating that the likelihood of the presence of *susceptible species* in the country or *zone* is negligible (e.g. data on physiological requirements, oceanographic information, biodiversity databases).

This pathway cannot be used for *diseases* where there is uncertainty regarding the full range of *susceptible species* (e.g. *diseases* with a broad host range), or where the *pathogenic agent* may not be obligate (e.g. able to survive indefinitely outside the host). In these cases, the pathway will be absent from the relevant disease-specific chapter of the *Aquatic Code*, and alternative pathways to demonstrate freedom should be utilised.

The pathway is intended primarily to be used by ~~the~~a *Competent Authority* wishing to establish freedom ahead of farming a new species.

Article 1.4.12.

**Pathway 2** – **Historical~~ly~~ freedom**

Unless otherwise specified in the relevant disease*-*specificchapter of the *Aquatic Code*, a *self-declaration of freedom from* *disease* may be made for a country or *zone* on the basis of historical freedom. The primary evidence for historical freedom is *passive surveillance* ~~data~~ information generated by a country’s *early detection system*. For this pathway to be utilised, the following conditions should be met:

1) the country or *zone* has *basic biosecurity conditions* in place, including an *early detection system*, that is sufficiently sensitive to detect the *disease* should it occur, and the ~~conditions~~ requirements for *basic biosecurity conditions* of Article 1.4.6., *early detection system* of Article 1.4.7. and *passive surveillance* of Article 1.4.8. are met;

2) the *disease* has not been reported in the country or *zone* (including in wild *aquatic animal* populations) for the minimum period specified in the relevant disease-specific chapter of the *Aquatic Code*.

Requirements for *passive surveillance*

~~The level of confidence provided by~~ *~~passive surveillance~~* ~~datainformation (generated by the~~ *~~early detection system~~* ~~of the~~ *~~Competent Authority~~*~~) to demonstrate historical freedom should be set at 95%, equivalent to that of other pathways for which the evidence is provided by~~ *~~targeted surveillance~~*~~. If a combination of~~ *~~surveillance~~* ~~data sources is to be used (e.g.~~ *~~passive surveillance~~* ~~and~~ *~~targeted surveillance~~*~~), the level of confidence should also be set at 95% that the~~ *~~disease~~* ~~is absent. The data sources for~~ *~~passive surveillance~~* ~~are described in Article 1.4.8. of this chapter.~~

A *Competent Authority* making a *self-declaration of freedom from* *disease* on the basis of historical freedom will need to provide an explanation of how the criteria (i.e. for *basic biosecurity conditions*) presented for this pathway have been met. Specifically, ~~the~~a *Competent Authority* needs to provide evidence that its *early detection system* meets the conditions ~~as~~ described in Article 1.4.7. ~~(and ideally a quantitative assessment of~~ *~~sensitivity~~* ~~would be included)~~ and the requirements for passive *surveillance* in Article 1.4.8. The *early detection system* needs to ~~cover~~ represent all the *susceptible species* populations in the country or *zone*. If ~~the~~a *Competent Authority* cannot demonstrate that the required characteristics are fulfilled, due to a country’s circumstances (e.g. nature of the *early detection system*, environmental conditions, nature of the *aquaculture* industry), this pathway is not considered valid. Instead, an alternative pathway that utilises *targeted surveillance* data will be required, or the *passive surveillance* ~~data~~information will need to be supplemented with *targeted surveillance* data (see below).

Need for *targeted surveillance*

If the requirements for *passive surveillance* specified in points 1 and 2 above would not be met for some defined populations of *susceptible species* (e.g. for wild populations), *targeted surveillance* may be used to provide additional evidence of freedom for those populations. ~~However, for this~~ ~~This pathway~~ Pathway 2 should only ~~pathway to~~ be utilised as the basis of a *self-declaration of freedom from* *disease*, if it is ~~it should be~~ based primarily on *passive surveillance* ~~data~~ information to demonstrate historical freedom; alternatively, pathway 3, as described in Article 1.4.13., should be used.

Article 1.4.13.

**Pathway 3 – Targeted surveillance**

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

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

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

~~Requirements for basic biosecurity conditions~~

*~~Targeted surveillance~~* ~~surveys should only commence following a period of time that~~ *~~basic biosecurity conditions~~* ~~have been in place, as specified in the relevant disease-specific chapter of the~~ *~~Aquatic Code~~*~~.~~

Requirements for targeted surveillance

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

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

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

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

~~For declared~~ *~~free zones~~* ~~or~~ *~~free compartments~~* ~~in infected countries, and in all cases where conditions are not conducive to clinical expression of the~~ *~~pathogenic agent~~*~~,~~ *~~targeted surveillance~~* ~~needs to be continued at a level, determined by the~~ *~~Competent Authority~~*~~, to generate an annual 95% confidence of detection.~~

Other sources of data

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

Article 1.4.14.

**Pathway 4 – Returning to freedom**

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

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

*Compartments* are able to return to freedom relatively rapidly; however, a minimum period of time is required as specified in each disease-specific chapter of the *Aquatic Code* to ~~test~~ demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective~~, and to undertake sufficient testing to demonstrate that eradication has been successful~~.

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

1. Infected zone and protection zone

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

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

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

2. Requirements for targeted surveillance ina country or zone

Once all infected populations have been depopulated and affected *aquaculture establishments* have been disinfected, as described in Chapter 4.~~3~~4., and synchronously fallowed as described in Chapter 4.~~6~~7., for a period determined by the biophysical properties of the *pathogenic agent* (i.e. survival in the environment), a *surveillance* programme within the *protection zones* and *infected zones* should commence. The programme should include both farmed and wild populations of *susceptible species* in the *protection zones* and *infected zones*. A *risk*-based approach to the design of the survey is recommended (~~refer to~~as described in Article 1.4.6.). The following *aquaculture establishments* or populations should be preferentially selected for sampling:

a) establishments which ~~were depopulated (following restocking)~~ have been restocked following depopulation;

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

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

It is recommended that at least two negative surveys are conducted prior to reclaiming freedom. The second survey should start at least three months after completion of the first survey. Surveys should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. If there are breaks in production, the surveys should also ideally span two production cycles. The number of *aquaculture establishments* and the samples taken per establishment in each survey should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* i~~s not present~~ would be detected if present above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence). If *disease* is detected in wild populations of susceptible species and eradication is not possible, the country or *zone* remains infected.

3. Requirements for targeted surveillancein a compartment

Once the infected populations have been depopulated and affected *aquaculture establishments* disinfected, ~~and fallowed~~ as described in Chapter 4.~~3~~4. and fallowed as described in Chapter 4.~~6~~7., for a period determined by the biophysical properties of the *pathogenic* *agent* (i.e. survival in the environment), the *compartment* can be restocked. A single survey is required following restocking to demonstrate that eradication has been successful. The survey should be undertaken at least sixth months, or at the maximum length of time allowed by the production cycle of species, after the *aquaculture establishment* has been restocked to ensure that the reviewed *basic biosecurity conditions* are effective. The survey~~; and~~ should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. The number of holding units (e.g. ponds, tanks) and the animals per holding unit sampled should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* ~~is not present above~~ would be detected above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

Article 1.4.15.

**Maintenance of disease free status**

A country, [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) or *compartment* that is declared free may maintain its free status provided that the *biosecurity* and *surveillance* requirements described in Article 1.4.5. are continuously maintained and the following requirements are met, as relevant:

1) For a country or *zone* with shared water bodies extending across the territory of other countries, free status can only be maintained if the requirements to maintain freedom are in place across all epidemiologically linked shared water bodies.

2) A country, *zone* or *compartment* declared free may maintain its free status without [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique) provided that the requirements for *passive surveillance* in Article 1.4.8. are met for the entire country, [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) or *compartment*, and in the case of:

a) a declared free [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone), the *zone* occurs within the territory of a country declared free;

b) a declared free *compartment,* the *compartment* occurs within the territory of a country declared free.

3) If the conditions of point 2 are not met, ongoing *targeted surveillance* for the *pathogenic agent,* as described in Article 1.4.16., is required at a level determined by ~~the~~a *Competent Authority,* to generate an annual 95% confidence of detection, taking into account the likelihood of *infection*.

4) *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* has been declared free. The investigation should be undertaken in accordance with Article 1.4.18. and the requirements of Chapters 1.1. and 5.1. should be met at all times.

~~For maintenance of~~ *~~disease~~* ~~free status achieved via pathways 2, 3 and 4, the~~ *~~Competent Authority~~* ~~should provide evidence that~~ *~~basic biosecurity conditions~~* ~~are continuously maintained.~~

~~If~~ *~~targeted surveillance~~*~~, that was required for initial demonstration of freedom, is to be discontinued for any identified population, evidence should be provided to demonstrate that conditions remain conducive to clinical expression of~~ *~~disease~~*~~, and that~~ *~~passive surveillance~~*~~, as provided by the country’s~~ *~~early detection system~~*~~, would rapidly detect the~~ *~~disease~~* ~~in those populations should it occur.~~

~~Any ongoing~~ *~~targeted surveillance~~* ~~to maintain freedom should be undertaken at a level necessary to maintain confidence of freedom, and should take into account the likelihood of~~ *~~infection~~*~~.~~

Article 1.4.16.

**Design of surveys to demonstrate freedom from disease**

Surveys to demonstrate freedom from a specified *disease* (i.e. *targeted surveillance*) are required for pathway 3 as described in Article 1.4.13. to achieve a *disease* free status, and to regain a *disease* free status following detection of the *pathogenic agent* as described in Article 1.4.14. and to maintain *disease* freedom~~)~~. Surveys may be required to supplement *passive* *surveillance* ~~data~~information generated by the *early detection system* required for pathway 2 as described in Article 1.4.12. In addition, where conditions are not conducive to clinical expression of *disease*, and, therefore, the *early detection system* cannot provide evidence for the maintenance of freedom, ongoing *targeted surveillance* is required.

It is not possible to provide absolute certainty of the absence of *disease*. Surveys can demonstrate freedom from *disease* by generating evidence that a *disease* is not present in a population at or above a predetermined *prevalence* (the design *prevalence*) and to an acceptable level of confidence. Apparent *disease* at any level in the *target population* automatically invalidates any freedom from *disease* claim, unless, on the basis of further testing, positive test results are accepted as false positives. A survey to demonstrate freedom from *disease* should meet the following requirements set out in this article:

1. Population

The population of *epidemiological units* should be clearly defined. *Aquaculture establishments* and holding *units* (e.g. ponds, tanks) within establishments are the most commonly used *epidemiological unit* in surveys to demonstrate *disease* freedom. It is, therefore, important that *Competent Authorities* should keep registries of *aquaculture establishments*, which include geographic location and species held.

The *target population* consists of all individuals within the selected population of ~~all~~ *susceptible species* to the *disease* in a country, *zone* or *compartment,* to which the *surveillance* results apply. ~~Exotic~~ *~~disease~~**Disease* introduction may be more likely to occur in some components of the *target population* than others. In these cases, it is advisable to focus *surveillance* efforts on this part of the population.

The design of the survey will depend on the size and structure of the population being studied. If the population ~~is relatively small, and~~ can be considered to be homogenous with regards to likelihood of exposure*~~risk~~* ~~of~~ *~~infection~~*, a single-stage survey can be used.

Farmed *aquatic animals* are not individually identified and usually kept in holding *units* (e.g. ponds, tanks) which can lead to clusters of *infection* within *aquaculture establishments*. Similarly, wild *aquatic animal* populations are not evenly distributed within a *zone*. For these reasons, multi-stage sampling is recommended. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. ~~ponds,~~ *aquaculture establishments* or villages) are selected. At the second stage, animals are selected for testing from each of the ~~selected~~first-stage sampling groups.

In the case of a complex (e.g. multi-level) population structure, multi-stage sampling may be used, and the data analysed accordingly.

2. Dossier of evidence

The sources of evidence should be fully described. A survey should include a description of the sampling strategy used for the selection of *units* for testing. For complex *surveillance* systems, a full description of the system is required, including consideration of any *biases* that may be inherent in the system. Evidence to support claims of freedom from *disease* can use non-random sources of information, provided that, overall, any *biases* introduced subsequently favour the detection.

3. Statistical methodology

The analysis and interpretation of test results from a survey shall be in accordance with the provisions of this chapter and consider the following factors:

a) the survey design;

b) the diagnostic *sensitivity* and *specificity* of the test or test system;

c) the design *prevalence* (or *prevalences* where a multi-stage design is used).

Analysis of data for evidence of freedom from *disease* involves estimating the probability (alpha) that the evidence observed (i.e. negative results for *disease* detection from *surveillance*) could have been produced assuming that *infection* is present in the population at or ~~below~~ above the minimum specified *prevalence* (the design *prevalence*). The confidence in (or, equivalently, the *sensitivity* of) the survey that produced the evidence is equal to 1–alpha. If the confidence level exceeds a pre-set threshold, the evidence is deemed adequate to demonstrate freedom from *infection*. The required level of confidence (that the survey would detect *infection* if *infection* were present at or above the specified level) should be equal to or greater than ~~or equal to~~ 95%.

The power (probability that the survey would report that no *infection* is present if *infection* is truly not present) is by convention set to 80%, but may be adjusted in accordance with the country’s or *zone*’s requirements.

Statistical analysis of *surveillance* data often requires assumptions about population parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or similar populations, and epidemiology of the *disease*.

The values for design *prevalence* used in calculations should be ~~those specified in the relevant disease-specific~~ *~~disease~~* ~~chapter (if present) of the~~ *~~Aquatic Manual~~*based on the epidemiology of the disease. ~~If not specified for the particular~~ *~~disease~~*~~, j~~Justification for the selection of design *prevalence* values should be provided, and should be based on the following recommendations:

a) At the individual animal level (e.g. *prevalence* of infected animals in a pond, tank or net pen, or cages), the design *prevalence* is based on the epidemiology of the *infection* in the population. It is equal to the minimum expected *prevalence* of *infection* in the *study population*, if the *infection* had become established in that population. A suitable design *prevalence* value at the animal level may be:

i) between 1% and 5% for *infections* that are present in a small part of the population, e.g. are transmitted slowly or have been recently introduced, etc.;

ii) over 5% for highly transmissible and persistent *infections*;

iii) if reliable information, including expert opinion, on the expected *prevalence* in an infected population is not available, a value of 2% should be used for the design *prevalence*.

b) At higher levels (e.g. net pen or cage, pond, *aquaculture establishments*, village, etc.) the design *prevalence* should be based on empirical evidence and reflect the expected behaviour of the *infection*. A higher establishment-level design *prevalence* can be used for *diseases* which spread rapidly between pens or cages, and establishments. *Diseases* which are transient or ~~that can remain sub-clinical~~ less contagious require lower design *prevalences*:

i) a suitable design *prevalence* value for the first level of clustering (e.g. proportion of infected establishments in a *zone*) is normally not greater than 2%. If a higher design *prevalence* is selected, it should be justified.

4. Risk-based sampling

*Risk*-based sampling is an approach to identify and sample populations that have the greatest likelihood of *infection*. It can be applied to the design of surveys to demonstrate freedom from *disease* for a country, *zone* or *compartment*. A key advantage of *risk*-based sampling is that it can improve the efficiency of *surveillance* to demonstrate freedom from *disease* compared to random sampling approaches.

*Risk*-based sampling requires the identification of *risk*-factors that are applied to *bias* sample collection to populations of *aquatic animals* considered most likely to be infected if the specific *disease* had been introduced and had established. Where *risk*-based sampling is used for demonstration of freedom, the *risk* factors that underpin survey design, and the evidence or assumptions for their selection, should be documented. Where existing *risk* *assessments* are available, these may be utilised to identify *risk* factors associated with *disease* introduction, exposure and establishment. The identification of appropriate *risk* factors may include consideration of:

1. the possible pathways of *disease* introduction (e.g. through ~~imported~~ *aquatic animals*, ~~imported~~ *aquatic animal products*, *feed*, fomites, *vectors* and ~~ship ballast~~ water~~or biofouling~~);

b) proximity of susceptible populations to sources of *disease* exposure (e.g. to *~~quarantine~~* ~~facilities,~~ *aquatic animal* processing facilities, or ports);

c) environmental or husbandry conditions that are permissive for *disease* establishment (e.g. temperature, salinity, production system type, habitat type, exposure to recent stressors);

d) conditions that are conducive for development of clinical *disease*; including the species or life stages that are most susceptible to clinical *disease*~~.~~;

e) evidence of morbidity or mortality.

5. Test characteristics

All *surveillance* involves performing one or more tests for evidence of the presence of current or past *infection*, ranging from laboratory assays to farmer observations. The performance level of a test is described in terms of its diagnostic *sensitivity* and *specificity*. Imperfect *sensitivity* or *specificity* impact on the interpretation of *surveillance* results, and should be taken into account in the analysis of *surveillance* data. For example, in the case of a test with imperfect diagnostic *specificity*, if the population is free of *disease* or has a very low *prevalence* of *infection*, all or a large proportion of positive tests will be false. Samples that test positive should be confirmed or refuted using a second highly specific test. Where more than one test is used (sometimes called using tests in series or parallel), the *sensitivity* and *specificity* of the test combination should be calculated.

All calculations should take the performance level (*sensitivity* and *specificity*) of any tests used into account. Information on test characteristics provided in the relevant disease-specific chapter of the *Aquatic Manual* should be used unless more appropriate information is available. The estimate of test *sensitivity* when the test was used in apparently healthy *aquatic animals* should be used. Samples should not be pooled before testing, unless approved in the relevant disease-specific chapter of the *Aquatic Manual*. If pooled testing is used, the results of testing should be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pooled testing procedure, and for the applicable pool sizes being used.

6. Sample size

In surveys conducted to demonstrate the absence or presence of an *infection*, t~~T~~he number of units to be sampled from a population should be calculated, using a statistically valid technique that takes at least the following factors into account:

a) the *sensitivity* and *specificity* of the diagnostic test,

b) the design *prevalence* (or *prevalences* where a multi-stage design is used),

c) the level of confidence that is desired of the survey results.

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

a) the size of the population (but it is acceptable to assume that the population is infinitely large),

b) the desired power of the survey.

Software for the calculation of sample sizes at varying parameter values are available. Table 1.~~1~~ 2 provides examples of sample sizes generated by the software for a type I and type II error of 5% (i.e. 95% confidence and 95% statistical power). However, this does not mean that a type 1 and type 2 error of 0.05 should always be used. For example, using a test with *sensitivity* and *specificity* of 99%, 528 *units* should be sampled. If nine or less of those *units* test positive, the population can still be considered free of the *infection* at a design *prevalence* of 2%, provided that all efforts are made to ensure that all presumed false positives are indeed false (i.e. by use of a second highly specific assay). This means that there is a 95% confidence that the *prevalence* is 2% or lower, which reflects the fact that false negative results can occur. Incorrectly concluding that a population is free can be reduced by increasing the sample size and using more than one assay but cannot be completely eliminated.

In the case in which the values of *sensitivity* and *specificity* are not known (e.g. no information is available in the relevant disease-specific chapter of the *Aquatic Manual*), they should not automatically be assumed to be 100%. All positive results should be included and discussed in any report regarding that particular survey, and all efforts should be made to ensure that all presumed false positives are indeed false.

7. Multi-stage structured survey design

In general, a survey to demonstrate freedom at *zone* or *country* level should use a multi-stage design. The first sampling level is often *aquaculture establishments* (or villages) or ~~discrete~~ populations of wild susceptible species, and the second stage may be ponds or individual animals within the establishment (or village) or defined stocks within a wild population. At each level, design levels need to be set and sample sizes calculated.

~~8.~~ ~~Discounting~~

~~Where conditions are not conducive to clinical expression of~~ *~~disease~~* ~~in a population, ongoing~~ *~~surveillance~~* ~~is required. Regions and~~ *~~aquaculture establishments~~* ~~at high risk of introduction of~~ *~~pathogenic agent~~* ~~should be regularly sampled.~~ *~~Targeted surveillance~~* ~~required to maintain confidence in~~ *~~disease~~* ~~freedom at 95% can be determined based on estimates of the likelihood of introduction of~~ *~~pathogenic agent~~* ~~(low due to basic~~ *~~biosecurity~~* ~~measures) and the discounting of historic~~ *~~surveillance~~*~~. Methods for using historical~~ *~~surveillance~~* ~~data have been developed.~~

~~9~~8. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

Table 1.2. Sample sizes for different design *prevalences* and test characteristics.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Design prevalence (%)** | **Sensitivity (%)** | **Specificity (%)** | **Sample size** | **Maximum number of  false positive if the  population is free** |
| 2 | 100 | 100 | 149 | 0 |
| 2 | 100 | 99 | 524 | 9 |
| 2 | 100 | 95 | 1,671 | 98 |
| 2 | 99 | 100 | 150 | 0 |
| 2 | 99 | 99 | 528 | 9 |
| 2 | 99 | 95 | 1,707 | 100 |
| 2 | 95 | 100 | 157 | 0 |
| 2 | 95 | 99 | 542 | 9 |
| 2 | 95 | 95 | 1,854 | 108 |
| 2 | 90 | 100 | 165 | 0 |
| 2 | 90 | 99 | 607 | 10 |
| 2 | 90 | 95 | 2,059 | 119 |
| 2 | 80 | 100 | 186 | 0 |
| 2 | 80 | 99 | 750 | 12 |
| 2 | 80 | 95 | 2,599 | 148 |
| 5 | 100 | 100 | 59 | 0 |
| 5 | 100 | 99 | 128 | 3 |
| 5 | 100 | 95 | 330 | 23 |
| 5 | 99 | 100 | 59 | 0 |
| 5 | 99 | 99 | 129 | 3 |
| 5 | 99 | 95 | 331 | 23 |
| 5 | 95 | 100 | 62 | 0 |
| 5 | 95 | 99 | 134 | 3 |
| 5 | 95 | 95 | 351 | 24 |
| 5 | 90 | 100 | 66 | 0 |
| 5 | 90 | 99 | 166 | 4 |
| 5 | 90 | 95 | 398 | 27 |
| 5 | 80 | 100 | 74 | 0 |
| 5 | 80 | 99 | 183 | 4 |
| 5 | 80 | 95 | 486 | 32 |

Article 1.4.17.

**Combining multiple sources of information**

Pathway 1 to achieving *disease* freedom (absence of *susceptible species*) relies on a range of data sources. Pathway 2 to achieving *disease* freedom (historical freedom) will primarily use evidence from *passive* *surveillance,* which may come from multiple sources (as described in Article 1.4.8.) and may be supplemented with *targeted surveillance* if necessary (as described in Article 1.4.12.). *Passive* *surveillance* ~~data~~ information can also be used to provide additional support ~~to case~~ for *disease* freedom, ~~primarily~~ based on *targeted surveillance* (i.e. pathway 3). Estimates of the confidence in each data source may be combined to provide an overall level of confidence of freedom from *disease* for the combined data sources. The methodology used to combine the estimates from multiple data sources:

1) should be scientifically valid and fully documented, including references to published material; and

2) should, where possible, take into account any lack of statistical independence between different data sources.

~~A scenario tree modelling approach can be used to combine evidence from different sources including~~ *~~passive~~* ~~and~~ *~~targeted surveillance~~*~~.~~If combining evidence from different sources including *passive surveillance* and *targeted surveillance*, a *Competent Authority* may choose to use various approaches, such as a scenario tree modelling approach.

Article 1.4.18.

**Diagnostic confirmation of a listed disease or an emerging disease**

A *Competent Authority* is required to provide *disease* *notifications* as described in Chapter 1.1.

The relevant disease-specific chapter of the *Aquatic Manual* provides recommendations for the appropriate diagnostic methods for presumptive and confirmatory diagnostic purposes. The assays recommended for these purposes are presented in Table 4.1 of the relevant disease-specific chapter of the *Aquatic Manual*.

The recommended standards of diagnostic evidence to confirm *infection* in either apparently healthy or clinically diseased animals are provided in Section 6 of the relevant disease-specific chapter of the *Aquatic Manual*. These case definitions for suspect and confirmed cases have been developed to support decision making in relation to trade and for confirmation of *disease* status at the level of a country, *zone* or *compartment*. A *Competent Authority* may choose to apply a lower standard of evidence for *disease* confirmation within its *territory* for known endemic *diseases*.

If standards of evidence are not met to confirm a suspect case of *disease* in accordance with the case definitions in Section 6 of the relevant disease-specific chapter of the *Aquatic Manual*, ongoing investigation is required until sufficient evidence is obtained to either:

1) exclude the presence of a *listed disease* or an *emerging disease*; or

2) to confirm the presence of a *listed disease* or an *emerging disease*.

If a Member Country does not have access to a laboratory with ~~does not have~~ the capability to undertake the necessary diagnostic tests and which meets the requirements of Chapter 1.1.1. of the *Aquatic Manual*~~,~~ it should seek advice from the relevant OIE Reference Laboratory.

In all circumstances, Member Countries should comply with the requirements described in Chapter 1.1. to provide transparent and timely *notification* to allow Member Countries to take appropriate action to prevent the transboundary spread of important *diseases* of *aquatic animals*.

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[Return to Agenda](#agenda)

**(CLEAN VERSION)**

CHAPTER 1.4.  
  
**AQUATIC ANIMAL DISEASE SURVEILLANCE**

Article 1.4.1.

**Purpose**

This chapter provides guidance on the *surveillance* approaches to be used by a *Competent Authority* to make and maintain a *self-declaration of freedom from disease* or to confirm the occurrence of a *listed disease* or an *emerging disease*.

Article 1.4.2.

**Introduction and scope**

This chapter supports a *Competent Authority* to meet the requirements for *self-declaration of freedom from disease* at the level of a country, *zone* or *compartment*, and for maintenance of freedom, that are presented in each disease-specific chapter. It also provides a *Competent Authority* with guidance to meet the requirements of *notification* of a *listed* *disease* or an *emerging disease* in accordance with Chapter 1.1.

This chapter is not intended to provide detailed technical guidance on *surveillance* design or analysis. *Competent Authorities* are encouraged to consult published literature and seek appropriate expertise to design and analyse *surveillance* programmes that meet the requirements of the *Aquatic Code*.

1) The general requirements of a *surveillance* system necessary to support a *self-declaration of freedom from* *disease* are specified in Articles 1.4.5. to 1.4.8.

2) The criteria that have been used to set the periods specified in each disease-specific chapter for *basic* *biosecurity conditions* to be in place, or for *targeted surveillance* that should be undertaken, prior to claiming freedom, are included in Articles 1.4.9. and 1.4.10.

3) The requirements for each of the four pathways for claiming freedom, and for maintaining freedom, are introduced in Article 1.4.3. and described in detail in Articles 1.4.11. to 1.4.15.

4) Guidance on the design of surveys to demonstrate freedom from *disease*, and for combining multiple sources of *surveillance* information are provided in Articles 1.4.16. and Article 1.4.17., respectively.

5) Article 1.4.18. provides guidance on diagnostic confirmation of *listed* *diseases* or an *emerging disease.*

*Competent Authorities* should refer to the relevant disease-specific chapter of the *Aquatic Manual* for recommendations on sample collection and appropriate diagnostic methods for *surveillance* and diagnosis of *listed diseases*. The relevant disease-specific chapter of the *Aquatic Manual* should also be consulted for the necessary information on epidemiology and diagnostic performance of assays required for *surveillance* programme design.

Article 1.4.3.

**Pathways for demonstrating freedom from disease**

*Competent Authorities* may use one of four pathways to make a *self-declaration of freedom from* *disease*. Each pathway outlines the *aquatic animal* health circumstances and requirements that should be met for a self-declarationto be made. Any one of these four pathways may be utilised; however, a *Competent Authority* should provide evidence that all relevant requirements to demonstrate *disease* freedom have been met as described in this chapter and the relevant disease-specific chapter of the *Aquatic Code* including when water bodies are shared with other countries or are under the control of different *Competent Authorities*. The four pathways are:

1. Absence of susceptible species

This pathway may be utilised if, as described in Article 1.4.11., it can be demonstrated that no *susceptible species* are present at the country or *zone*.

2. Historical freedom

This pathway may be utilised if, as described in Article 1.4.12., there is evidence of historical absence of a *disease* at the country or *zone* level, that is supported primarily by *passive surveillance* information generated by a country’s *early detection system*. *Targeted surveillance* data may also be used in this pathway, where appropriate.

3. Targeted surveillance

This pathway may be utilised at the country, *zone* or *compartment* level. The pathway primarily uses *targeted surveillance* data, but other sources of evidence may be utilised as described in Article 1.4.13. *Passive surveillance* information may also be used in this pathway, where appropriate.

4. Returning to freedom

This pathway may be utilised, as described in Article 1.4.14., in circumstances where a self-declaration had been made, but free status was subsequently lost due to detection of the *disease* for a country, *zone* or *compartment*.

Table 1.1. A summary of the four pathways for *self-declaration of freedom from* *disease*, including the types of primary and secondary *surveillance* information, and the applicable level of application for either a country, *zone* or *compartment*.

|  |  |  |  |
| --- | --- | --- | --- |
| **Pathway** | **Primary surveillance evidence to claim *disease* freedom** | **Secondary evidence to claim freedom (if required)** | **Applicable level of application** |
| 1. Absence of *susceptible species* | Surveys, historical data, import records, environmental information | None | Country, *zone* |
| 1. Historical freedom | *Passive* *surveillance* | *Targeted surveillance* (in populations where *passive* *surveillance* is not appropriate) | Country, *zone* |
| 1. *Targeted surveillance* | *Targeted surveillance* | *Passive* *surveillance* (in appropriate populations) | Country, *zone*, *compartment* |
| 1. Returning to freedom | *Targeted surveillance* | *Passive* *surveillance* (in appropriate populations) | Country, *zone*, *compartment* |

Article 1.4.4.

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

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

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

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

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

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

4) the *surveillance* analysis and results;

5) the measures implemented to maintain freedom.

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

An *outbreak* in a Member Country, a *zone* or a *compartment* having a self-declared free status results in the loss of the self-declared free status. The notification of an *outbreak* in a country, *zone* or *compartment* for which a *self-declaration of freedom* has been made, will result in an update of the OIE website concerning the original declaration. A Member Country wishing to reclaim a lost free status should submit a new self-declaration following the procedure described in this chapter.

Article 1.4.5.

**Biosecurity and surveillance system requirements**

The following *biosecurity* and *surveillance* system requirements should be met for any *self-declaration of freedom* *from disease* in the given country, *zone* or *compartment*:

1) the quality of *Aquatic Animal Health Services* can be substantiated to meet the requirements of Chapter 3.1.:

2) *basic biosecurity conditions* (which include an *early detection system*) as described in Article 1.4.6. are in place;

3) there has been no vaccination of *susceptible aquatic animals* for the specific *disease* from the implementation of the *basic biosecurity conditions* prior to self-declaration;

4) the *Aquatic Animal Health Services* have sufficient capacity and expertise to investigate and report *disease* events to a *Competent Authority*;

5) a *Competent Authority* has access to appropriate diagnostic capability (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed diseases* and *emerging diseases* in accordance with Article 1.4.18.

Article 1.4.6.

**Basic biosecurity conditions**

*Basic biosecurity conditions* include requirements for preventing the introduction and spread of a specific *disease* and for detection of the *disease* should it occur. The requirements for *basic biosecurity conditions* include:

1) an *early detection system* (as described in Article 1.4.7.);

2) measures to prevent the introduction of the *pathogenic agent* into a country, *zone* or *compartment*, or the spread within or from *infected zones* and *protection zones*, in accordance with the relevant disease-specific chapter.

In making aself-declaration of freedom froma specific *disease* for a country, *zone* or *compartment,* a C*ompetent Authority* should describe how all of the requirements for *basic biosecurity conditions* relevant to its declaration, are continuously met.

Article 1.4.7.

**Early detection system**

The *early detection system* of a *Competent Authority* is important to generate evidence for claims of disease freedom and to provide assurance that a change in disease status would be rapidly discovered.

A *self-declaration of freedom from disease* needs to document that the *early detection system* fulfils each of the requirements below:

1) observers (e.g. the personnel of *aquaculture establishments,* processors, transportation services) have broad awareness of the characteristic signs of *listed diseases* and *emerging diseases*;

2) *veterinarians* and *aquatic animal health professionals* are trained in recognising and reporting suspicion of *listed disease* and *emerging disease* occurrence;

3) the *Aquatic Animal Health Services* have capacity to undertake rapid and effective *disease* investigation based on a national chain of command led by a *Competent Authority*;

4) the *Aquatic Animal Health Services* have access to sufficient diagnostic capability (from a laboratory with a quality management system that meets requirements of Chapter 1.1.1. of the *Aquatic Manual*) to confirm or exclude cases of *listed* *diseases* and the capacity and expertise to investigate *emerging* *diseases* as described in Article 1.4.18.;

5) *veterinarians,* *aquatic animal health professionals* and others with an occupational role with *aquatic animals* have a legal obligation to report suspicion of the occurrence of *listed* *diseases* or *emerging* *diseases* to a *Competent Authority*.

The sensitivity of an *early detection system* is the likelihood that the *disease* will be detected if present. Of fundamental importance is *disease* reporting by farmers, *aquatic animal health professionals, veterinarians* and others to initiate the necessary steps of *passive surveillance*. Specifically, a *Competent Authority* should be able to demonstrate that efforts have been made to make relevant observers (e.g. farmers and fishers) aware of signs of *listed diseases* and *emerging diseases*, and secondly the obligation of farmers, *aquatic animal health professionals,* *veterinarians* and others with an occupational role with *aquatic animals* to report suspicion. The underpinning legal instruments should be cited.

The capacity of the *Aquatic Animal Health Services* to respond to suspicion of a *listed diseas*e can be evidenced by response plans, and a descriptive chain of command that will result in an official declaration that the *pathogenic agent* has been detected. Standard operating procedures for diagnostic assays for *listed diseases* and accreditation to internationally recognised laboratory standards can demonstrate the capacity of the *Aquatic Animal Health Services* to detect *listed diseases*. In addition, the effective functioning of the *early detection system* is best illustrated through examples of investigations in response to reported suspicion of *disease*. The sensitivity of an *early detection system* (i.e. the likelihood of *pathogenic agent* detection following introduction) can be quantified, for example, by use of a scenario tree model; however, in most circumstances a qualitative assessment will be sufficient.

Article 1.4.8.

**Requirements for passive surveillance**

In addition to the characteristics of an *early detection system* described in Article 1.4.7., the conditions described in this article should be met for *passive surveillance* information to be utilised for a *self-declaration of freedom from* *disease.*

1) The conditions, which apply to each defined *study population* of *susceptible species* of a specific *disease*, are that:

a) conditions (biotic and abiotic) are conducive to clinical expression of the *infection*, such that if the *pathogenic agent* were present within the population of *susceptible species*, it would produce signs of the *disease* at least seasonally;

b) observation of signs of the *disease*, which may include increased mortality, would lead to investigation and where appropriate, reporting to a *Competent Authority*;

c) populations of susceptible farmed *aquatic animals* should be under sufficient observation, such that, if signs of the *disease* were to occur, they would be observed;

d) for populations of susceptible wild *aquatic animals*, they should:

i) be under sufficient observation, such that if signs of the *disease* were to occur, they would be observed and reported, or

ii) be epidemiologically linked to farmed populations, such that if the *disease* were to occur in wild *aquatic animal* populations it would be observed and reported in adjacent farmed populations.

2) *Passive surveillance* depends primarily on observers (e.g. farmers, *aquatic animal health professionals,* *veterinarians* andothers)recognizing signs of *disease* that are suspicious of a *listed disease*  or unexplained increased mortality and reporting them to a *Competent Authority*. For wild populations, the requirements of points 1a), b) and d) may not be met under most circumstances and, therefore, *passive* *surveillance* will be insufficiently sensitive. If a *Competent Authority* utilises *passive surveillance* information for defined populations of wild *aquatic animals*, it should demonstrate that the conditions of this article have been met, and that the *early detection system* will result in detection of the *disease* should it occur.

3) Awareness of signs of *disease* and the necessary level of observation is best demonstrated through examples of reporting by farmers, *aquatic animal health professionals, veterinarians* and others to a *Competent Authority*. In addition to reporting, information for *passive surveillance* may originate from inspections at processing plants, routine visits by government officials and surveys (e.g. fisheries and aquatic fauna surveys), submissions to laboratories, *aquaculture establishment* records (e.g. mortality, medicine use, etc.).

4) Evidence from published literature will generally be sufficient to demonstrate the environmental conditions in which *infection* of *susceptible species* will result in clinical signs. This information should be supplemented with data on the environmental conditions for the *target populations*.

5) *Passive surveillance* only contributes to the *early detection system* if observations and investigations that lead to suspicion of *listed diseases* or *emerging diseases* are rapidly reported, to allow a *Competent Authority* to undertake their own investigation.

Article 1.4.9.

**Required periods for basic biosecurity conditions**

1) Prior to a Member Country making a *self-declaration of freedom from disease*, *basic biosecurity conditions* should be in place for a sufficient duration*,* so that, by the end of the period, should the *disease* have been introduced before the *basic biosecurity conditions* began:

a) the specific *pathogenic agent* would not remain present in the environment (see pathway 1 – absence of *susceptible species*) or;

b) the *disease* would manifest clinically and be detected by the country’s *early detection system* (see pathway 2 – historical freedom); or

c) by the time *targeted surveillance* commenced (see pathway 3 – *Targeted surveillance*), *infection* levels would have reached the minimum *prevalence* estimate (i.e. the design *prevalence*) used in the survey design to calculate the sample sizes (e.g. number of *aquaculture establishments* and *aquatic animals* needed to demonstrate freedom).

2) Each disease-specific chapter of the *Aquatic Code* includes minimum periods that *basic biosecurity conditions* should be in place prior to a *self-declaration of freedom from* *disease*.These periods reference a default minimum period or a longer period if determinednecessarybased on the factors described below:

a) For pathway 1, the default minimum period of *basic biosecurity conditions* required prior to a self-declaration, for all *listed diseases,* is six months. It is expected that this period will be sufficient for most *diseases* to ensure that no viable *pathogenic agent* introduced via *aquatic animal* commodities has remained present in the environment, and the *early detection system* was well established and demonstrated to be functioning. The required period that *basic biosecurity conditions* should be in place prior to making a self-declaration*,* using this pathway, is determined for each *listed disease* based on its epidemiology (e.g. agent stability in the environment, presence of resistant life stages, *vectors*), and a period longer than the default minimum may be specified in the relevant disease-specific chapter of the *Aquatic Code*.

b) For pathway 2, the default minimum period of *basic biosecurity conditions* required prior to a self-declaration, for all *listed diseases,* is ten years. This period is the minimum required to achieve 95% likelihood of freedom, if the annual likelihood of detection is approximately 30%. However, if the average annual likelihood of detection is considered to be less than 30% (following consideration of the factors below), the minimum period required for *basic biosecurity conditions* defined in the relevant disease-specific chapter of the *Aquatic Code* will be set to a period longer than ten years, as appropriate. An evaluation of the following factors will determine whether a period longer than ten years is recommended in the disease-specific chapters:

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

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

iii) the variation in predilection to clinical *disease* among *susceptible species*;

iv) the expected severity and duration of clinical signs in the *susceptible species*;

v) environmental conditions that influence levels of *infection* and clinical expression, including seasonality of the *disease* (i.e. periods of the year when *prevalence* and intensity of *infection* are highest and most conducive to detection);

vi) factors specific to the *pathogenic agent* (e.g. production of spores);

vii) production systems and management practices that would affect observation of clinical signs if they were to occur;

viii) any other relevant factors that may influence presentation of clinical signs and observation of the *disease* should it be present.

c) For pathway 3, the default minimum period of *basic biosecurity conditions* required prior to commencement of *targeted surveillance* will be one year. It is 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 this chapter. However, the epidemiology of a *disease* and nature of production systems may limit the increase in *prevalence* and intensity of *infection* in the *susceptible species* following introduction of the *disease*. In these instances, the minimum period required for *basic biosecurity conditions* defined in the relevant disease-specific chapter of the *Aquatic Code* will be set to a period longer than one year, as appropriate. An evaluation of the following factors will determine whether a period longer than one year is required:

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

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

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

iv) production systems and management practices that would affect occurrence of *infection*;

v) any other relevant factors that may influence the expected rate of increase in *prevalence* and intensity of *infection* in *susceptible species* following introduction of the *disease*.

d) Pathway 4 is only applicable following the loss of *disease* freedom due to a *disease* *outbreak*. This circumstance implies a failure of *basic biosecurity conditions* to prevent the introduction of the *disease*. The pathway of *disease* introduction should be investigated and *basic biosecurity conditions* should be reviewed and modified as necessary to reduce the likelihood of *disease* introduction by the same or similar routes. Mitigation measures should be implemented following eradication of the *disease*, and prior to commencement of any *targeted surveillance* that will be utilised as evidence for a subsequent self-declaration.

Article 1.4.10.

**Required periods for targeted surveillance**

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

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

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

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

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

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

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

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

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

Article 1.4.11.

**Pathway 1** – **Absence of susceptible species**

Unless otherwise specified in the relevant disease-specific chapter of the *Aquatic Code*, a self-declaration of freedom from a specific *disease* may be made for a country or *zone* without applying *targeted surveillance* if there are no *susceptible species* (as listed in Article X.X.2. of the relevant disease-specific chapter of the *Aquatic Code*) present in that country or *zone*.

*Basic biosecurity conditions* should be in place for a period of time prior to a *self-declaration of freedom from* *disease*.

This pathway relies on confidence that *susceptible species* are in fact absent from a country or *zone*. To be confident that *susceptible species* are absent there should be:

1) sound knowledge of the range of *susceptible species* of a *pathogenic agent;* and

2) sufficient knowledge, of the local *aquatic animal* fauna (including wild populations) demonstrated by the following forms of evidence:

a) reports which provide evidence regarding the absence of the *susceptible species* in the country or *zone* from structured surveys (e.g. of fisheries and aquatic fauna surveys, historical fisheries data);

b) documentation from the relevant *Competent Authority* showing that those *susceptible species* have not been imported into the country or *zone*;

c) provision of documentation which sets out scientific evidence indicating that the likelihood of the presence of *susceptible species* in the country or *zone* is negligible (e.g. data on physiological requirements, oceanographic information, biodiversity databases).

This pathway cannot be used for *diseases* where there is uncertainty regarding the full range of *susceptible species* (e.g. *diseases* with a broad host range), or where the *pathogenic agent* may not be obligate (e.g. able to survive indefinitely outside the host). In these cases, the pathway will be absent from the relevant disease-specific chapter of the *Aquatic Code*, and alternative pathways to demonstrate freedom should be utilised.

The pathway is intended primarily to be used by a *Competent Authority* wishing to establish freedom ahead of farming a new species.

Article 1.4.12.

**Pathway 2** – **Historical freedom**

Unless otherwise specified in the relevant disease*-*specificchapter of the *Aquatic Code*, a *self-declaration of freedom from* *disease* may be made for a country or *zone* on the basis of historical freedom. The primary evidence for historical freedom is *passive surveillance* information generated by a country’s *early detection system*. For this pathway to be utilised, the following conditions should be met:

1) the country or *zone* has *basic biosecurity conditions* in place, including an *early detection system*, that is sufficiently sensitive to detect the *disease* should it occur, and the requirements for *basic biosecurity conditions* of Article 1.4.6., *early detection system* of Article 1.4.7. and *passive surveillance* of Article 1.4.8. are met;

2) the *disease* has not been reported in the country or *zone* (including in wild *aquatic animal* populations) for the minimum period specified in the relevant disease-specific chapter of the *Aquatic Code*.

Requirements for *passive surveillance*

A *Competent Authority* making a *self-declaration of freedom from* *disease* on the basis of historical freedom will need to provide an explanation of how the criteria (i.e. for *basic biosecurity conditions*) presented for this pathway have been met. Specifically, a *Competent Authority* needs to provide evidence that its *early detection system* meets the conditions described in Article 1.4.7. and the requirements for passive *surveillance* in Article 1.4.8. The *early detection system* needs to represent all the *susceptible species* populations in the country or *zone*. If a *Competent Authority* cannot demonstrate that the required characteristics are fulfilled, due to a country’s circumstances (e.g. nature of the *early detection system*, environmental conditions, nature of the *aquaculture* industry), this pathway is not considered valid. Instead, an alternative pathway that utilises *targeted surveillance* data will be required, or the *passive surveillance* information will need to be supplemented with *targeted surveillance* data (see below).

Need for *targeted surveillance*

If the requirements for *passive surveillance* specified in points 1 and 2 above would not be met for some defined populations of *susceptible species* (e.g. for wild populations), *targeted surveillance* may be used to provide additional evidence of freedom for those populations. Pathway 2 should only be utilised as the basis of a *self-declaration of freedom from* *disease*, if it is based primarily on *passive surveillance* information to demonstrate historical freedom; alternatively, pathway 3, as described in Article 1.4.13., should be used.

Article 1.4.13.

**Pathway 3 – Targeted surveillance**

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

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

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

Requirements for targeted surveillance

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

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

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

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

Other sources of data

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

Article 1.4.14.

**Pathway 4 – Returning to freedom**

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

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

*Compartments* are able to return to freedom relatively rapidly; however, a minimum period of time is required as specified in each disease-specific chapter of the *Aquatic Code* to demonstrate that eradication has been successful and to ensure the reviewed *basic biosecurity conditions* are effective.

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

1. Infected zone and protection zone

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

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

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

2. Requirements for targeted surveillance ina country or zone

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

a) establishments which have been restocked following depopulation;

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

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

It is recommended that at least two negative surveys are conducted prior to reclaiming freedom. The second survey should start at least three months after completion of the first survey. Surveys should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. If there are breaks in production, the surveys should also ideally span two production cycles. The number of *aquaculture establishments* and the samples taken per establishment in each survey should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected if present above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence). If *disease* is detected in wild populations of susceptible species and eradication is not possible, the country or *zone* remains infected.

3. Requirements for targeted surveillancein a compartment

Once the infected populations have been depopulated and affected *aquaculture establishments* disinfected, as described in Chapter 4.4. and fallowed as described in Chapter 4.7., for a period determined by the biophysical properties of the *pathogenic* *agent* (i.e. survival in the environment), the *compartment* can be restocked. A single survey is required following restocking to demonstrate that eradication has been successful. The survey should be undertaken at least sixth months, or at the maximum length of time allowed by the production cycle of species, after the *aquaculture establishment* has been restocked to ensure that the reviewed *basic biosecurity conditions* are effective. The survey should take place during optimum seasons, temperatures, and priority life stages to optimise *pathogenic agent* detection. The number of holding units (e.g. ponds, tanks) and the animals per holding unit sampled should be sufficient to demonstrate with 95% confidence that the *pathogenic agent* would be detected above a *prevalence* of 2% (a higher design *prevalence* can be used if justified by epidemiological evidence).

Article 1.4.15.

**Maintenance of disease free status**

A country, [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) or *compartment* that is declared free may maintain its free status provided that the *biosecurity* and *surveillance* requirements described in Article 1.4.5. are continuously maintained and the following requirements are met, as relevant:

1) For a country or *zone* with shared water bodies extending across the territory of other countries, free status can only be maintained if the requirements to maintain freedom are in place across all epidemiologically linked shared water bodies.

2) A country, *zone* or *compartment* declared free may maintain its free status without [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique) provided that the requirements for *passive surveillance* in Article 1.4.8. are met for the entire country, [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) or *compartment*, and in the case of:

a) a declared free [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone), the *zone* occurs within the territory of a country declared free;

b) a declared free *compartment,* the *compartment* occurs within the territory of a country declared free.

3) If the conditions of point 2 are not met, ongoing *targeted surveillance* for the *pathogenic agent,* as described in Article 1.4.16., is required at a level determined by a *Competent Authority,* to generate an annual 95% confidence of detection, taking into account the likelihood of *infection*.

4) *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* has been declared free. The investigation should be undertaken in accordance with Article 1.4.18. and the requirements of Chapters 1.1. and 5.1. should be met at all times.

Article 1.4.16.

**Design of surveys to demonstrate freedom from disease**

Surveys to demonstrate freedom from a specified *disease* (i.e. *targeted surveillance*) are required for pathway 3 as described in Article 1.4.13. to achieve a *disease* free status, and to regain a *disease* free status following detection of the *pathogenic agent* as described in Article 1.4.14. and to maintain *disease* freedom. Surveys may be required to supplement *passive* *surveillance* information generated by the *early detection system* required for pathway 2 as described in Article 1.4.12. In addition, where conditions are not conducive to clinical expression of *disease*, and, therefore, the *early detection system* cannot provide evidence for the maintenance of freedom, ongoing *targeted surveillance* is required.

It is not possible to provide absolute certainty of the absence of *disease*. Surveys can demonstrate freedom from *disease* by generating evidence that a *disease* is not present in a population at or above a predetermined *prevalence* (the design *prevalence*) and to an acceptable level of confidence. Apparent *disease* at any level in the *target population* automatically invalidates any freedom from *disease* claim, unless, on the basis of further testing, positive test results are accepted as false positives. A survey to demonstrate freedom from *disease* should meet the following requirements set out in this article:

1. Population

The population of *epidemiological units* should be clearly defined. *Aquaculture establishments* and holding *units* (e.g. ponds, tanks) within establishments are the most commonly used *epidemiological unit* in surveys to demonstrate *disease* freedom. It is, therefore, important that *Competent Authorities* should keep registries of *aquaculture establishments*, which include geographic location and species held.

The *target population* consists of all individuals within the selected population of *susceptible species* to the *disease* in a country, *zone* or *compartment,* to which the *surveillance* results apply. *Disease* introduction may be more likely to occur in some components of the *target population* than others. In these cases, it is advisable to focus *surveillance* efforts on this part of the population.

The design of the survey will depend on the size and structure of the population being studied. If the population can be considered to be homogenous with regards to likelihood of exposure, a single-stage survey can be used.

Farmed *aquatic animals* are not individually identified and usually kept in holding *units* (e.g. ponds, tanks) which can lead to clusters of *infection* within *aquaculture establishments*. Similarly, wild *aquatic animal* populations are not evenly distributed within a *zone*. For these reasons, multi-stage sampling is recommended. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. *aquaculture establishments* or villages) are selected. At the second stage, animals are selected for testing from each of the first-stage sampling groups.

In the case of a complex (e.g. multi-level) population structure, multi-stage sampling may be used, and the data analysed accordingly.

2. Dossier of evidence

The sources of evidence should be fully described. A survey should include a description of the sampling strategy used for the selection of *units* for testing. For complex *surveillance* systems, a full description of the system is required, including consideration of any *biases* that may be inherent in the system. Evidence to support claims of freedom from *disease* can use non-random sources of information, provided that, overall, any *biases* introduced subsequently favour the detection.

3. Statistical methodology

The analysis and interpretation of test results from a survey shall be in accordance with the provisions of this chapter and consider the following factors:

a) the survey design;

b) the diagnostic *sensitivity* and *specificity* of the test or test system;

c) the design *prevalence* (or *prevalences* where a multi-stage design is used).

Analysis of data for evidence of freedom from *disease* involves estimating the probability (alpha) that the evidence observed (i.e. negative results for *disease* detection from *surveillance*) could have been produced assuming that *infection* is present in the population at or above the minimum specified *prevalence* (the design *prevalence*). The confidence in (or, equivalently, the *sensitivity* of) the survey that produced the evidence is equal to 1–alpha. If the confidence level exceeds a pre-set threshold, the evidence is deemed adequate to demonstrate freedom from *infection*. The required level of confidence (that the survey would detect *infection* if *infection* were present at or above the specified level) should be equal to or greater than 95%.

The power (probability that the survey would report that no *infection* is present if *infection* is truly not present) is by convention set to 80%, but may be adjusted in accordance with the country’s or *zone*’s requirements.

Statistical analysis of *surveillance* data often requires assumptions about population parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or similar populations, and epidemiology of the *disease*.

The values for design *prevalence* used in calculations should be based on the epidemiology of the disease. Justification for the selection of design *prevalence* values should be provided, and should be based on the following recommendations:

a) At the individual animal level (e.g. *prevalence* of infected animals in a pond, tank or net pen, or cages), the design *prevalence* is based on the epidemiology of the *infection* in the population. It is equal to the minimum expected *prevalence* of *infection* in the *study population*, if the *infection* had become established in that population. A suitable design *prevalence* value at the animal level may be:

i) between 1% and 5% for *infections* that are present in a small part of the population, e.g. are transmitted slowly or have been recently introduced, etc.;

ii) over 5% for highly transmissible and persistent *infections*;

iii) if reliable information, including expert opinion, on the expected *prevalence* in an infected population is not available, a value of 2% should be used for the design *prevalence*.

b) At higher levels (e.g. net pen or cage, pond, *aquaculture establishments*, village, etc.) the design *prevalence* should be based on empirical evidence and reflect the expected behaviour of the *infection*. A higher establishment-level design *prevalence* can be used for *diseases* which spread rapidly between pens or cages, and establishments. *Diseases* which are transient or less contagious require lower design *prevalences*:

i) a suitable design *prevalence* value for the first level of clustering (e.g. proportion of infected establishments in a *zone*) is normally not greater than 2%. If a higher design *prevalence* is selected, it should be justified.

4. Risk-based sampling

*Risk*-based sampling is an approach to identify and sample populations that have the greatest likelihood of *infection*. It can be applied to the design of surveys to demonstrate freedom from *disease* for a country, *zone* or *compartment*. A key advantage of *risk*-based sampling is that it can improve the efficiency of *surveillance* to demonstrate freedom from *disease* compared to random sampling approaches.

*Risk*-based sampling requires the identification of *risk*-factors that are applied to *bias* sample collection to populations of *aquatic animals* considered most likely to be infected if the specific *disease* had been introduced and had established. Where *risk*-based sampling is used for demonstration of freedom, the *risk* factors that underpin survey design, and the evidence or assumptions for their selection, should be documented. Where existing *risk* *assessments* are available, these may be utilised to identify *risk* factors associated with *disease* introduction, exposure and establishment. The identification of appropriate *risk* factors may include consideration of:

a) the possible pathways of *disease* introduction (e.g. through *aquatic animals*, *aquatic animal products*, *feed*, fomites, *vectors* and water);

b) proximity of susceptible populations to sources of *disease* exposure (e.g. to *aquatic animal* processing facilities, or ports);

c) environmental or husbandry conditions that are permissive for *disease* establishment (e.g. temperature, salinity, production system type, habitat type, exposure to recent stressors);

d) conditions that are conducive for development of clinical *disease*; including the species or life stages that are most susceptible to clinical *disease*;

e) evidence of morbidity or mortality.

5. Test characteristics

All *surveillance* involves performing one or more tests for evidence of the presence of current or past *infection*, ranging from laboratory assays to farmer observations. The performance level of a test is described in terms of its diagnostic *sensitivity* and *specificity*. Imperfect *sensitivity* or *specificity* impact on the interpretation of *surveillance* results, and should be taken into account in the analysis of *surveillance* data. For example, in the case of a test with imperfect diagnostic *specificity*, if the population is free of *disease* or has a very low *prevalence* of *infection*, all or a large proportion of positive tests will be false. Samples that test positive should be confirmed or refuted using a second highly specific test. Where more than one test is used (sometimes called using tests in series or parallel), the *sensitivity* and *specificity* of the test combination should be calculated.

All calculations should take the performance level (*sensitivity* and *specificity*) of any tests used into account. Information on test characteristics provided in the relevant disease-specific chapter of the *Aquatic Manual* should be used unless more appropriate information is available. The estimate of test *sensitivity* when the test was used in apparently healthy *aquatic animals* should be used. Samples should not be pooled before testing, unless approved in the relevant disease-specific chapter of the *Aquatic Manual*. If pooled testing is used, the results of testing should be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pooled testing procedure, and for the applicable pool sizes being used.

6. Sample size

In surveys conducted to demonstrate the absence or presence of an *infection*, the number of units to be sampled from a population should be calculated, using a statistically valid technique that takes at least the following factors into account:

a) the *sensitivity* and *specificity* of the diagnostic test,

b) the design *prevalence* (or *prevalences* where a multi-stage design is used),

c) the level of confidence that is desired of the survey results.

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

a) the size of the population (but it is acceptable to assume that the population is infinitely large),

b) the desired power of the survey.

Software for the calculation of sample sizes at varying parameter values are available. Table 1.2. provides examples of sample sizes generated by the software for a type I and type II error of 5% (i.e. 95% confidence and 95% statistical power). However, this does not mean that a type 1 and type 2 error of 0.05 should always be used. For example, using a test with *sensitivity* and *specificity* of 99%, 528 *units* should be sampled. If nine or less of those *units* test positive, the population can still be considered free of the *infection* at a design *prevalence* of 2%, provided that all efforts are made to ensure that all presumed false positives are indeed false (i.e. by use of a second highly specific assay). This means that there is a 95% confidence that the *prevalence* is 2% or lower, which reflects the fact that false negative results can occur. Incorrectly concluding that a population is free can be reduced by increasing the sample size and using more than one assay but cannot be completely eliminated.

In the case in which the values of *sensitivity* and *specificity* are not known (e.g. no information is available in the relevant disease-specific chapter of the *Aquatic Manual*), they should not automatically be assumed to be 100%. All positive results should be included and discussed in any report regarding that particular survey, and all efforts should be made to ensure that all presumed false positives are indeed false.

7. Multi-stage structured survey design

In general, a survey to demonstrate freedom at *zone* or *country* level should use a multi-stage design. The first sampling level is often *aquaculture establishments* (or villages) or populations of wild susceptible species, and the second stage may be ponds or individual animals within the establishment (or village) or defined stocks within a wild population. At each level, design levels need to be set and sample sizes calculated.

8. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

Table 1.2. Sample sizes for different design *prevalences* and test characteristics.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Design prevalence (%)** | **Sensitivity (%)** | **Specificity (%)** | **Sample size** | **Maximum number of  false positive if the  population is free** |
| 2 | 100 | 100 | 149 | 0 |
| 2 | 100 | 99 | 524 | 9 |
| 2 | 100 | 95 | 1,671 | 98 |
| 2 | 99 | 100 | 150 | 0 |
| 2 | 99 | 99 | 528 | 9 |
| 2 | 99 | 95 | 1,707 | 100 |
| 2 | 95 | 100 | 157 | 0 |
| 2 | 95 | 99 | 542 | 9 |
| 2 | 95 | 95 | 1,854 | 108 |
| 2 | 90 | 100 | 165 | 0 |
| 2 | 90 | 99 | 607 | 10 |
| 2 | 90 | 95 | 2,059 | 119 |
| 2 | 80 | 100 | 186 | 0 |
| 2 | 80 | 99 | 750 | 12 |
| 2 | 80 | 95 | 2,599 | 148 |
| 5 | 100 | 100 | 59 | 0 |
| 5 | 100 | 99 | 128 | 3 |
| 5 | 100 | 95 | 330 | 23 |
| 5 | 99 | 100 | 59 | 0 |
| 5 | 99 | 99 | 129 | 3 |
| 5 | 99 | 95 | 331 | 23 |
| 5 | 95 | 100 | 62 | 0 |
| 5 | 95 | 99 | 134 | 3 |
| 5 | 95 | 95 | 351 | 24 |
| 5 | 90 | 100 | 66 | 0 |
| 5 | 90 | 99 | 166 | 4 |
| 5 | 90 | 95 | 398 | 27 |
| 5 | 80 | 100 | 74 | 0 |
| 5 | 80 | 99 | 183 | 4 |
| 5 | 80 | 95 | 486 | 32 |

Article 1.4.17.

**Combining multiple sources of information**

Pathway 1 to achieving *disease* freedom (absence of *susceptible species*) relies on a range of data sources. Pathway 2 to achieving *disease* freedom (historical freedom) will primarily use evidence from *passive* *surveillance,* which may come from multiple sources (as described in Article 1.4.8.) and may be supplemented with *targeted surveillance* if necessary (as described in Article 1.4.12.). *Passive* *surveillance* information can also be used to provide additional support for *disease* freedom, based on *targeted surveillance* (i.e. pathway 3). Estimates of the confidence in each data source may be combined to provide an overall level of confidence of freedom from *disease* for the combined data sources. The methodology used to combine the estimates from multiple data sources:

1) should be scientifically valid and fully documented, including references to published material; and

2) should, where possible, take into account any lack of statistical independence between different data sources.

If combining evidence from different sources including *passive surveillance* and *targeted surveillance*, a *Competent Authority* may choose to use various approaches, such as a scenario tree modelling approach.

Article 1.4.18.

**Diagnostic confirmation of a listed disease or an emerging disease**

A *Competent Authority* is required to provide *disease* *notifications* as described in Chapter 1.1.

The relevant disease-specific chapter of the *Aquatic Manual* provides recommendations for the appropriate diagnostic methods for presumptive and confirmatory diagnostic purposes. The assays recommended for these purposes are presented in Table 4.1 of the relevant disease-specific chapter of the *Aquatic Manual*.

The recommended standards of diagnostic evidence to confirm *infection* in either apparently healthy or clinically diseased animals are provided in Section 6 of the relevant disease-specific chapter of the *Aquatic Manual*. These case definitions for suspect and confirmed cases have been developed to support decision making in relation to trade and for confirmation of *disease* status at the level of a country, *zone* or *compartment*. A *Competent Authority* may choose to apply a lower standard of evidence for *disease* confirmation within its *territory* for known endemic *diseases*.

If standards of evidence are not met to confirm a suspect case of *disease* in accordance with the case definitions in Section 6 of the relevant disease-specific chapter of the *Aquatic Manual*, ongoing investigation is required until sufficient evidence is obtained to either:

1) exclude the presence of a *listed disease* or an *emerging disease*; or

2) to confirm the presence of a *listed disease* or an *emerging disease*.

If a Member Country does not have access to a laboratory with the capability to undertake the necessary diagnostic tests and which meets the requirements of Chapter 1.1.1. of the *Aquatic Manual* it should seek advice from the relevant OIE Reference Laboratory.

In all circumstances, Member Countries should comply with the requirements described in Chapter 1.1. to provide transparent and timely *notification* to allow Member Countries to take appropriate action to prevent the transboundary spread of important *diseases* of *aquatic animals*.

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

**Note:** time periods in these model articles will be determined by the Aquatic Animals Commission for each disease-specific chapter based on criteria that will be included in 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. Where a period is shown (e.g. ‘the last [X] years’) this indicates an intended default period that may vary depending on the circumstances of each disease.

Article X.X.4.

[**Note**: this is a new article that will outline general requirements for making a self-declaration of freedom for a country, zone or compartment.]

**Requirements for self-declaration of freedom from infection with [PATHOGEN X]**

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

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

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

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

Article X.X.5.

[**Note**: this article will replace the existing Article X.X.4.]

**Country free from infection with [PATHOGEN X]**

If a country shares water bodies ~~a~~ *~~zone~~*with ~~one or more~~ other countries, it can only make a self-declaration  [of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) from infection with [PATHOGEN X] if ~~the~~ all shared water bodies are within countries or [*zones*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) declared free from infection with [PATHOGEN X] (see Article [X.X.6.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_vhs.htm#article_vhs.5.)).

As described in Article [1.4.X.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#article_aqua_ani_surveillance.6.), a Member Country may make a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) from infection with [PATHOGEN X] for its entire *territory* if it can demonstrate that:

1) none of the [*susceptible species*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_espece_sensible) referred to in Article [X.X.2.](https://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_ihn.htm#article_ihn.2.) are present and [*basic biosecurity conditions*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least the last ~~[two] years~~ [six] months;

OR

2) there has been no occurrence of infection with [PATHOGEN X] for at least the last [ten] years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with [PATHOGEN X], as described in the corresponding chapter of the [*Aquatic Manual*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_manuel_aquatique); and

b) [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique)as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for at least the last [two] years without detection of [PATHOGEN X], and~~:~~

~~a)~~ [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met ~~from~~ for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) from infection with [PATHOGEN X] and subsequently lost its free status due to the detection of [PATHOGEN X] but the following conditions have been met:

a) on detection of [PATHOGEN X], the affected area was declared an [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) and a [*protection zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_de_protection) was established; and

b) infected populations within the [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) have been killed and disposed of by means that minimise the likelihood of further transmission of [PATHOGEN X], and the appropriate [*disinfection*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_desinfection) procedures (as described in Chapter [4.~~3~~4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_disinfection.htm#chapitre_disinfection)) have been completed followed by *fallowing* as described in Chapter 4.~~6~~7.; and

c) previously existing [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been reviewed and modified as necessary and have continuously been in place since eradication of infection with [PATHOGEN X]; and

d) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for:

i) at least the last [two] years in wild and farmed *susceptible species* without detection of [PATHOGEN X]; or

ii) at least the last [one] year without detection of [PATHOGEN X] if affected ~~farms~~ *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

In the meantime, part or all of the country, apart from the *infected* and *protection zones,* may be declared a free [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) provided that such a part meets the conditions in point 2 of Article [X.X.6.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_vhs.htm#article_vhs.5.)

Article X.X.6.

[**Note**: this new article for zone freedom is based on the existing Article X.X.5.]

**Zone free from infection with [PATHOGEN X]**

If a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) extends over the *territory* of more than one country, it can only be declared a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) free from infection with [PATHOGEN X] if all of the relevant [*Competent Authorities*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_autorite_competente) confirm that all relevant conditions have been met.

As described in Article [1.4.X.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#article_aqua_ani_surveillance.6.), a Member Country may make a self-declaration of freedom from infection with [PATHOGEN X] for a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) within its [*territory*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_territoire) if it can demonstrate that:

1) none of the [*susceptible species*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_espece_sensible) referred to in Article X.X.2. [~~10.6.2~~.](https://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_ihn.htm#article_ihn.2.) are present and [*basic biosecurity conditions*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least the last ~~[two] years~~ [six] months;

OR

2) there has been no occurrence of infection with [PATHOGEN X] for at least the last [ten] years, and;

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with [PATHOGEN X], as described in Article 1.4.8. of Chapter 1.4. ~~the corresponding chapter of the~~ [*~~Aquatic Manual~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_manuel_aquatique); and

b) [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique)as described in Chapter 1.4. have been continuously met for the [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) for at least the last [ten] years;

OR

3) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place in the [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) for at least the last [two] years without detection of [PATHOGEN X], and:

~~a)~~ [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) for a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) from infection with [PATHOGEN X] and subsequently lost its free status due to the detection of [PATHOGEN X] in the [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) but the following conditions have been met:

a) on detection of [PATHOGEN X], the affected area was declared an [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) and a [*protection zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_de_protection) was established; and

b) infected populations within the [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) have been killed and disposed of by means that minimise the likelihood of further transmission of [PATHOGEN X], and the appropriate [*disinfection*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_desinfection) procedures (as described in Chapter [4.~~3~~4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_disinfection.htm#chapitre_disinfection)) have been completed followed by *fallowing* as described in Chapter 4.~~6.~~7.; and

c) previously existing [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been reviewed and modified as necessary and have continuously been in place since eradication of infection with [PATHOGEN X]; and

d) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for at least the last [two] years without detection of [PATHOGEN X].

Article X.X.7.

[**Note**: this is a new article to address free compartments].

**Compartment free from infection with [PATHOGEN X]**

As described in Article [1.4.X.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#article_aqua_ani_surveillance.6.), a Member Country may make a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie)from infection with [PATHOGEN X] for a[*compartment*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_compartiment) within its [*territory*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_territoire) if it can demonstrate that:

1) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place in the [*compartment*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_compartiment) for at least the last [two] years without detection of [PATHOGEN X], and~~:~~

~~a)~~ [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) for a *compartment* from infection with [PATHOGEN X] and subsequently lost its free status due to the detection of [PATHOGEN X] in the *compartment* [*~~zone~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone)but the following conditions have been met:

a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of [PATHOGEN X], the appropriate [*disinfection*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_desinfection) procedures (as described in Chapter [4.~~3.~~4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_disinfection.htm#chapitre_disinfection)) have been completed, and the *compartment* has been fallowed as described in Chapter 4.~~6.~~7. ~~for at least [X] weeks~~; and

b) previously existing [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique), including the *compartment* *biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles X.X.9. and X.X.10. as appropriate; and

c) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for at least the last [one] year without detection of [PATHOGEN X].

Article X.X.8.

[**Note**: this article is based on the current Article X.X.6.]

**Maintenance of free status**

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

~~A country or~~ [*~~zone~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) ~~that is declared free from infection with [PATHOGEN X] following the provisions of point 1 of in Articles~~[~~X.X.5.~~](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_vhs.htm#article_vhs.5.) ~~or X.X.6. (as relevant) may maintain its status as free from infection with [PATHOGEN X] provided that~~ [*~~basic biosecurity conditions~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) ~~are continuously maintained.~~

~~A country or~~ [*~~zone~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) ~~that is declared free from infection with [PATHOGEN X] following the provisions of point 2 of in Article~~[~~X.X.5.~~](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_vhs.htm#article_vhs.4.) ~~may discontinue~~ [*~~targeted surveillance~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique) ~~and maintain its free status provided that conditions are conducive to clinical expression of infection with [PATHOGEN X], as described in the corresponding chapter of the~~ [*~~Aquatic Manual~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_manuel_aquatique)~~, and~~ [*~~basic biosecurity conditions~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) ~~are continuously maintained.~~

~~For declared free~~ [*~~zones~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) ~~or~~ [*~~compartments~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_compartiment) ~~within the~~ *~~territory~~* ~~of a country not declared free,~~ [*~~targeted surveillance~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique) ~~should be continued at a level determined by the~~ [*~~Aquatic Animal Health Service~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_services_sante) ~~on the basis of the likelihood of~~ [*~~infection~~*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_infection)*~~.~~*

~~In all cases where conditions are not conducive to clinical expression of infection with [PATHOGEN X], ongoing~~ *~~targeted surveillance,~~* ~~as described in Chapter~~ [~~1.4.~~](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance)~~, is required at a level that maintains the level of confidence in freedom from infection with [PATHOGEN X] that was required for the initial declaration of freedom.~~

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**(CLEAN VERSION)**

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

Article X.X.4.

**Requirements for self-declaration of freedom from infection with [PATHOGEN X]**

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

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

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

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

Article X.X.5.

**Country free from infection with [PATHOGEN X]**

If a country shares water bodies with other countries, it can only make a self-declaration  [of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) from infection with [PATHOGEN X] if all shared water bodies are within countries or [*zones*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) declared free from infection with [PATHOGEN X] (see Article [X.X.6.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_vhs.htm#article_vhs.5.)).

As described in Article [1.4.X.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#article_aqua_ani_surveillance.6.), a Member Country may make a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) from infection with [PATHOGEN X] for its entire *territory* if it can demonstrate that:

1) none of the [*susceptible species*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_espece_sensible) referred to in Article [X.X.2.](https://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_ihn.htm#article_ihn.2.) are present and [*basic biosecurity conditions*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with [PATHOGEN X] for at least the last [ten] years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with [PATHOGEN X], as described in the corresponding chapter of the [*Aquatic Manual*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_manuel_aquatique); and

b) [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique)as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for at least the last [two] years without detection of [PATHOGEN X], and [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) from infection with [PATHOGEN X] and subsequently lost its free status due to the detection of [PATHOGEN X] but the following conditions have been met:

a) on detection of [PATHOGEN X], the affected area was declared an [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) and a [*protection zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_de_protection) was established; and

b) infected populations within the [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) have been killed and disposed of by means that minimise the likelihood of further transmission of [PATHOGEN X], and the appropriate [*disinfection*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_desinfection) procedures (as described in Chapter [4.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_disinfection.htm#chapitre_disinfection)) have been completed followed by *fallowing* as described in Chapter 4.7.; and

c) previously existing [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been reviewed and modified as necessary and have continuously been in place since eradication of infection with [PATHOGEN X]; and

d) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for:

i) at least the last [two] years in wild and farmed *susceptible species* without detection of [PATHOGEN X]; or

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

In the meantime, part or all of the country, apart from the *infected* and *protection zones,* may be declared a free [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) provided that such a part meets the conditions in point 2 of Article [X.X.6.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_vhs.htm#article_vhs.5.)

Article X.X.6.

**Zone free from infection with [PATHOGEN X]**

If a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) extends over the *territory* of more than one country, it can only be declared a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) free from infection with [PATHOGEN X] if all of the relevant [*Competent Authorities*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_autorite_competente) confirm that all relevant conditions have been met.

As described in Article [1.4.X.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#article_aqua_ani_surveillance.6.), a Member Country may make a self-declaration of freedom from infection with [PATHOGEN X] for a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) within its [*territory*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_territoire) if it can demonstrate that:

1) none of the [*susceptible species*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_espece_sensible) referred to in Article X.X.2. are present and [*basic biosecurity conditions*](https://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with [PATHOGEN X] for at least the last [ten] years, and;

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with [PATHOGEN X], as described in Article 1.4.8. of Chapter 1.4. and

b) [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique)as described in Chapter 1.4. have been continuously met for the [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) for at least the last [ten] years;

OR

3) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place in the [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) for at least the last [two] years without detection of [PATHOGEN X], and [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least [one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) for a [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) from infection with [PATHOGEN X] and subsequently lost its free status due to the detection of [PATHOGEN X] in the [*zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone) but the following conditions have been met:

a) on detection of [PATHOGEN X], the affected area was declared an [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) and a [*protection zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_de_protection) was established; and

b) infected populations within the [*infected zone*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_zone_infectee) have been killed and disposed of by means that minimise the likelihood of further transmission of [PATHOGEN X], and the appropriate [*disinfection*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_desinfection) procedures (as described in Chapter [4.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_disinfection.htm#chapitre_disinfection)) have been completed followed by *fallowing* as described in Chapter 4.7.; and

c) previously existing [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been reviewed and modified as necessary and have continuously been in place since eradication of infection with [PATHOGEN X]; and

d) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for at least the last [two] years without detection of [PATHOGEN X].

Article X.X.7.

**Compartment free from infection with [PATHOGEN X]**

As described in Article [1.4.X.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#article_aqua_ani_surveillance.6.), a Member Country may make a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie)from infection with [PATHOGEN X] for a[*compartment*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_compartiment) within its [*territory*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_territoire) if it can demonstrate that:

1) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place in the [*compartment*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_compartiment) for at least the last [two] years without detection of [PATHOGEN X], and [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique) have been continuously met for at least [one] year prior to commencement of *targeted surveillance*;

OR

2) it previously made a [self-declaration of freedom](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_auto_declaration_de_l_absence_de_maladie) for a *compartment* from infection with [PATHOGEN X] and subsequently lost its free status due to the detection of [PATHOGEN X] in the *compartment* but the following conditions have been met:

a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of [PATHOGEN X], the appropriate [*disinfection*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_desinfection) procedures (as described in Chapter [4.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_disinfection.htm#chapitre_disinfection)) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

b) previously existing [*basic biosecurity conditions*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_conditions_elementaires_de_securite_biologique), including the *compartment* *biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles X.X.9. and X.X.10. as appropriate; and

c) [*targeted surveillance*](http://www.oie.int/index.php?id=171&L=0&htmfile=glossaire.htm#terme_surveillance_specifique), as described in Chapter [1.4.](http://www.oie.int/index.php?id=171&L=0&htmfile=chapitre_aqua_ani_surveillance.htm#chapitre_aqua_ani_surveillance), has been in place for at least the last [one] year without detection of [PATHOGEN X].

Article X.X.8.

**Maintenance of free status**

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**ASSESSMENT OF *OSTREA EQUESTRIS* AND REASSESSMENT OF *OSTREA STENTINA* AS SUSCEPTIBLE SPECIES TO INFECTION WITH *BONAMIA EXITIOSA***

*Background*

In response to a comment questioning whether *Ostrea stentina* and *Ostrea equestris* should be considered as distinct species, the Aquatic Animals Commission requested that the *ad hoc* Group on Susceptibility of mollusc species to infection with OIE listed diseases (the *ad hoc* Group) review any new scientific information and provide its opinion on this. If the species were distinct, the Commission requested that the *ad hoc* Group determine the impact on the species proposed for inclusion in Article 11.2.2. of Chapter 11.2. Infection with *Bonamia exitiosa.*

The November - December 2020 report on the susceptibility of mollusc species to infection with *Bonamia exitiosa* can be found on the [OIE website](https://www.oie.int/en/what-we-do/standards/standards-setting-process/ad-hoc-groups/#ui-id-3).

The November-December 2020 *ad hoc* Group report noted that “According to WoRMS, *Ostrea stentina* and *Ostrea equestris* are considered distinct species, however there are some papers (Hill *et al*., 2010; Shilts *et al*., 2007) that consider them synonyms.” Based on this information the *ad hoc* Group considered the two species synonyms for their assessment of species susceptible to infection with *Bonamia exitiosa*.

At its February 2021 meeting, based on the *ad hoc* Group’s recommendation that *Ostrea stentina* and *Ostrea equestris* were synonyms, the Aquatic Animals Commission proposed to include *Ostrea stentina* in Article 11.2.2. of Chapter 11.2. of the *Aquatic Code*.

***Ad hoc* Group review of evidence and recommendations (January 2022)**

The *ad hoc* Group reviewed the scientific evidence regarding the taxonomic status of flat oysters to resolve whether *Ostrea equestris* and *Ostrea stentina* are synonyms or distinct species for the purposes of assessing susceptibility to infection with *Bonamia exitiosa*.

The status of the complex *Ostrea equestris / Ostrea stentina / Ostrea aupouria* has been controversial for many years. Studies investigating this issue have been based on both morphological and phylogenetical data. The *ad hoc* Group reviewed new evidence on phylogenetic analysis using genetic distances estimated from COI sequences and contacted several experts to support its recommendation to the Aquatic Animals Commission.

In light of new scientific evidence and personal communications, the *ad hoc* Group recommended that *Ostrea stentina* and *Ostrea equestris* be considered distinct species. The *ad hoc* Group also noted that the two species had a different geographic distribution. *Ostrea equestris* is distributed in the Americas (North and South) and the western Pacific (New Zealand), while *Ostrea stentina* is distributed in the eastern Atlantic (Tunisia, Spain).

Based on the recommendation that *Ostrea equestris* and *Ostrea stentina* are distinct species, the *ad hoc* Group assessed *Ostrea equestris* and reassessed *Ostrea stentina* for listing as susceptible to infection with *Bonamia exitiosa*.

**Methodology**

* The AHG applied criteria, as outlined in Article 1.5.3 of the *Aquatic Code*), to assess *Ostrea equestris* and reassess *Ostrea stentina* in order to determine susceptibility to infection with *Bonamia exitiosa*. The same methodology and considerations outlined in the *ad hoc* Group report (<https://www.oie.int/app/uploads/2021/11/a-ahg-susceptibility-of-mollusc-species-to-infection-with-oie-listed-diseases-november-december-2020.pdf>) was applied to these assessments.

**Assessments of host susceptibility to infection with *Bonamia exitiosa***

***Summary***

The *ad hoc* Group agreed that Ostrea *equestris* met the criteria for listing as susceptible to infection with *Bonamia exitiosa* in accordance with Chapter 1.5. of the *Aquatic Code*. *Ostrea equestris* was proposed to be included in Article 11.2.2. of the *Aquatic Code*. The outcomes of this assessment are shown in Table 1.

The *ad hoc* Group agreed that *Ostrea stentina* had incomplete evidence of susceptibility and proposed it be removed from Article 11.2.2. of the *Aquatic Code* and be included in Section 2.2.2. of Chapter 2.4.2., Infection with *Bonamia* *exitiosa* of the *Aquatic Manual*. The outcomes of this re-assessment are shown in Table 1.

Table 1. Assessments for *O.equestris* and *O.stentina* for susceptibility to infection with *B. exitiosa* .

| **Family** | **Scientific name** |  | **Common name** | **Stages 1: Route of infection** | **Stage 2: Pathogen identification** | | **Stage 3: Evidence for infection** | | | | | | | | **Individual Outcome** | | **References** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **A** | | **B** | | **C** | | **D** | |
| **Overall Score 1** | | | | | | | | | | | | | | | | | |
| Ostreidae | *Ostrea equestris* | Crested oyster0F0F[[1]](#footnote-2) | | N1F1F[[2]](#footnote-3) | PCR and sequencing (18S & ITS) | YES | | ND | | YES | | YES | | 1 | | Hill *et al*., 2014 | |
| **Overall Score 2** | | | | | | | | | | | | | | | | | |
| Ostreidae | *Ostrea stentina* | Dwarf oyster | | N | PCR & sequencing  (18S &ITS) | YES | | ND | | ND | | YES | | 1 | | Hill *et al*., 2010 | |

**Assessment Table Key**

N: Natural infection

E: Experimental (non-invasive)

EI: Experimental (invasive)

YES: Demonstrates criterion is met.

NO: Criterion is not met.

ND: Not determined.

**Species specific comments**

*Ostrea equestris*: Only one paper was available for the assessment (Hill *et al*., 2014) but was determined by the *ad hoc* Group to provide sufficient information to demonstrate that the criteria for susceptibility be scored as a ‘1’ as there were multiple collections of oysters from different locations and time periods.

*Ostrea stentina:* Only one study (Hill *et al*., 2010) was available for the assessment and within that study there was only one sample collected from one location at one time point. The *ad hoc* Group was unable to find any additional studies or evidence to corroborate the *O. stentina* assessment. Consequently, even though the assessment criteria were met for the one individual animal sampled and that the paper was assigned an outcome of ‘1’, based on the limited data presented in Hill *et al.,* 2010, the *ad hoc* Group assessed *Ostrea stentina* as an overall score of ‘2’

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1. The common names of mollusc species are in accordance with FAOTERM (http://www.fao.org/faoterm/collection/faoterm/en/). Where the common mollusc name was not found in FAOTERM, the naming was done in accordance with https://www.sealifebase.ca. [↑](#footnote-ref-2)
2. Samples were investigated from geographically separated locations and time periods. [↑](#footnote-ref-3)