92nd General Session
World Organisation for Animal Health
World Assembly
Paris, May 25-29, 2025
GS

92GS/Tech-07/En

Original: English

April 2025

Activities of the Specialist Commissions

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Proposed Revisions to the *Aquatic Code*
and the *Aquatic Manual*

[Technical Working Document]

World Organisation
for Animal Health

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1. Introduction

1. Since the 91st General Session in May 2024, the Aquatic Animal Health Standards Commission (the Aquatic Animals Commission) met twice from 18 to 25 September 2024 and from 12 to 19 February 2025. Among its activities, the Commission progressed work on the development of new and revised texts of the *Aquatic Animals Health Code* (the *Aquatic Code*) and the *Manual of Diagnostic Tests for Aquatic Animals* (the *Aquatic Manual*), in accordance with its work plan. Details of the Aquatic Animals Commission's meetings are available on the Delegates' website and the WOAH website.

2. This document provides background information for each of the new and revised texts of the *Aquatic Code* and the *Aquatic Manual* that will be proposed for adoption at the 92nd General Session in May 2025. When revising these texts, the Commission considered comments submitted by Members, recommendations from several *ad hoc* Group reports, as well as Reference Laboratory experts. The Aquatic Animals Commission also worked in cooperation with the Terrestrial Animal Health Standards Commission and the Biological Standards Commission on any relevant activities.

3. Details of the Commission's most recent considerations of comments received on draft texts circulated for comment were provided in the Commission's September 2024 and February 2025 reports. **The Commission encourages Members to refer to these reports for more details on the revised texts to be proposed for adoption**.

4. The revisions to the Aquatic *Code* and the *Aquatic Manual* presented in Annexes 5 to 18, 22 to 27, and 30 to 31 will be proposed for adoption at the 92nd General Session. The annex numbers used in this document align with the annex numbers provided in the Commission's February 2025 report. However, Annex 30 and Annex 31 are new annexes and present chapters that will be deleted from the *Aquatic Code* as outlined in the Commission's February 2025 report. Proposed revisions are shown in the usual manner by 'double underline' and strikethrough' for consistency.

1. *Aquatic Code* texts to be proposed for adoption

1.1 New Chapter 4.X. 'Emergency disease preparedness' (Annex 5)

5. This new Chapter 4.X. provides guidance on emergency disease preparedness for aquatic animal diseases. This new chapter was drafted at the same time as the new Chapter 4.Y. 'Disease outbreak management' as the chapters are closely related.

6. The draft chapter has been circulated for comment three times; the first time was in the September 2023 Commission report.

7. The new Chapter 4.X. 'Emergency disease preparedness' is presented in **Annex 5** and will be proposed for adoption at the 92nd General Session in May 2025.

1.2 New Chapter 4.Y. 'Disease outbreak management' (Annex 6)

8. This new Chapter 4.Y. provides guidance on disease outbreak management for aquatic animal diseases. This new chapter was drafted at the same time as the new Chapter 4.X. 'Emergency disease preparedness' as the chapters are closely related.

9. The draft chapter has been circulated for comment three times; the first time was in the September 2023 Commission report.

10. The new Chapter 4.Y. 'Disease outbreak management' is presented in **Annex 6** and will be proposed for adoption at the 92nd General Session in May 2025.

1.3 Deletion of Chapter 4.6. 'Contingency planning' (Annex 30)

11. The adoption of the new Chapters 4.X. 'Emergency disease preparedness' and 4.Y. 'Disease outbreak management' will make Chapter 4.6. obsolete. Consequently, Chapter 4.6. is proposed for deletion.

12. The proposed deletion of Chapter 4.6. has been reported in Commission reports twice; the first time was in the September 2024 Commission report.

13. The deletion of Chapter 4.6. 'Contingency planning' is presented in **Annex 30** and will be proposed for adoption at the 92nd General Session in May 2025.

1.4 New Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' (Annex 7)

14. This new Chapter 4.Z. provides guidance on the risk management of aquatic animal genetic material beyond the importation of disinfected eggs for aquaculture detailed in the *Aquatic Code*. The new chapter was developed in collaboration with industry experts to provide recommendations for safe trade in milt and fertilised eggs of fish from areas which have not been declared free from infection with a listed disease in accordance with Chapter 1.4. 'Aquatic animal disease surveillance'.

15. The draft chapter has been circulated for comment three times; the first time was in the September 2023 Commission report.

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

1.5 Model Article 10.X.10. of Chapter 10.5. 'Infection with salmonid alphavirus', Chapter 10.6. 'Infection with infectious haematopoietic necrosis virus' and Chapter 10.10. 'Infection with viral haemorrhagic septicaemia virus' and Article 10.4.15. of Chapter 10.4. 'Infection with infectious salmon anaemia virus' (Annex 8)

17. Revisions proposed in the model Article 10.X.10. are to integrate provisions of the new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' into relevant fish disease-specific chapters. The Commission agreed the revised model Article 10.X.10. was applicable to Chapters 10.5., 10.6., 10.10. and Article 10.4.15. of Chapter 10.4.

18. The revised model article has been circulated for comment three times; the first time was in the September 2023 Commission report.

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

1.6 Model Article 10.X.15. of Chapter 10.5. 'Infection with salmonid alphavirus', Chapter 10.6. 'Infection with infectious haematopoietic necrosis virus' and Chapter 10.10. 'Infection with viral haemorrhagic septicaemia virus' and Article 10.4.20. of Chapter 10.4. 'Infection with infectious salmon anaemia virus' (Annex 9)

20. Revisions proposed in the model Article 10.X.15. are to integrate the provisions of new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish' into the relevant fish disease-specific chapters. The Commission agreed the revised model Article 10.X.15. was applicable to Chapters 10.5., 10.6., 10.10. and Article 10.4.20. of Chapter 10.4.

21. The revised model article has been circulated for comment three times; the first time was in the September 2023 Commission report.

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

1.7 Glossary definitions for 'fertilised eggs', 'gametes' 'collection and incubation centre' and 'ornamental aquatic animal' (Annex 10)

23. Revisions proposed to the Glossary definitions for 'fertilised eggs' and 'gametes' and a new definition for 'collection and incubation centre' for alignment of usage in the new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'.

24. A new Glossary definition for 'ornamental aquatic animal' has been proposed for alignment of usage in the new Chapter 5.X. 'Movement of ornamental aquatic animals'.

25. The revised and new Glossary definitions have been circulated for comment three times; the first time was in the September 2023 Commission report.

26. The revised Glossary definitions for 'fertilised eggs' and 'gametes' and new definitions for 'collection and incubation centre' and 'ornamental aquatic animal' are presented in **Annex 10** and will be proposed for adoption at the 92nd General Session in May 2025.

1.8 New Chapter 5.X. 'Movement of ornamental aquatic animals' (Annex 11)

27. This new Chapter 5.X. provides recommendations for managing the disease risks associated with the movement of ornamental aquatic animals and aligns with other provisions of the *Aquatic Code*.

28. The new chapter has been circulated for comment three times; the first time was in the September 2023 Commission report.

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

1.9 Periods of basic biosecurity conditions and targeted surveillance in Articles X.X.5.–X.X.7. for disease-specific chapters (Annex 12)

30. Revisions proposed for periods of basic biosecurity conditions and targeted surveillance in Article X.X.5. (country free from infection), X.X.6. (zone free from infection) and X.X.7. (compartment free from infection) are based on disease-specific assessments and are consistent with recommendations in Chapter 1.4. 'Aquatic animal disease surveillance'.

31. Revisions are proposed for Articles 8.X.5.–8.X.7. of Chapters 8.1. to 8.3., diseases of amphibians.

32. Revisions are proposed for Articles 9.X.5.–9.X.7. of Chapters 9.1. to 9.10., diseases of crustaceans.

33. Revisions are proposed for Articles 10.X.5.–10.X.7. of Chapters 10.1. to 10.7. and 10.9. to 10.11., diseases of fish; Chapter 10.8. is not included as it will be deleted with the adoption of Chapter 10.X. 'Infection with *Megalocytivirus pagrus1'* (refer to Item 1.14).

34. Revisions are proposed for Articles 11.X.5.–11.X.7. of Chapters 11.1. to 11.7., diseases of molluscs.

35. The revised articles have been circulated for comment two times; the first time was in the February 2024 Commission report.

36. The revised Articles X.X.5.–X.X.7. for all disease-specific chapters are presented in **Annex 12** and will be proposed for adoption at the 92nd General Session in May 2025.

1.10 Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus' (Annex13)

37. Revisions to the list of susceptible species in Article 9.9.2. of Chapter 9.9. are proposed. The Commission agreed to apply Article 1.5.9. 'Listing species at a taxonomic ranking of Genus or higher' and utilised considerations provided in the 2024 September Commission report when reviewing evidence of susceptibility.

38. The *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases November 2023 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

39. The revised article has been circulated for comment two times; the first time in the February 2024 Commission report.

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

1.11 Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with Aphanomyces invadans *(epizootic ulcerative syndrome)' (Annex 14)*

41. Revisions proposed to Article 10.2.1. include genus and family information for consistency with other disease-specific chapters.

42. Revisions to the list of susceptible species in Article 10.2.2. of Chapter 10.2. are proposed. The Commission agreed to apply Article 1.5.9. 'Listing species at a taxonomic ranking of Genus or higher' and utilised considerations provided in the 2024 September Commission report when reviewing evidence of susceptibility.

43. The *ad hoc* Group on Susceptibility of Fish Species to Infection with WOAH Listed Diseases April 2024 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

44. The revised articles have been circulated for comment one time; the first time in the September 2024 Commission report.

45. The revised Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)' are presented in **Annex 14** and will be proposed for adoption at the 92nd General Session in May 2025.

1.12 Articles 10.4.11. and 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia virus' (Annex 15)

46. Revisions proposed in Articles 10.4.11. and 10.4.12. of Chapter 10.4. are to address discrepancies in these articles between the English, French and Spanish editions of the *Aquatic Code*. Revisions are proposed in Article 10.4.11. in the French and Spanish editions, and in Article 10.4.12. in the English, French and Spanish editions.

47. The revised articles have been circulated for comment one time; the first time was in the September 2024 Commission report.

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

1.13 New Chapter 10.X. 'Infection with Megalocytivirus pagrus1*' (Annex 16)*

49. This new Chapter 10.X. was drafted to provide disease-specific information following the listing of infection with *Megalocytivirus pagrus1* that was adopted at the 91st General Session in May 2024.

50. The *ad hoc* Group on Susceptibility of Fish Species to Infection with WOAH Listed Diseases November 2022 report, provides details of the assessments undertaken to determine the proposed list of susceptible species included in Article 10.X.2. The Commission agreed to apply Article 1.5.9. 'Listing species at a taxonomic ranking of Genus or higher' and utilised considerations provided in the 2024 September Commission report when reviewing evidence of susceptibility.

51. The new chapter has been circulated for comment one time; the first time was in the September 2024 Commission report.

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

1.14 Deletion of Chapter 10.8. 'Infection with red sea bream iridovirus' (Annex 31)

53. The adoption of the new Chapter 10.X. 'Infection with *Megalocytivirus pagrus1*' will make Chapter 10.8. obsolete. Consequently, Chapter 10.8. is proposed for deletion.

54. The proposed deletion of Chapter 10.8. has been reported two times in Commission reports; the first time was in the September 2024 Commission report.

55. The deletion of Chapter 10.8. 'Infection with red sea bream iridovirus' is presented in **Annex 31** and will be proposed for adoption at the 92nd General Session in May 2025.

1.15 Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with Perkinsus olseni' *(Annex 17)*

56. Revisions proposed to Article 11.6.1. of Chapter 11.6. include genus and family information for consistency with other disease-specific chapters.

57. Revisions to the list of susceptible species in Article 11.6.2. of Chapter 11.6. are proposed.

58. The *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases December 2023 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

59. The revised articles have been circulated for comment two times; the first time in the February 2024 Commission report.

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

1.16 Articles 11.7.1. and 11.7.2. of Chapter 11.7. 'Infection with Xenohaliotis californiensis*' (Annex 18)*

61. Revisions proposed to Article 11.7.1. of Chapter 11.7. include genus and family information for consistency with other disease-specific chapters.

62. Revisions to the list of susceptible species in Article 11.7.2. of Chapter 11.7. are proposed.

63. The *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases June 2024 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

64. The revised articles have been circulated for comment one time; the first time in the September 2024 Commission report.

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

2. *Aquatic Manual* texts to be proposed for adoption

2.1 Sections 2.2.1. and 2.2.2. of Chapter 2.2.9. 'Infection with white spot syndrome virus' (Annex 22)

66. Revisions to the list of susceptible species in Section 2.2.1. 'Susceptible host species' of Chapter 2.2.9. are proposed. The Commission agreed to apply Article 1.5.9. 'Listing species at a taxonomic ranking of Genus or higher' and utilised considerations provided in the 2024 September Commission report when reviewing evidence of susceptibility.

67. Revisions to the list of species in Section 2.2.2. 'Species with incomplete evidence for susceptibility' of Chapter 2.2.9. are proposed.

68. The *ad hoc* Group on Susceptibility of Crustacean Species to Infection with WOAH Listed Diseases November 2023 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

69. The revised sections have been circulated for comment two times; the first time in the February 2024 Commission report.

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

2.2 Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with Aphanomyces invadans *(epizootic ulcerative syndrome)' (Annex 23)*

71. Revisions to the list of susceptible species in Section 2.2.1. 'Susceptible host species' of Chapter 2.3.1. are proposed. The Commission agreed to apply Article 1.5.9. 'Listing species at a taxonomic ranking of Genus or higher' and utilised considerations provided in the 2024 September Commission report when reviewing evidence of susceptibility.

72. Revisions to the list of species in Section 2.2.2. 'Species with incomplete evidence for susceptibility' are proposed.

73. The *ad hoc* Group on Susceptibility of Fish Species to Infection with WOAH Listed Diseases April 2024 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

74. The revised sections have been circulated for comment one time; the first time in the September 2024 Commission report.

75. The revised Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)' are presented in **Annex 23** and will be proposed for adoption at the 92nd General Session in May 2025.

2.3 Chapter 2.4.2. 'Infection with Bonamia exitiosa*' (Annex 24)*

76. A comprehensive revision of Chapter 2.4.2. including reformatting to align with the new disease chapter template is proposed.

77. The revised chapter has been circulated for comment two times; the first time in the September 2024 Commission report.

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

2.4 Chapter 2.4.3. 'Infection with Bonamia ostreae*' (Annex 25)*

79. A comprehensive revision of Chapter 2.4.3., including reformatting to align with the new disease chapter template, is proposed.

80. The revised chapter has been circulated for comment two times; the first time in the September 2024 Commission report.

81. The revised Chapter 2.4.3. 'Infection with *Bonamia ostreae'* is presented in **Annex 25** and will be proposed for adoption at the 92nd General Session in May 2025.

2.5 Section 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with Perkinsus olseni*' (Annex 26)*

82. Revisions to the list of susceptible species in Section 2.2.1. 'Susceptible host species' of Chapter 2.4.6. are proposed.

83. Revisions to the list of species in Section 2.2.2. 'Species with incomplete evidence of susceptibility' of Chapter 2.4.6. are proposed.

84. The *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases December 2023 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

85. The revised sections have been circulated for comment two times; the first time in the February 2024 Commission report.

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

2.6 Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with Xenohaliotis californiensis*' (Annex 27)*

87. Revisions to the list of susceptible species in Section 2.2.1. 'Susceptible host species' of Chapter 2.4.7. are proposed.

88. Revisions of the list of species in Section 2.2.2. 'Species with incomplete evidence of susceptibility' of Chapter 2.4.7. are proposed.

89. The *ad hoc* Group on Susceptibility of Mollusc Species to Infection with WOAH Listed Diseases June 2024 report, provides details of the assessments undertaken to determine the proposed list of susceptible species.

90. The revised sections have been circulated for comment one time; the first time in the September 2024 Commission report.

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

3. ANNEXES

Annex 5. – Draft new Chapter 4.X. 'Emergency disease preparedness'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.X.

EMERGENCY DISEASE PREPAREDNESS

Article 4.X.1.

Purpose

To describe the essential elements of an emergency disease preparedness framework which a *Competent Authority* should develop in accordance with country priorities and resources to ensure that *outbreaks* of important ~~and *emerging*~~ *aquatic animal diseases* can be rapidly identified and efficiently managed, and which will guide a country, *zone* or *compartment*, towards a suitable path to recovery.

An important *aquatic animal disease* is one which has been identified by the *Competent Authority* in accordance with Article 4.X.6. and which is subject to emergency *disease* preparedness measures. Such *diseases* may be listed in Chapter 1.3., or they may be *emerging diseases* or other *aquatic animal diseases*.

Article 4.X.2.

Scope

This chapter describes recommendations for the development of an emergency disease preparedness framework. This framework encompasses all the elements that will enable the *Competent Authority* to activate an efficient response to a *disease outbreak*, in order to minimise~~thereby minimising~~ the impact on *aquatic animal* populations, trade, the economy, and the financial resources that are required to manage the *disease outbreak*~~s~~. The specific actions which are necessary to operationalise the framework in the event of a *disease outbreak* are described in Chapter 4.Y.

Article 4.X.3.

Introduction

~~*Aquatic animal diseases* have the potential to spread quickly, often with serious consequences. In many parts of the world, these *disease* events appear to be increasing in frequency and severity, due to increased *aquaculture* production and *international trade*.~~ This chapter provides recommendations for a *Competent Authority* to identify and coordinate the elements of a framework, which will achieve a suitable level of preparedness for *aquatic animal disease*~~those~~ emergencies.

When developing the framework, it is of fundamental importance to ensure that the *aquatic animal disease*s which are important to a country, *zone* or *compartment*, are identified in advance of a *disease outbreak* (i.e. in peacetime) by the *Competent Authority*, and that their future control is supported by adequate legislative and funding measures. The ~~statutory~~ list of important *disease*s that is developed after conducting a *risk analysis* as described in 4.X.6., may include *aquatic animal disease*s which are listed in Chapter 1.3., as well as other *disease*s which have been identified as being of importance to the country, *zone* or *compartment*. In addition to the *diseases* which a *Competent Authority* has identified through *risk analysis*, they may choose to add additional *diseases* to the list of important *diseases* to take account of other national considerations.

Also in peacetime, the *Competent Authority* should take a systematic approach to planning every element of the framework that will be applied from the point at which an important *disease* is suspected during the alert phase, through the activation of the *contingency plan* in the emergency phase, to the point at which the recovery phase begins and the emergency officially ends.

The *Competent Authority* should consider whether the *contingency plan* and recovery plan elements of the emergency disease preparedness framework apply either to a specific *aquatic animal disease* or to a group of such *diseases*. The *Competent Authority* should decide in peacetime, which of these approaches is most suitable~~best meets their needs~~, taking into account the *aquatic animal diseases* that are listed in their country, the relevant *susceptible species,* and types of production.

Article 4.X.4.

General principles

Emergency *disease* preparedness is a core function of the *Competent Authority.* The various elements that are necessary to ensure that the *Competent Authority* is prepared to deal with an *outbreak* of an important *disease*, are elaborated in a framework. The framework is constructed in peacetime before the occurrence of a *disease outbreak*.

The ultimate success of the framework will be influenced by the quality of the preparations which have been made by the *Competent Authority*, and the commitment and coordination of the *Aquatic Animal Health Services*~~,~~ and relevant industry stakeholders.

The general principles to be considered when developing an emergency disease preparedness framework are as follows:

1) legal provisions and funding should be available to allow a *Competent Authority* to execute all elements of the framework and to manage *disease outbreaks* in compliance with the *contingency plan*, and with the detailed operational measures which are referred to in Chapter 4.Y.;

2) ~~case~~ definitions for suspect and confirmed cases should be established for all important *diseases* which are subject to the emergency disease preparedness framework. For *diseases* which are listed in Chapter 1.3., case definitions are set out in Sections 6.1. and 6.2. of the disease-specific chapters of the *Aquatic Manual*. For non-listed *diseases*, the *Competent Authority* should establish such definitions in peacetime, so that delays can be avoided in confirming or ruling out the presence of the *disease*. This task is more difficult to achieve in advance for *emerging diseases*, but the generic approach that the *Competent Authority* will take for suspect and confirmed cases of *emerging diseases* should be considered in peacetime.

3~~2~~) *risk analysis* should be used in advance of, during and after a *disease outbreak* as described in Article 4.X.6. The *risk analysis* that is carried out in advance will identify the important *aquatic animal diseases* which will be subject to emergency measures. The *risk analysis* that is carried out during and after the *disease outbreak* will inform the response and recovery actions which will be taken by the *Competent Authority*, ~~and~~ the *Aquatic Animal Health Services*, and relevant industry stakeholders;

4~~3~~) a *contingency plan should be developed* for a specific *aquatic animal disease* or group of related *aquatic animal diseases*, following appropriate consultation with the *Aquatic Animal Health Services*, which contains at least the components outlined in points 1 to 7~~(a) to (f)~~ of Article 4.X.7. The *contingency plan* is:

a) partially activated in compliance with Article 4.Y.4.~~Chapter 4.Y.~~ when the presence of an important *disease* is suspected during the 'alert phase';

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

5~~4~~) simulation exercises should be planned and executed to test, and ultimately to improve, relevant elements of the disease preparedness framework. Simulation exercises support~~ensure that~~ *Competent Authorities* and *Aquatic Animal Health Services* to be~~are~~ trained and properly equipped and resourced~~to manage suspicion and confirmation of an important *disease* in their *territory*~~, in accordance with Article 4.X.8.;

6~~5~~) all elements of the framework should be regularly reviewed and revised as described in Article 4.X.9.;

7~~6~~) a 'recovery plan' should be prepared as described in Article 4.X.11., which will be based on *risk analysis* and on the recovery options which are described in Article 4.X.10.

Article 4.X.5.

Legal provisions and funding

There are certain pre-requisites for an emergency disease preparedness framework including~~. Such pre-requisites include~~ that the *Competent Authority* has:

1) ~~recourse to *aquatic animal* health~~ legislation which underpins the execution of all the elements and actions that are necessary to manage suspicion and confirmation of an *outbreak* of an important *aquatic animal disease* as described in Article 4.X.6.*;*

2) access to emergency resources including funds which are sufficient to allow the execution of the relevant elements of the disease preparedness framework, including~~as well as the~~ operational measures and compensation which are set out in Chapter 4.Y.

Any delay in the ability of the *Competent Authority* to rely on legal provisions, or to access finance, can hamper the effective management of a *disease* emergency. Delays should be avoided, or at least minimised, by ensuring that all the administrative steps that must be followed to transmit the necessary funds from the central funding authority to the *Competent Authority* are identified.

Article 4.X.6.

Risk analysis

Risk analysis plays an important role before, during and after a *disease outbreak*. It is therefore, of critical importance that this expertise is available to the *Competent Authority* to ensure that the emergency disease preparedness framework can be efficiently executed. This article elaborates the principles described in Chapter 2.1. and applies them in the context of emergency *disease* preparedness.

Identification of *aquatic animal diseases* which will be subject to emergency measures

Risk analysis should be used by the *Competent Authority* to determine which important *diseases* of *aquatic animal*s present a threat and should, therefore, be subject to emergency measures in the event of a *disease outbreak*.

The *risk analysis* should take account of a country's circumstances. In particular, the knowledge of relevant wild and farmed *aquatic animal* species in the *territory*, as well as their geographic distribution, *disease* status and economic and trade importance, are critical to the completion of an effective *risk analysis*. Such *risk analysis* should also include information on the most important routes of introduction, transmission pathways, life cycle stages, persistence in the environment~~,~~ and likelihood of eradication, which will inform *disease* control strategies and response options which are referred to in Article 4.X.10.

The list of important *aquatic animal* dise*ases* that may be subject to emergency measures should be under regular~~continual~~ review by the *Competent Authority*. The *risk analysis* should utilise~~take into account~~ the latest relevant scientific findings and should be repeated regularly to assess the threat of *emerging diseases.* Changes in the species or strains farmed, and in the distribution or virulence of known *pathogenic agents* should inform changes in national *disease* listings. *Competent Authorities* should ensure they collate the data required for completing and updating *risk analysis.*

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

Suspicion of an *outbreak* of an important *aquatic animal disease*, which is subject to statutory control, often results from *surveillance* activities and the *early detection system*. Therefore, emergency *disease* preparedness systems and the outcomes from those systems are heavily reliant on the quality of the *surveillance* and on the proper application of an *early detection system* ~~reporting activities carried out~~ by the *Aquatic Animal Health Services*~~,~~ and relevant industry stakeholders in accordance with Chapter 1.4. ~~The~~

~~outcomes from an emergency disease preparedness framework are fundamentally reliant on the quality of *surveillance* and reporting activities.~~

In addition, when the presence of an important *aquatic animal disease* is suspected or has been confirmed, *risk analysis* has a crucial role to play in prioritising *surveillance* activities as part of forward and backward epidemiological tracing, and establishing *protection zones* and *infected zones*.

Response actions during the *disease* emergency

As part of preparedness planning, *risk analysis*~~assessment~~ protocols should be developed to support decision making by the *Competent Authority* during an *outbreak*. The *risk analysis* should be able to identify the *risk* mitigation measures and protocols that~~Protocols~~ are required to cover a range of *disease* control options e.g. the possibility to on-grow stock on an infected *aquaculture establishment* to slaughter weight (which will include an assessment of the *risk* of spread within a particular water body), and the possibility to move live *aquatic animals* within *infected zones*.

A *risk analysis*~~assessment~~ of depopulation activities should be undertaken to ensure that they are carried out with the minimum risk of *disease* spread. In addition, prior to repopulation, a *risk analysis*~~assessment~~ should be completed to determine if further *risk* mitigation measures are required to prevent reinfection of the new stock of *aquatic animals*.

Article 4.X.7.

Contingency plan

The *Competent Authority* should decide whether the *contingency plan* applies either to a specific *aquatic animal disease* or to a group of such *diseases* which, because of their similarity to each other, may be managed effectively using the same principles ~~e.g. certain finfish *diseases* that occur in freshwater, certain mollusc *diseases* that occur in seawater~~.

The *Competent Authority* should also consider that because of the nature of *emerging diseases*, the *contingency plan* and the recovery plan, ~~which are devised~~ for such *aquatic animal diseases*, should be generic. Such generic plans will, however, require rapid and effective fine-tuning, once the details of the *emerging disease* have become known, and the *Competent Authority* has assessed that the *disease* in question should be subject to emergency *disease* preparedness measures.

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

The *contingency plan* should include at least the following components:

1) the establishment of a clear chain of command within the country, from the central level to the regional and local levels, with a~~the~~ *Competent Authority* in overall command. This chain of command should include decision makers from other *Competent Authorities*~~the *Aquatic Animal Health Services*~~ who may not deal directly with *aquatic animal* health, but who play a role in the emergency disease preparedness framework;

2) a framework for cooperation between the *Competent Authorities*~~*Authority*~~, ~~and the~~ *Aquatic Animal Health Services* and industry stakeholders. This cooperation should:

    a) ensure that all actions, and roles and responsibilities which form part of the plan are well understood and discussed in advance of and during, any *disease outbreaks*, thereby ensuring that rapid and effective decisions can be made when necessary;

    b) result in the establishment of at least the following groups which meet at frequencies which may vary depending on the phase of the emergency:

        i) a formally recognised emergency management group which is chaired by the *Competent Authority*;

ii) specialist sub-groups which will provide specific advice to the emergency management groupEmergency Task Force for consideration e.g. epidemiology group, laboratory group, logistics group, communications group, environmental group, producers' group, welfare group, mental health and psychological support group.

3) identification of, and arrangements for access to, appropriate:

a) central and local *disease* control centres;

b) laboratories;

c) equipment;

d) trained personnel;

e) communications and media liaison;

f) data management or information systems;

gf) additional materials and resources that may be required, including for instance, telecommunications, transport, vaccines, experts (e.g. in the areas of logistics, fisheries management, environmental protection);

hg) service providers (e.g. waste disposal contractors, Personal Protective Equipment (PPE) suppliers, chemical suppliers, standby generators).

4) the general *biosecurity* and *disease* control measures which will be taken in the event of suspicion or confirmation of the presence of an important *aquatic animal disease* to which the *contingency plan* applies. The general *biosecurity* measures which will apply to *aquaculture establishments* should follow the guidance oncomply with the measures which are described in Chapter 4.1. Coordination of control measures with neighbouring countries with shared waterbodies should be taken into account;

5) concerning specific *disease* control measures, the duration of the *fallowing* period that may apply following de-population, cleaning and *disinfection*, should be considered, using *risk assessment*. The duration of the fallowing periodSuch an assessment takingshould take into account relevant factors such as the nature of the relevant *pathogenic agent*, the type and extent of the production system, hydrographical factors and the nature of local wild *aquatic animal* populations or vectors. The *risk assessment* should also inform the need for synchronisedSynchronised *fallowing* of a number of *aquaculture establishments*, should be considered in certain circumstances;

6) possible response options that can be applied to manage a *disease outbreak*, based on *risk assessment*. Such response options would depend on the progression of the *disease outbreak* and could include measures such as eradication, containment through *biosecurity* measures, mitigation of *disease* consequences, or no *disease* response;

7) *risk communication* strategy which will apply during each stage of the process, both within and between the various authorities and services and with relevant stakeholders. For example, the *contingency plan* should set out the nature and timing of communications with the personnel who are described in points 2(b)(i) and (ii) above, as well as taking community engagement into account, where appropriate. The *risk communication* strategy should be based on the principles of *risk communication* described in Chapter 2.1.

The actions necessary to operationalise points 1 to 7 above are described in Chapter 4.Y. and are included in an Operations Manual.

Article 4.X.8.

Simulation exercises

Simulation exercises are a crucial component of emergency *disease* preparedness. The objectives of such exercises are to validate and test the functionality and suitability of the *contingency plan* and the operational measures which are described in Chapter 4.Y. Simulation exercises will also validate and test the capacity of

Competent Authorities, ~~and~~ *Aquatic Animal Health Services*, and industry stakeholders to respond to an important *aquatic animal disease*. The emergency disease preparedness framework should include a requirement for the regular completion of simulation exercises to test that all personnel are adequately trained and prepared for the tasks which have been allocated to them. An outcome report should be produced following each simulation exercise, highlighting lessons learnt, describing the actions necessary to address~~close~~ any gaps which have been identified in the *contingency plan*, and any~~or~~ other necessary amendments ~~which are required~~ to the operational measures which are described in Chapter 4.Y. This should include identification of individuals responsible for delivery and a timeframe within which the actions should be completed.

The *Competent Authority* should set a minimum frequency for the completion of such exercises, to ensure readiness to efficiently execute the various elements of the *contingency plan,* should it be activated. Simulation exercises may be organised within a country, covering the entire territory, or *zones* or *compartments* thereof, or among the *Competent Authorities* and *Aquatic Animal Health Services* of countries or *zones* with shared waterbodies where relevant.

A simulation exercise should have clearly defined objectives with respect to the elements of the emergency disease preparedness framework or *outbreak* response capability that is being evaluated. The objectives will inform the type of exercise, participation and the exercise design. A simulation exercise should be designed based on realistic scenarios that reflect actual risks with operational feasibility.

The planning, organisation, and completion of simulation exercises should take account of the following points:

1) different types of exercises may be used e.g. tabletop, limited field exercises or more extensive field exercises;

2) the scale, frequency and scope of the exercises should be based on *risk* prioritisation, which has been completed by the *Competent Authority,* taking account of any new *risk* factors which have been identified;

3) exercises should include the *Competent Authority* at different administrative levels, as well as the *Aquatic Animal Health Services,* and relevant industry stakeholders that will be involved in the application of the *contingency plan* in the event of a *disease* emergency;

4) exercises should test the capacity of the *Competent Authority* to manage every element of the emergency disease preparedness framework, from the initial *disease* alert to the end of the recovery phase;

5) once completed, each simulation exercise should be thoroughly evaluated by the organiser, and an outcome report should be prepared, with the objective of identifying:

    a) the elements of the emergency disease preparedness framework that are fit-for-purpose, and those that are not;

    b) the readiness and capacity of the *Competent Authority*, ~~and~~ the *Aquatic Animal Health Services*, and relevant industry stakeholders to respond to the elements of the emergency disease preparedness framework, that were tested during the exercise.

    c) any gaps/issues raised and any actions to be taken forward, including a timeframe within which these should be addressed.

Article 4.X.9.

Revision and review

The *Competent Authority* should establish a mechanism to improve its emergency disease preparedness framework through regular review, and where necessary, revision of its various elements.

The list of *aquatic animal diseases* which are subject to the emergency disease preparedness framework should be under regular~~continual~~ review, as described in Article 4.X.6.

Review and revision of the *contingency plan* and the operational measures which are set out in Chapter 4.Y. should take into account, the outcomes from the evaluation of the simulation exercises described in Article 4.X.8., and the implementation of an emergency *disease* response, where this is relevant.

The review process consequently may necessitate a revision of the *contingency plan* or other elements of the emergency *disease* preparedness framework. Such exercises and responses should also be used to highlight the training needs of personnel from the *Competent Authority* and the *Aquatic Animal Health Services,* and to inform the possible revision of the legislation which underpins the framework.

The regular review and revision of the emergency disease preparedness framework should also take into account measures to strengthen the *contingency plan* or to prevent another *disease* emergency event, (e.g. updated scientific information including diagnostic tests, improvements in technology or relevant industry practices, as well as any other new elements which will improve the overall suitability and effectiveness of the framework).

All revisions which are made as a result of the review process described above should be communicated to the *Aquatic Animal Health Services* and relevant industry stakeholders within an agreed timeframe.

Article 4.X.10.

Response Options

The *Competent Authority* should take into account that the initial objective of successfully completing an eradication programme and re-gaining *disease* freedom in a country, *zone* or *compartment* following a *disease outbreak*, may change as *the outbreak* develops.

While the purpose of the recovery plan, may be to re-establish the disease-free situation which existed before the *disease outbreak* occurred, it should be considered that in certain cases, the *aquatic animal health status* which is achieved after the emergency has ended, may not be the same as the one which existed before the *outbreak* occurred. Various response options should, therefore, be set out in the emergency disease preparedness framework, upon which the recovery plan can be based, depending on the epidemiological situation which exists at the end of the emergency.

Concerning the *aquatic animal diseases* which are listed in Chapter 1.3., and taking into account Chapter 1.4., the possible options the *Competent Authority* could consider as part of their recovery plan are as follows:

1) demonstrate the re-establishment of disease freedom at country, *zone* or *compartment* level;

2) establish a ~~*disease*~~ *free zone* in a previously ~~*disease*~~ *free country*;

3) establish a redefined (reduced) ~~*disease*~~ *free zone*;

4) establish one or more ~~*disease*~~ *free compartments*;

5) relinquish disease-free status and take measures to contain the *disease*;

6) take measures which are designed to mitigate the impacts of the *disease*;

7) accept that none of the options outlined above are feasible and no official *disease* control measures will be applied.

If *disease* control operations are halted before regaining the pre-outbreak disease-free status at country or *zone* level, the recovery plan should set out how the *Competent Authority* could explore the potential to establish redefined ~~*disease*~~ *free zones* or *free compartments.*

Where the options described in points 1 to 6 above are not possible for epidemiological, logistical or economic reasons, the *Competent Authority* may accept an evolution from the original disease-free status, to one where the *disease* has become endemic, but where the epidemiological situation is stable.

Concerning important *aquatic animal diseases* which are not listed in Chapter 1.3., but which are listed in the national legislation of a country, the *Competent Authority* may decide to apply a similar range of options to those described in points 1 to 4 above. However, these would not fall within the scope of the ~~official~~ disease-free statuses for *listed diseases* that may be established for a country, *zone* or *compartment*, as described in Chapter 1.4.

Article 4.X.11.

Recovery plan

The *Competent Authority* should decide whether the recovery plan applies either to a specific *aquatic animal disease* or to a group of such diseases which, because of their similarity to each other, may be managed effectively using the same principles e.g. certain finfish *diseases* that occur in freshwater, certain mollusc *diseases* that occur in seawater.

The recovery plan should be activated when the end of the emergency has been declared by the *Competent Authority*. The point at which the emergency ends, and the nature of the recovery plan, will be determined by *risk analysis* ~~*assessment*~~, which will take account of the following factors as well as the options described in Article 4.X.10.:

1) the current geographic distribution of the *pathogenic agent;*

2) whether or not, the *disease* has become established in wild *aquatic animal* populations;

3) the costs and feasibility of establishing and maintaining *disease*-freedom at the level of country, *zone* or *compartment,* taking into account hydrological and epidemiological connections;

4) the socio-economic impact of the possible recovery option(s) considering the availability of compensation;

5) any *risk* the *disease* may pose to vulnerable wild *aquatic animal* populations in the infected or adjacent areas.

Concerning the response options described in points 1 to 6 of Article 4.X.10., the recovery plan should include details of the actions which the *Competent Authority* and the operators of *aquaculture establishments* should take to:

6) prepare a *self-declaration of freedom from disease*, as referred to in points 1 to 4 of Article 4.X.10.; or

7) put in place appropriate *biosecurity* measures in compliance with Chapter 4.1., to ensure the *disease* is contained, as referred to in point 5 of Article 4.X.10.; or

8) put in place the mitigation measures which are referred to in point 6 of Article 4.X.10.~~,~~ (e.g. vaccination, change of production species, or change in husbandry practices);

9) consider research requirements to support the actions referred to in points 6 to 8.

Annex 6. – Draft new Chapter 4.Y. 'Disease outbreak management'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.Y.

DISEASE OUTBREAK MANAGEMENT

Article 4.Y.1.

Purpose

To provide recommendations concerning the actions which should be taken by the *Competent Authority* and the *Aquatic Animal Health Services* to manage the emergency response to suspicion or confirmation of the presence of an important *aquatic animal disease*, and activate its contingency plans as described in Chapter 4.X.

Article 4.Y.2.

Scope

To provide recommendations concerning the actions to be taken by the *Competent Authority* and the *Aquatic Animal Health Services,* from the point at which an important *disease*, as described in Article 4.X.1.~~6.~~, is suspected in a *free country*, *free zone* or *free compartment*, or has been suspected or confirmed in an epidemiologically linked population, to the point at which the recovery phase begins. These actions operationalise the elements described in Chapter 4.X., which are required to manage the *disease outbreak*.

Article 4.Y.3.

General Principles

The successful management of an emergency response should take the following principles into account:

1) the actions to be taken by the *Competent Authorities*~~*Authority*~~ and the *Aquatic Animal Health Services*, should be based on the emergency disease preparedness framework which has been developed in accordance with Chapter 4.X.;

2) the operational elements of the emergency disease preparedness framework should be described in an Operations Manual. The Operations Manual may be a single document or a series of documents which together.~~The *Competent Authority* can rely on the Operations Manual to~~ provide guidance on all aspects of the emergency response, including actions to be taken during the alert, emergency, and recovery phases (refer to Articles 4.Y.4., 4.Y.5. and 4.Y.9. respectively);

3) the preferred~~initial~~ response objective following a *disease outbreak* is to eradicate the *disease*, thereby allowing a country, *zone* or *compartment* to return to *disease* freedom. However, should the progression of the *outbreak* prevent this objective from being achieved, other actions should be described, which will assist the *Competent Authority* and the *Aquatic Animal Health Services* to pursue an alternative pathway to recovery;

4) the actions described in the Operations Manual should be executed in a timely and co-ordinated fashion, by competent personnel, who have access to all the resources which are necessary to manage the *disease outbreak*.

Article 4.Y.4.

Alert phase

The alert phase begins when there is suspicion of the presence of an important *aquatic animal disease* ~~of *aquatic animals*~~, generally as a consequence of active or *passive surveillance* in the country, or in another country, which is a neighbouring country that share common waterways or which is a trading partner. During this phase, the *Competent Authority* will take steps to detect the presence of the *disease* and to prevent possible *disease* spread.

The main actions to be taken ~~into account~~ during the alert phase of an emergency should include ~~take~~ the following ~~factors into account~~:

~~1)~~ ~~the alert phase begins when there is suspicion of the presence of an important *disease* of *aquatic animals*, generally as a consequence of active or *passive surveillance* in the country, or in another country, which is a neighbour or a trading partner. During this phase, the *Competent Authority* will take steps to detect the presence of the *disease* and to prevent possible *disease* spread;~~

1~~2~~) ~~following the commencement of this phase,~~ the initiation of an epidemiological investigation ~~should be initiated~~ in order to:

a) confirm or rule out the presence of the *disease*, in the shortest possible time frame by using the case definitions for suspect and confirmed cases of *listed diseases* and non-listed *diseases*, which have been recommended in Article 4.X.4. For an *emerging disease* establish working case definitions for suspect and confirmed cases based on the best scientific knowledge which exists at the time;

~~b)~~ ~~establish a working case definition for outbreak investigation where this is necessary (e.g. in the case of a disease which is not listed in Chapter 1.3., or of an emerging disease);~~

b~~c~~b) gather information to determine potential ~~if the~~ *disease* ~~has~~ spread from or to *aquaculture establishments* or waterbodies other than the one in which the original suspicion was raised. This information can be used to inform *risk*-based *surveillance* as described in point 2 (a), which may commence during the alert phase and become fully applicable during the emergency phase, if the *disease* is confirmed;~~.~~

2~~3~~) during the alert phase, taking into account Chapter 4.1., the *Competent Authority* should take steps to prevent *disease* spread by implementing *biosecurity* measures in the *aquaculture establishment* or waterbody in question. Additional specific *disease* control measures should also be considered, such as:

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

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

3) during the epidemiological investigation:

a) *risk*-based *surveillance* is used to prioritise which *aquatic animal* populations, identified through tracing, should be prioritised for sampling. For example, *aquaculture establishments* which are ~~highly~~ connected to the *aquaculture establishment* or waterbody in which the suspicion arose, through movements of live *aquatic animals* and other transmission pathways, as described in Article 4.1.7., should be considered~~prioritised~~ for clinical inspection and sampling;

b) the samples should be submitted to laboratories identified in the *Contingency Plan,* as described in Chapter 4.X., with suitable capacity~~as being suitably equipped and staffed~~ to produce reliable results in the shortest possible timeframe.

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

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

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

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

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

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

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

~~5~~6) whilst confirmation of the presence of the *disease* in question is ongoing, the *Competent Authority* should communicate with *Aquatic Animal Health Services* including relevant personnel, ~~relevantindustry~~ industry stakeholders, diagnostic laboratories, and contractors, putting them on alert to ensure they review their readiness to act quickly in compliance with the *Contingency Plan*, should the *disease* be confirmed. Such communications are made using the contact details which are kept in accordance with Chapter 4.X.;

~~6~~7) the *Competent Authority* should endeavour to ensure that the alert phase is short enough to minimise *disease* spread, and long enough to ensure the suspicion has been accurately confirmed or ruled out;

~~7~~8) should the suspicion not be confirmed, the alert phase is terminated by the *Competent Authority*, relevant stakeholders~~actors~~ are informed that the situation is moving back to peacetime, and any outcomes which warrant review of the *Contingency Plan*, are made;

~~8~~9) ~~the alert phase ends when~~ should the presence of an important *disease* be~~is either~~ confirmed ~~or ruled out~~ by the *Competent Authority*, relevant~~. Relevant~~ stakeholder~~actors~~ are informed ~~in the *Aquatic Animal Health Services* should be communicated with to advise them~~ that the alert phase is being terminated, and that the situation is ~~either~~ moving~~ back to peacetime or~~ forward to the emergency phase as described in Article 4.Y.5.

Article 4.Y.5.

Emergency Phase

The emergency phase of *disease outbreak* management commences when the presence of an important *aquatic animal disease* has been confirmed. The steps which should be taken during the emergency phase are set out in the *Contingency Plan*, and the associated detailed actions are set out in the Operations Manual, taking the following factors into account:

1) the chain of command as described in Article 4.Y.6.;

2) the *risk*-based *surveillance* and sampling referred to in Article 4.Y.4.;

3) the appropriate facilities, ~~skills,~~ resources, personnel and skills as described in Article 4.Y.7.;

4~~3~~) the *biosecurity* and other *disease* control measures as described in Article 4.Y.8.

Article 4.Y.6

Chain of command

As soon as the *disease outbreak* has been confirmed, the *Competent Authority* convenes a meeting of the emergency management group as described in Chapter 4.X., and the activation of all elements of the *contingency plan* commences.

The ~~first meeting of the emergency management group considers at least the~~ following issues should be considered, with the assistance of relevant specialist sub-groups:

1) the most up-to-date epidemiological information available concerning the *disease* emergency, including:

   a) location of confirmed case(s) including grid references and maps;

   b) inventory including relevant information on~~of~~ species kept in the infected *aquaculture establishment(s)* ~~and the numbers and weights of the *aquatic animals*~~;

   c) clinical situation including description of clinical signs and estimates of morbidity and mortality;

   d) identification of the index *case*;

   e) details of *susceptible species* and vectors with a potential epidemiological link to~~in the vicinity of~~ the confirmed case(s);

   f) outcomes from preliminary tracing and *surveillance*;

   g) outcome from preliminary *risk assessment*.

2) immediate response objectives and options, taking into account the available epidemiological information referred to above, including:

   a) official confirmation of the *disease outbreak* to the operators concerned;

   b) international notification in accordance with Chapter 1.1.;

   c) the reinforcement of the preliminary *biosecurity* measures described in point 4 of Article 4.Y.4. which were put in place during the 'alert phase', the imposition of new biosecurity and other *disease* control measures described in Article 4.Y.8., or both.

3) trade issues which are likely to arise, both within the country and with trading partners elsewhere;

4) review of appropriate facilities, skills and resources, as well as the legal, administrative and financial arrangements which are in place to ~~ensure all relevant enablers are in place~~ enable the *Competent Authority* to immediately manage the *disease* emergency. This review should include:

   a) details of the infrastructure, skill sets and other necessary resources which are available to support the effective management of the *disease* emergency;

   b~~a~~) details of the legal instrument~~s~~ which support~~s the provision of funding for~~ the management of *disease* emergencies concerning *aquatic animals*, including the provision of funding;

   c~~b~~) contact details for the relevant department which will process the request for funds, and which ensure that payments are executed smoothly once the *contingency plan* has been activated;

   ~~c) details concerning the mechanisms by which the funds will be transferred, in addition to the frequency of transfer and the personnel who are authorised to draw down the funding~~.

5) agreed messages, format ~~for~~, and timing of, communications with the *Aquatic Animal Health Services* and other relevant stakeholders who are responding to the emergency, relevant trading partners, and the public. Communications may be based on generic templates which have been prepared in peacetime and are adapted as appropriate to the circumstances~~Those communications are based on generic draft press releases and letters to the *Aquatic Animal Health Services* which have been prepared in peacetime, and which are appropriately fine-tuned to meet the current circumstances~~;

6) a schedule for future meetings throughout the emergency phase of the response, as well as a distribution list for the minutes of those meetings. Flexibility should be introduced to allow~~allowing for flexibility to schedule~~ meetings to be scheduled at short notice, should this be required.

Article 4.Y.7.

Appropriate facilities, skills, resources

1) Disease control centres

a) The *Competent Authority* establishes a central *disease* control centre and where necessary, an appropriate number of local *disease* control centres. Those centres, identified in the *Contingency Plan,* should be capable of providing at least the following:

i) appropriate information technology and telecommunication infrastructure;

ii) information systems to manage data collection concerning *aquaculture establishments*, details of sample collection and associated laboratory results, as well as the imposition of *disease* control measures on affected *aquaculture establishments* and other relevant stakeholders~~transporters~~;

iii) space for preparing and storing sampling kits for dispatch to the field;

iv) *disinfection* points for staff who are involved in sampling and inspection of *aquaculture establishments*, *vehicles* and other premises;

v) storage area for fields kits, personal protective equipment, cleaning and *disinfection* materials;

vi) *biosecurity* measures which are appropriate for the specific facilities and the purpose for which they are used.

b) The personnel from the *Aquatic Animal Health Services* who staff the central and local *disease* control centres have been identified in the *Contingency Plan.* Operationally, this group includes technical, administrative and legal personnel, as necessary, who are fully trained to complete the following tasks in accordance with detailed standard procedures which are set out in the Operations Manual:

i) clinical inspections of *aquaculture establishments*, other establishments and wild *aquatic animals* ~~and wild aquatic habitats,~~ as relevant;

ii) sample collection and transportation;

iii) preparation and issuance of legal notices;

iv) management of general biosecurity measures and other specific *disease* control measures;

v) communications with relevant personnel and stakeholders;

vi) data and record management;

vii) human resources management including workplace health and safety;

viii) finance and resource procurement.

2) Laboratories

a) During the emergency, the *Aquatic Animal Health Services* and relevant industry stakeholders should submit samples to the laboratories which have been identified in the *Contingency Plan* as per Article 4.X.7. Those laboratories provide rapid and accurate testing and reporting, which is dependent on the following resources:

i) appropriately trained and competent staff;

ii) appropriate equipment, which has been suitably serviced and is fit-for-purpose;

iii) a sufficient range and quantity of consumables;

iv) appropriate information systems to ensure sample traceability and reporting of laboratory results;

v) *biosecurity* measures which are suitable to contain the *pathogenic agent* in question.

Contact details of the staff which are referred to in point (i) and the companies which provide the services and goods, which are referred to in points (ii), (iii) and (iv), are detailed in the Operations Manual.

b) For *listed diseases*, laboratory methods should follow the relevant chapter of the ~~WOAH~~ *Aquatic Manual* and where relevant the case definitions for non-listed and *emerging diseases* which are referred to in Articles 4.X.4. and 4.Y.4. For *diseases* other than *listed diseases*, a procedure identified in the Operations Manual should be utilised, or another method which has been validated for the purpose of use.

3) Service ~~P~~providers

The availability of relevant service providers during the emergency phase is of crucial importance, in particular, considering that a *disease outbreak* may include ~~extend to~~ multiple *aquaculture establishments* in dispersed locations, and potentially ~~to~~ wild *aquatic animals*. Action should, therefore, be taken to ensure the availability of:

a) mortality management providers involved in retrieval and/or transport, who have capacity for the required daily tonnage;

b) sanitary slaughter facilities, which can cater for the required daily tonnage;

c) predatory animal, pest and bird control specialists;

d) telecommunications providers;

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

~~fc) telecommunications providers;~~

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

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

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

i~~j~~g) experts in areas which are relevant to the successful management of the emergency, and who have appropriate skills (e.g. in the areas of logistics, fisheries management, environmental protection, vaccination or treatment of *aquatic animals*), and who are available to deal with emergency situations;

jkh) back-up providers for each type of service, should they be required for an extensive *disease outbreak*.

Subject to the relevant regulatory requirements, likely outbreak scenarios, and operational infrastructure which apply in a country, contactContact details of the providers referred to in points (a) to (jkh) above are detailed in the Operations Manual.

Article 4.Y.8.

Biosecurity and other disease control measures

The actions which athe *Competent Authority* should takes concerning *biosecurity* and other *disease* control measures during the emergency phase, are described in the Operations Manual and may include:

1) defining the *infected zone* and *protection zones* which apply in freshwater or marine environments, as relevant, following confirmation of a *disease outbreak*, and taking into account the recommendations of Chapter 4.2.;

2) appropriate classification of the health status of *aquaculture establishments* to define their *disease* status or *risk* of infection;

32) providing maps which will demonstrate the *infected zone* and the surrounding *protection zone*, as well as the *aquaculture establishments* which are located within those *zones*;

43) coordinating actions concerning *biosecurity* and other *disease* control measures with other *Competent Authorities*, when the establishment of such *infected zone* or *protection zones* impacts neighbouring countries;

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

a) controlling the movement of *aquatic animals*, *aquatic animal products*, *feed*, and equipment, *vehicles*, waste, fomites and *vectors* to or from the infected establishment(s) or *infected zone*, unless authorised by the *Competent Authority* following *risk assessment*;

b) extending the movement controls referred to above, to other *aquaculture establishments* or waterbodies which have an epidemiological link with the *aquaculture establishment* in which the suspicion arose;

c) exemptions from the movement prohibitions described above, should *risk assessment* have indicated that these represent an acceptable *risk* (e.g. emergency harvesting, on-site processing, cooking for human consumption), or alternatively that more stringent movement measures are required due to the developing *disease* situation;

d) specifying the procedures to be used when *aquatic animals* are slaughtered or killed, depending on their species, size and the number of *aquatic animals* involved, including:

i) details of the equipment and where relevant, veterinary products to be used, and their suppliers;

ii) the appointment of a named Welfare Officer to ensure that procedures are carried out to the highest possible standards, and in the case of fish, to ensure that slaughtering or killing is carried out in accordance with Chapter 7.4.;

iii) details of the *biosecurity* measures required to ensure the slaughter or killing process does not cause *disease* spread. This includes measures for the containment and safe disposal of dead or destroyed stock. Also measures which apply to *vehicles* which are authorised to move animals or products from the infected establishments (or from additional establishments, as directed by the *Competent Authority*), to processing factories or animal by product establishments;

eiv) the vaccination options that may be employed, depending on the circumstances of the *disease outbreak*, including:

i) no vaccination;

ii) vaccination which is implemented in *aquaculture establishments* within the infected zone i.e. suppressive vaccination, the aim of which is to reduce the spread of *disease* from the infected zone;

iii) vaccination which is implemented outside the infected zone where the *disease* has not been suspected or confirmed i.e. protective vaccination, the aim of which is to prevent the spread of the *disease* in populations of aquatic animals which are at risk of infection;

iv) a combination of suppressive and protective vaccination.

fe) the decontamination options which are available, taking into account the recommendations of Chapter 4.4.. A list of the cleaning agents, *disinfectants* and equipment that are appropriate to use, are commercially available, authorised for use by the relevant *Competent Authority*, and which meet the decontamination requirements concerning the *pathogenic agent* in question, should also be specified;

gf) procedures for the containment of wastewaters which are produced following equipment, facility and *vehicle disinfection* activities, which have been drawn up in accordance with the instructions of the *Competent Authorities* with responsibility for discharges to the environment;

h) where relevant, specifying the procedures to be used for the containment, *disinfection* and disposal of ~~*disease* contaminated~~ water contaminated by a *pathogenic agent* which is used for *aquatic animal* production.

Article 4.Y.9.

Recovery phase

The recovery phase of *disease outbreak* management is activated when the end of the emergency has been declared by the *Competent Authority*. This phase takes into consideration the recovery plan described in Chapter 4.X., and the associated detailed actions which are set out in the Operations Manual.

1. Return to freedom.

   In cases where the recovery phase includes the intention~~ambition~~ to return to *disease* freedom in accordance with ~~Pathway 4 as referred to in~~ Chapter 1.4. (Pathway 4), either for:

   a) the entity (country, *zone* or *compartment*), which was previously *disease* free; or ~~to make a *self-declaration of freedom from disease* for~~

   b) a smaller entity or entities (*zone*(s) or *compartment*(s));

   this phase should begin with a review of the *basic biosecurity conditions* which applied before the *disease outbreak* occurred. This review will determine if additional *sanitary measures* are required to strengthen the *basic biosecurity conditions* which will apply in the entity for which the new declaration of freedom will be made.

   This step will be followed in due course, by the re-population of *aquatic animals*, the required surveillance (as per Chapter 1.4.) and the re-commencement of trade. The ultimate aims of the recovery phase are to successfully return to peacetime operations.

2. In cases where the recovery phase does not include the intention~~ambition~~ to return to *disease* freedom, the actions which are necessary to either contain the *disease*, or to mitigate the impacts of the *disease*, should be identified and set out in the Operations Manual.

   a) Containment. Where the aim of the recovery plan is to contain the *disease*, the following measures may be described:

      i) zoning and movement controls;

ii) *biosecurity* measures, as described in Chapter 4.1.;

iii) *disinfection* of *aquaculture establishments* and equipment, as described in Chapter 4.4.;

iv) periodic *fallowing*, as described in Chapter 4.7.;

v) handling, disposal and treatment of *aquatic animal waste*, as described in Chapter 4.8.

b) Mitigation. Where the aim of the recovery plan is to mitigate the impact of the *disease*, the following measures may be described:

i) vaccination, using one or more of the strategies, which are referred to in Article 4.Y.5.;

ii) the possibility to change to the production of a species of *aquatic animals*, which are not susceptible to the *disease* which caused the emergency;

iii) the possibility to change production and husbandry practices, so that *risk* factors which are known to result in morbidity or mortality of *susceptible species* are minimised as far as possible;

iv) training which may be provided to operators to create improved awareness of the *disease* in question, as well as the steps that can be taken at establishment level to mitigate its impact.

3. In addition, the recovery plan may include details of:

a) the steps that are necessary to:

i) allow relevant movement controls to be partially or completely lifted (including permitting arrangements), so that affected trade may recommence within the country;

ii) start communications with producers and international partners, with a view to supporting an early recommencement of *international trade*, or to seek alternative trading partners.

b) any increased *surveillance* or *biosecurity* measures which may apply to facilitate resumption of trade, and that is undertaken once~~as~~ trade recommences within the country and with international partners;

c) any resources that a~~the~~ *Competent Authority* intends to provide including research, monetary, technical, or other relevant supports (e.g. compensation);

d) any review of national legislation and *disease outbreak* management procedures that may be required to underpin the recovery plan that has been developed concerning the *disease outbreak* in question;

e) ongoing communication with *Aquatic Animal Health Services* and relevant industry stakeholders to explain ~~relevant~~ details of the recovery plan and to reinforce their~~the~~ role ~~the *Aquatic Animal Health Services* and industry play~~ in future *disease* prevention and control.

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Annex 7. – Draft new Chapter 4.Z. 'Control of pathogenic agents in traded gametes and fertilised eggs of fish'

SECTION 4

DISEASE PREVENTION AND CONTROL

CHAPTER 4.Z.

CONTROL OF PATHOGENIC AGENTS IN TRADED GAMETES~~MILT~~ AND FERTILISED EGGS OF FISH

Article 4.Z.1.

Purpose

To provide recommendations for safe trade of *gametes*~~milt~~ and *fertilised eggs* of fish intended for *aquaculture* purposes and to define *risk management*~~mitigation~~ for trade~~import~~ to a *free country*, *free zone* or *free compartment* when:

1) the intention is to grow out and harvest the ~~traded~~ fish from the traded *gametes* and *fertilised eggs* ~~imported *aquatic animals*~~; or

2) the intention is to establish a new stock for *aquaculture*.

For disease-specific recommendations, refer to Article 10.X.15. (and Article 10.4.20. for infection with ISAV)~~Section 10~~.

Article 4.Z.2.

Scope

This chapter describes general recommendations for safe trade in *gametes*~~milt~~ and *fertilised eggs* of fish from an area other than a *free country*, *free zone* or *free compartment*. These recommendations include the measures outlined in Article 4.Z.3. which cumulatively reduce the *risk* of transfer of *infection* to *aquatic animal* populations in a *free country, free zone* or *free compartment*.

Trade of *gametes*~~milt~~ and *fertilised eggs* of fish from a *free country*, *free zone* or *free compartment* should meet the requirements in Articles 10.X.9. (and Article 10.4.14. for infection with ISAV) of the fish disease-specific chapters, and is not addressed in this chapter.

Article 4.Z.3.

Specific measures required for trade of gametes~~milt~~ and fertilised eggs of fish

Trade of *gametes*~~milt~~ and *fertilised eggs* of fish from a country, *zone* or *compartment* not declared free from infection with the *listed diseases* of concern should meet the following requirements:

1) the health status of the broodstock at the *aquaculture establishment* of origin must~~should~~ be determined. Only populations of broodstock which are demonstrated to be ~~test~~ free from the *pathogenic agents* of concern, as described in point 3 of Article 4.Z.4., are suitable for movement~~supply~~ to *collection and incubation centres*~~, as described in Article 4.Z.4.~~;

2) *gametes*~~milt~~ and *fertilised eggs* must~~should~~ originate~~come~~ from a *collection and incubation centre* which has been approved for that purpose by the *Competent Authority* of the place of origin, and which operates in compliance with the conditions described in Articles 4.Z.5., 4.Z.6. and 4.Z.7.;

3) in the event of a positive detection in a *collection and incubation centre*, the *Competent Authority* of the *importing country* should assess the *risks* associated with importation of *gametes* and *fertilised eggs* from that establishment, taking all relevant factors into account, including the *biosecurity plan* which is applied to prevent cross contamination of gametes and fertilised eggs from individual parents which have tested negative;

43) ~~the~~ *fertilised eggs* must~~should~~ be~~have been~~ surface disinfected prior to the export using a method proven to inactivate *pathogenic agents*, for salmonid eggs as described in Chapter 4.5.~~ and in accordance with the recommendations in the fish disease-specific chapters (Articles 10.X.15. for infection with SAV, infection with IHNV, and infection with VHSV; Article 10.4.20. for infection with ISAV)~~;

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

Application of the measures recommended in this chapter should comply with the requirements of Chapters 5.1., 5.2. and 5.3.

Article 4.Z.4.

Health status of broodstock at the aquaculture establishment~~place~~ of origin

Aquaculture establishments keeping broodstock for movement to a *collection and incubation centre* for the production of~~and~~ *gametes*~~milt~~ and *fertilised eggs* of fish ~~from a country, *zone* or *compartment* not declared free from infection with a *listed disease*,~~ should meet the following requirements:

1) the *aquaculture establishment* ~~it~~ must~~should~~ be approved for that purpose by the *Competent Authority* and be under its official control;

2) ~~it should implement~~have in place a *biosecurity plan* should be implemented which has been developed ~~drawn up~~ in accordance with Chapter 4.1.;

3) the broodstock to be transferred should be sampled and tested for the *pathogenic agents* of concern no more than 30 days before the broodstock's entry to ~~the date on which they enter~~ prior to entry to the *collection and incubation centre* using a sample size that is sufficiently large to demonstrate with 95% confidence that the *pathogenic agent* would be detected if present above a prevalence of 2%, using the diagnostic methods provided in the *Aquatic Manual*. A lower design prevalence should be used if justified by epidemiological evidence. I If the results of this testing produce a positive result, the broodstock should not be moved to the *collection and incubation centre*;

4) broodstock intended for movement to a *collection and incubation centre* should be clinically healthy at the time of movement, should not originate~~be~~ from a population experiencing recent or ongoing mortality, and should not be exposed to animals or other sources of *disease* that can~~of a~~ lower their health status following the testing referred to in~~at~~ point 3.

Article 4.Z.5.

Collection and incubation centres

Collection and incubation centres should be approved for that purpose by the *Competent Authority*, and be under its official control. ~~for that purpose on the basis that the~~ The *collection and incubation centre* should meet the following requirements~~ should~~:

1) be~~is~~be under the supervision of an *Aquatic Animal Health Professional* or *veterinarian*, who takes overall responsibility for *aquatic animal* health at the establishment ~~its operation~~;

2) have implemented ~~have~~ a *biosecurity plan* which has been developed ~~drawn up~~ in accordance with Chapter 4.1.;

3) be~~is~~be structured to contain epidemiologically separate individual broodstock or groups of broodstock;

4) havehashave in place a valid traceability system in place to ensure that *gametes* milteach batch of *gametes* or *fertilised eggs* can be traced back to an epidemiologically separate individual or group as relevant, and which includesinclude documentation and auditing of testing results, *disease* history and movements of *aquatic animals*;

5) isbe separated into dedicated areas for:

a) holding broodstock prior to *gamete* collection;

ba) a collection ofroom for eggs and milt;

c) milt testing and storage;

d) disinfection of *fertilised eggs*;

eb) an incubation ofcentre for *fertilised eggs*;

c) a milt laboratory and milt storage area;

fd) administration offices.

56) isbe subject to inspections carried outand pass audits by the *Competent Authority* or aan approved third party approved by the *Competent Authority* at a frequency sufficient to ensure that the *collection and incubation centre* is in compliance withleast once per year against the requirements of this chapter.

Article 4.Z.6.

Biosecurity conditions applicable to collection and incubation centres

Collection and incubation centres must have a *biosecurity plan* which has been developed in accordance with Chapter 4.1. To further minimise the risk of contamination of *gametes* and *fertilised eggs* by common microorganisms, some which may be pathogenic, the following measures should be taken:

1) the *collection and incubation centre* should be separated into dedicated areas for:

a) holding broodstock prior to *gamete* collection;

b) collection of *gametes*;

c) milt testing and cryopreservationstorage;

d) disinfection of *fertilised eggs*;

e) incubation of *fertilised eggs*;

f) collection of *aquatic animal products* and waste;

g) administration;

2) water used, including for production and shipment (such as ice), should be free from *pathogenic agents* of concern;

3) only fish directly associated with the production of *gametes* should be permitted to enter the *collection and incubation centre*;

4) when collecting *gametes* from broodstock, all necessary precautions should be taken to prevent the risk of contamination from the skin, surface, or blood;

5) procedures should include the use of sterile equipment, gloves and any other appropriate contamination prevention measures to maintain the sanitary integrity of the *gametes* or *fertilised eggs*;

6) incubators should be cleaned and disinfected before and after each use;

~~7) each broodstock should be euthanized after removal of eggs or after the last collection of milt;~~

7~~8~~) the system described in point 4 of Article 4.Z.5. should ensure that *gametes* or *fertilised eggs* can be traced back to the individual parent and the associated screening results;

8~~9~~) where the system only allows tracking to the group and not to the individual, the measures referred to in point 5 of Article 4.Z.7. should apply to the group;

9~~10~~) if *fertilised eggs* from multiple parents are incubated together and a positive individual is detected, all *fertilised eggs* that were incubated together should be disposed of in a biosecure manner in accordance with Chapter 4.8. ~~discarded~~.

Article 4.Z.7~~6~~.

Testing of broodstock at the collection and incubation centre

Broodstock for the production of~~and~~ *gametes*~~milt~~ and *fertilised eggs* of fish, should meet the following requirements at the *collection and incubation centre*:

1) extraction of *gametes*~~stripping~~ and collection of broodstock samples for *disease* testing~~sampling~~ should be carried out under the oversight~~supervision~~ of the *Aquatic Animal Health Professional* or *veterinarian* who has responsibility for the *collection and incubation centre*;

2) at *gamete* extraction, ~~stripping~~ the broodstock should be individually sampled~~,~~ and tested for the *listed diseases* of concern, in accordance with the methods for diagnosis provided in the *Aquatic Manual,* in a laboratory that has been approved by the *Competent Authority*;

3~~2~~) fish that test positive, and any *gametes* or *fertilised eggs*~~milt or eggs~~ derived from them should not be traded;

4) details of the results from testing relevant cohorts of broodstock as described in point 2 ~~paragraph 1~~ should be provided to the *Competent Authority* of an *importing country* on request;

5) in accordance with the *biosecurity plan* for the *collection and incubation centre*,~~and~~ all *gametes*, *fertilised eggs* and fish from the~~that~~ epidemiological group that tested positive should be disposed of in a biosecure manner. Affected facilities should be disinfected to ensure that cross-contamination of other batches of *gametes* or *fertilised eggs*~~milt or eggs~~ does not occur;

6) *fertilised eggs* should be surface disinfected using a method proven to inactivate ~~inactive~~ *pathogenic agents*, for salmonid eggs in accordance with the protocol as described in Article 4.5.2.;Chapter 4.5.

~~7) any broodstock mortality should be investigated to determine cause of death.~~

Article 4.Z.8~~7~~.

Conditions applicable to the collection and storage of milt and preparation of milt samples ~~in the laboratory~~

The following conditions should be in place ~~at the laboratory~~ for milt collection and storage:

1) the integrity of the traceability system as described in Article 4.Z.5. should be maintained at all times;

2) receptacles used to freeze milt should be sterilized before use;

3) diluents should be pathogen free ~~produced in a way to protect against contamination with *pathogenic agents*~~;

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

Annex 8. – Model Article 10.X.10. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Article 10.4.15. for Chapter 10.4. 'Infection with ISAV'

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

CHAPTER 10.X.

INFECTION WITH [PATHOGEN X]

[…]

Article 10.X.10.

Importation of aquatic animals~~, excluding gametes and fertilised eggs,~~ for aquaculture from a country, zone or compartment not declared free from infection with [pathogen X]

When importing, for *aquaculture, aquatic animals*~~, excluding *gametes* and *fertilised eggs,*~~ of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with [pathogen X], the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider ~~applying~~ the *risk* mitigation measures in either~~either~~ points~~s~~ 1 or~~and~~or~~and~~ 2 below:~~:~~

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   Either~~Either~~

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.X.3. or other products authorised by the *Competent Authority*; and

   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate [pathogen X] in accordance with Chapters 4.4., 4.8. and 5.5.

   Or~~Or~~

   d)~~d) apply the requirements of Chapter 4.Z.~~ apply the requirements of Article 10.X.15~~apply the requirements of Chapter 4.Z.~~ regarding *gametes* or *fertilised~~fertilized eggs~~*.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

   Either~~Either~~

   a) In the *exporting country*:

      i) identify potential source populations and evaluate their *aquatic animal* health records;

      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with [pathogen X].

b) in the *importing country*:

i) import the F-0 population into a *quarantine* facility;

ii) test the F-0 population for [pathogen X] in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with [pathogen X], and sample and test for [pathogen X] in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.6. of the *Aquatic Manual;*

v) if [pathogen X] is not detected in the F-1 population, it may be defined as free from infection with [pathogen X] and may be released from *quarantine*;

vi) if [pathogen X] is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Or~~Or~~

c)~~c) apply the requirements of Chapter 4.Z.~~ apply the requirements of Article 10.X.15~~apply the requirements of Chapter 4.Z.~~ regarding *gametes* or *fertilised~~fertilized eggs~~*.

[…]

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

Article 10.4.15.

Importation of aquatic animals~~, excluding gametes and fertilised eggs,~~ for aquaculture from a country, zone or compartment not declared free from infection with ISAV

In this article, all statements referring to infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

When importing, for *aquaculture, aquatic animals*~~, excluding *gametes* and *fertilised eggs,*~~ of a species referred to in Article 10.4.2. from a country, *zone* or *compartment* not declared free from infection with ISAV, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider ~~applying~~ the *risk* mitigation measures in either~~either~~ point~~s~~ 1 or~~and~~or~~and~~ 2 below:~~.~~

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   Either~~Either~~

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.4.3. or other products authorised by the *Competent Authority*; and

   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate ISAV in accordance with Chapters 4.4., 4.8. and 5.5.

   Or~~Or~~

   d)~~d) apply the requirements of Chapter 4.Z.~~ apply the requirements of Article 10.4.20~~apply the requirements of Chapter 4.Z.~~ regarding *gametes* or *fertilised*~~*fertilized eggs*~~.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

   Either~~Either~~

   a) In the *exporting country*:

      i) identify potential source populations and evaluate their *aquatic animal* health records;

      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with ISAV.

   b) in the *importing country*:

      i) import the F-0 population into a *quarantine* facility;

      ii) test the F-0 population for ISAV in accordance with Chapter 1.4. to determine their suitability as broodstock;

iii) produce a first generation (F-1) population in *quarantine*;

iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with ISAV, and sample and test for ISAV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.6. of the *Aquatic Manual;*

v) if ISAV is not detected in the F-1 population, it may be defined as free from infection with ISAV and may be released from *quarantine*;

vi) if ISAV is detected in the F-1 population, those animals should not be released from quarantine and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Or~~Or~~

c)~~c) apply the requirements of Chapter 4.Z.~~ apply the requirements of Article 10.4.20~~apply the requirements of Chapter 4.Z.~~ regarding *gametes* or *fertilised~~fertilized~~ eggs*.

[…]

_____

Annex 9. – Model Article 10.X.15. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV' and Chapter 10.10. 'Infection with VHSV', and Article 10.4.20. for Chapter 10.4. 'Infection with ISAV'

Model Article 10.X.15. for Chapter 10.5. 'Infection with SAV', Chapter 10.6. 'Infection with IHNV', and Chapter 10.10. 'Infection with VHSV'

CHAPTER 10.X.

INFECTION WITH [PATHOGEN X]

[…]

Article 10.X.15

Importation of gametes~~milt~~ and fertilised eggs of fish ~~disinfected eggs~~ for aquaculture from a country, zone or compartment not declared free from infection with [pathogen X]

When importing *gametes~~milt~~* or *fertilised eggs* of a species referred to in Articles 10.X.2., for *aquaculture* from a country, *zone* or *compartment* not declared free from infection with [pathogen X], the *Competent Authority* of the *importing country* should ensure that:

1) the consignment meets the requirements in Chapter 4.Z.; and

2) *fertilised eggs* have been disinfected using a method proven to inactivate *pathogenic agents*, for salmonid eggs in accordance with recommendations in Chapter 4.5.; and

3) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of [pathogen X] or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

4) all effluent and waste materials are treated to ensure inactivation of [pathogen X] or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

The *Competent Authority* should consider internal measures, such as additional *disinfection* of the *fertilised eggs* upon arrival in the *importing country*.

The *Competent Authority* of the *importing country* should require that the consignment~~The consignment should~~ be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* certifying that the *gametes~~milt~~* and *fertilised eggs* fulfil the recommendations in Articles 4.Z.3. to 4.Z.7.

~~1) When importing disinfected eggs of the species referred to in Article 10.X.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from infection with [pathogen X], the *Competent Authority* of the *importing country* should assess at least the following:~~

~~a) the likelihood that water used during the *disinfection* of the eggs is contaminated with [pathogen X];~~

~~b) the prevalence of infection with [pathogen X] in broodstock (including results from testing of ovarian fluid and milt).~~

~~2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should request that *risk* mitigation measures are applied, including:~~

a) *disinfection* of the eggs prior to importing, in accordance with recommendations in Chapter 4.5.; and

b) that between *disinfection* and importation, eggs should not come into contact with anything which may affect their health status.

The *Competent Authority* should consider internal measures, such as additional *disinfection* of the eggs upon arrival in the *importing country*.

3) When importing *disinfected* eggs of the species referred to in Article 10.X.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from infection with [pathogen X], the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* certifying that the procedures described in point 2(a) and (b) of this article have been fulfilled.

[…]

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

Article 10.4.20.

Importation of gametes~~milt~~ and fertilised eggs of fish ~~disinfected eggs~~ for aquaculture from a country, zone or compartment not declared free from infection with ISAV

In this article, all statements referring to infection with ISAV include~~s~~ HPR-deleted ISAV and HPR0 ISAV.

When importing *gametes*~~milt~~ or *fertilised eggs* of a species referred to in Articles 10.4.2., for *aquaculture* from a country, *zone* or *compartment* not declared free from infection with ISAV, the *Competent Authority* of the *importing country* should ensure that:

1) the consignment meets the requirements in Chapter 4.Z.; and

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

3~~5~~) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

4~~6~~) all effluent and waste materials are treated to ensure inactivation of ISAV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

The *Competent Authority* should consider internal measures, such as additional *disinfection* of the *fertilised eggs* upon arrival in the *importing country*.

The *Competent Authority* of the *importing country* should require that the consignment~~The consignment should~~ be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* certifying that the *gametes*~~milt~~ and *fertilised eggs* fulfil the recommendations in Articles 4.Z.3. to 4.Z.7.

~~1) When importing disinfected eggs of the species referred to in Article 10.4.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from infection with ISAV, the *Competent Authority* of the *importing country* should assess at least the following:~~

~~a) the likelihood that water used during the *disinfection* of the eggs is contaminated with ISAV;~~

~~b) the prevalence of infection with ISAV in broodstock (including results from testing of ovarian fluid and milt).~~

~~2) If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should request that *risk* mitigation measures are applied, including:~~

~~a) *disinfection* of the eggs prior to importing, in accordance with recommendations in Chapter 4.5.; and~~

~~b) that between *disinfection* and importation, eggs should not come into contact with anything which may affect their health status.~~

~~The *Competent Authority* should consider internal measures, such as additional *disinfection* of the eggs upon arrival in the *importing country*.~~

3) When importing *disinfected* eggs of the species referred to in Article 10.4.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from infection with ISAV, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* certifying that the procedures described in point 2(a) and (b) of this article have been fulfilled.

[…]

_____

Annex 10. – Glossary

GLOSSARY

[...]

COLLECTION AND INCUBATION CENTRE

means a facility approved by the *Competent Authority* in conformity with the provisions of Chapter 4.Z. for holding broodstock, the collection of eggs, fertilisation and incubation, and the collection, processing, and storage of milt.

[...]

FERTILISED EGG

means a viable fertilised *ovum* of an *aquatic animal*. 'Uneyed~~Green~~ eggs' means newly fertilised ova of fish. 'Eyed eggs' means *fertilised eggs* of fish where the eyes of the embryo are visible and that ~~the *fertilised eggs*~~ may be transported.

[...]

GAMETES

means the sperm (contained within seminal fluid or milt) or unfertilised eggs of aquatic animals that are held or transported separately prior to fertilisation.

[...]

ORNAMENTAL AQUATIC ANIMAL

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

[…]

Annex 11. – Draft new Chapter 5.X. 'Movement of ornamental aquatic animals'

SECTION 5

TRADE MEASURES, IMPORTATION/EXPORTATION PROCEDURES AND HEALTH CERTIFICATION

CHAPTER 5.X.

MOVEMENT OF ORNAMENTAL AQUATIC ANIMALS

Article 5.X.1.

Introduction

This chapter provides recommendations to address the *risk* of *pathogenic agent*~~*disease*~~ transmission via the movement of *ornamental aquatic animals* ~~to prevent entry into a country, *zone* or *compartment* that is free from the *pathogenic agents* of concern~~.

Ornamental aquatic animals may originate from the wild or from *aquaculture establishments*. Once they have entered the supply chain they may be epidemiologically separated from farmed or wild populations but can be diverted to other end uses for which they were not intended. This may provide a pathway for ~~*disease*~~ transmission of *pathogenic agents* and place other populations of *susceptible species* at *risk*.

International movement of *ornamental aquatic animals* is characterised by translocation of numerous individual animals comprised of many species of fish, crustaceans, molluscs and amphibians originating from diverse environments. Supply chains may involve the aggregation of animals from multiple sources and their dissemination through retail trade as pets, for display or for competition providing opportunities for ~~*disease*~~ transmission of p*athogenic agents*. These characteristics of the movement of *ornamental aquatic animals* may present challenges for managing *aquatic animal disease risks*.

Article 5.X.2.

Scope

This chapter provides recommendations for managing the pathogen~~*disease*~~ *risks* associated with movement of *ornamental aquatic animals*. The standards concerning trade in species that are susceptible to the *diseases* listed in Chapter 1.3., are set out in the disease-specific chapters. This Chapter provides additional guidance for managing *risk* associated with the movement of *ornamental aquatic animals* which are susceptible to *listed diseases* or other *diseases* identified as *hazards*. ~~that complement other provisions of the *Aquatic Code*, including the measures specified in the disease-specific chapters.~~

Article 5.X.3.

General principles

The general principles for the movement of *ornamental aquatic animals* that should be considered when developing *risk* mitigation measures are:

1) an importer should take into account the eligibility for international movement of a consignment of *ornamental aquatic animals,* as described in Article 5.X.4.; ~~the legality~~eligibility for the movement of a species (or a taxonomic group of species) should be determined considering existing regulatory measures in the importing country regarding its conservation status (e.g. species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora), and potential biodiversity and ecosystem impacts in the *importing country* (e.g. potential to become an invasive alien species), as described in Article 5.X.4.;

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

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

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

5) any *risk management* measures should be the least trade restrictive measures required to mitigate the *disease* risks identified by a *risk assessment,* as described in Articles 5.X.8. to 5.X.11.;

6) measures should be taken to maintain the welfare of *ornamental aquatic animals* during transit, including as described in Article 5.X.12.

Article 5.X.4.

Eligibility for the international movement of ornamental aquatic animals

Prior to consulting the *Competent Authority* with responsibility for *aquatic animal* health concerning ~~considering~~ the *aquatic animal* health *risks* associated with the movement~~import~~ of a species of *ornamental aquatic animal*, an importer and exporter ~~the *Competent Authority* of an *importing country*~~ should first determine that the movement~~import~~ of the species would be compliant with ~~consult~~ relevant national regulations and international obligations ~~to determine that the species is eligible for import~~. ~~Species~~ For example, species of *ornamental aquatic animal* may be subject to controls on international movement or trade due to their conservation status (e.g. listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or listed as an endangered species or preserved species by a *Competent Authority* or other authorities of an *importing country*). These controls may prohibit international movement or may necessitate additional import documentation.

Species of *ornamental aquatic animals* (or taxonomic groups of species) may also be identified as invasive by a *Competent Authority* or other authority of an *importing country*. Such species may be prohibited from being~~to be~~ traded, owned or farmed due to the risks they present to biodiversity, ecosystems, industry, ~~or~~ public amenity or public health in the *importing country*.

Article 5.X.5.

General health status of ornamental aquatic animals

Aquaculture establishments holding or packaging *ornamental aquatic animals* for international movement should have suitable facilities and husbandry practices for maintaining the health status of all species held within the facility.

The *Competent Authority* of an *exporting country* should ensure that *aquaculture establishments* are under sufficient supervision to ensure that requirements of the *Competent Authority* of the *importing country* for *ornamental aquatic animals* can be met. The *Aquatic Animal Health Services* relevant to meeting *importing country* requirements should comply with the principles of Chapter 3.1.

If *aquaculture establishments* are required by the *Competent Authority* to maintain a *biosecurity plan,* or if this is required to meet *importing country* requirements, the *biosecurity plan* should be developed as described in Chapter 4.1.

Ornamental aquatic animals should not be moved or traded from an *aquaculture establishment* if they are exhibiting clinical signs of *disease* or experiencing unexplained mortalities.

Article 5.X.6.

Application of sanitary measures for listed diseases

Sanitary measures applied to manage the *risk* of transmission of *listed diseases* associated with movement of *ornamental aquatic animals* should be in accordance with the relevant disease-specific chapters. The *Competent Authority* of an *importing country* can only require disease-specific measures if it is free from the *disease* of concern, or if the *disease* of concern is under an official control programme, as described in Chapter 5.1.

When importing *ornamental aquatic animals* of *susceptible species* (as listed in Article X.X.2. of each disease-specific chapter), from a *free country*, *free zone* or *free compartment*, the *Competent Authority* of the *importing country* should require, in accordance with Article X.X.9. of the relevant disease-specific chapter, that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that the consignment originates from a *free country*, *free zone* or *free compartment*.

The *Competent Authority* of an *importing country* can only require *sanitary measures* for a *listed disease* more stringent than the standards of the *Aquatic Code* if those measures are supported by a *risk analysis* in accordance with Chapter 2.1.

Article 5.X.7.

Risk analysis

The *Competent Authority* of an *importing country* should use *risk analysis* to justify any *sanitary measures* for non-listed *diseases* associated with imported *ornamental aquatic animals*. *Risk analysis* should also be used to justify any *sanitary measures* for *listed diseases* if the measures are more stringent than the standards of the *Aquatic Code*. The *Competent Authority* of an *importing country* can only require pathogen-specific *sanitary measures* if the country is free from the *disease* of concern, or if the *disease* of concern is under an official control programme, as described in Chapter 5.1.

Risk analysis for the import of *ornamental aquatic animals* should be conducted as described in Chapter 2.1. In addition to the factors provided in Chapter 2.1, the *risk analysis* should take into account the following factors relevant to the assessment of likelihood of entry and exposure of *hazards* associated with *ornamental aquatic animals*.

Entry

1) The *disease* status of identified *hazards* within the country, *zone* or *compartment* of origin, including information on the prevalence of identified *hazards* within populations of *ornamental aquatic animals* or within their source populations (e.g. wild animals).

2) The *disease* prevention and control practices within the supply chain for *ornamental aquatic animals* in the *exporting country*, and the quality of the *aquatic animal health services* supporting *disease* prevention and control.

3) The range of species that are susceptible to the specific *pathogenic agents* identified as *hazards* and the evidence to substantiate susceptibility in accordance with Chapter 1.5.

4) The suitability of environmental conditions (e.g. temperature, salinity) for the *hazard* at the place of origin of the *ornamental aquatic animals* which support *hazard* viability, transmission and infection in *susceptible species*.

5) The nature of supply chains and the degree of mixing or epidemiological separation of populations originating from sources with different health status.

Exposure

6) The presence of populations of *susceptible species* in the *importing country*.

7) The suitability of environmental conditions (e.g. temperature, salinity) for the *susceptible species* of imported *ornamental aquatic animals* in the *importing country*.

8) The suitability of environmental conditions (e.g. temperature, salinity) for the *hazard* in the *importing country.*

9) Intended end uses of the *ornamental aquatic animals* and the implications for exposure. For example:

   a) display in zoos or public aquariums – *ornamental aquatic animals* may be displayed in professionally managed facilities which may have veterinary oversight and *biosecurity* measures in place;

   b) exhibition or competition – *ornamental aquatic animals* may be moved internationally for short periods for participation in exhibitions or competitions, may be kept epidemiologically isolated, and then returned to the country of origin;

   c) pets – *ornamental aquatic animals* may be moved internationally in large numbers and widely distributed through retail trade for sale as pets.

10) Cultural practices that may influence exposure, including diversion from intended end-uses (e.g. deliberate release into waterways, use as bait).

11) Internal measures for *disease* prevention and control and to limit diversion to unintended~~non-intended~~ end uses.

Article 5.X.8.

Risk management

The standards of the *Aquatic Code* are the preferred choice of *sanitary measures* for *risk management* of *listed diseases* associated with *ornamental aquatic animals*.

To develop *sanitary measures* for non-listed *diseases*, or to justify measures for *listed diseases* that are more stringent than the standards of the *Aquatic Code*, the *Competent Authority* of an *importing country* should follow the recommendations for *risk management* as described in Chapter 2.1. The *sanitary measures* should also comply with the requirements of Section 5 of the *Aquatic Code*.

Sanitary measures for imported *ornamental aquatic animals* can be applied along the import pathway. The *Competent Authority* of the *importing country* should select the least trade restrictive measures required to mitigate the *disease risks* identified by a *risk assessment.* Options for *risk management* are provided in articles 5.X.9. to 5.X.11. and include those applied:

1) within the *exporting country,* as described in Article 5.X.9.;

2) at the *frontier post,* as described in Article 5.X.10.;

3) within the *importing country*, as described in Article 5.X.11.

Article 5.X.9.

Risk management measures in the exporting country

Where required by the *Competent Authority* of the *importing country* based on *risk analysis*, *risk management* measures can be applied within the *exporting country* to mitigate the *disease risks* associated with international movement of *ornamental aquatic animals* from a country, *zone* or *compartment* not declared free from *diseases* of concern. ~~The *Competent Authority* of the *importing country* should select the least restrictive measures required to mitigate the *disease risks* identified by a *risk assessment.* *Risk management*~~ measures may include:

1) registration or approval by a *Competent Authority* of *aquaculture establishments* that produce, hold or package *ornamental aquatic animals* for export. Registration or approval is a means for ensuring that any *aquaculture establishments* meet any necessary requirements for export of *ornamental aquatic animals* (e.g. general health requirements, *biosecurity*, record keeping);

2) confirmation that the exported *ornamental aquatic animals* are free from clinical signs of *disease* or unexplained mortality at the *aquaculture establishment* from which they are exported~~place of origin (as described in point 2 of Article 5.X.7.)~~ and meet general health requirements in accordance with Article 5~~X~~.X.5.;

3) pre-export *quarantine* in an *aquaculture establishment* (e.g. packaging facility) to ascertain the health status of the animals to be exported. The duration~~length~~ of *quarantine* period and the *quarantine* conditions would be based on the *risk assessment* and may vary depending on the species and specific *diseases* of concern;

4) pre-export testing ~~of consignments~~ of *ornamental aquatic animals* to confirm that the consignment is ~~they are~~ free from *pathogenic agents* of concern; for *listed diseases* testing should comply with the recommendations in the *Aquatic Manual*;

5) systems for traceability and record keeping to ensure transparency of the health status of specific populations and~~or~~ consignments of *ornamental aquatic animals*;

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

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

8~~7~~) certification or provision of other documentation to verify that the *risk management* measures required by the *Competent Authority* of the *importing country* have been met.

Article 5.X.10.

Risk management measures at the border

Where required by the *Competent Authority* of the *importing country* based on *risk assessment*, *risk management* measures can be applied at the border to mitigate the *disease risks* associated with international movement of *ornamental aquatic animals* from a country, *zone* or *compartment* not declared free from *diseases* of concern. ~~The *Competent Authority* of the *importing country* should select the least restrictive measures required to mitigate the *disease risks* identified by a *risk assessment.* *Risk management* measures may include:

1) upon arrival at the *frontier post,* the *Competent Authority* of the *importing country* may perform an inspection of the containers, checking that the consignment matches information included on the accompanying certificate or other documentation. The inspection may include checking for damage to the containers, and observing the animals for abnormal behaviour and suspected clinical signs;

2) at border *quarantine* under the supervision of the *Competent Authority*. The length of *quarantine* would be based on the *risk assessment* and may vary depending on the species and specific *pathogenic agents*~~*diseases*~~ of concern. Conditions in *quarantine* should optimise the health of the animal and also provide opportunity of expression of *disease*. Effluent and waste materials from the *quarantine* facilities should~~may~~ be treated or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.;

3) at border testing under the supervision of the *Competent Authority*. Any testing requirements would be based on the *risk assessment*;

4) destruction (as described in Chapter 7.4.) and biosecure disposal of infected or clinically affected animals. All water (including ice), equipment, containers and packaging material used in transport should~~may~~ be treated or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.

Article 5.X.11.

Risk management measures in the importing country

The *Competent Authority* of the *importing country* may apply internal *risk management* measures, including to address the *risks* associated with *ornamental aquatic animals* being used for non-intended purposes or being released into the wild. *Risk management* measures may include:

1) prohibiting the diversion of *ornamental aquatic animals* for an unintended~~alternative~~ end use (e.g. for *aquaculture*, *feed*, bait, research) or from being released into the wild;

2) notifying the *Competent Authority* of the *exporting country* of the detection of a *pathogenic agent* of concern in a consignment, in accordance with Chapter 5.3.;

3) traceability of imported *ornamental aquatic animals* to commercial establishments~~through the commercial supply chain~~.

Article 5.X.12.

Animal welfare during transport

Welfare of *ornamental aquatic animals* during international movement relies on the maintenance of environmental conditions appropriate to the biological characteristics of the species. The minimum requirements to maintain welfare will vary among different species.

Transport of *ornamental aquatic animals* in conditions that are not suited to their biological characteristics may increase vulnerability to infection and the development of clinical *disease*, leading to an increased likelihood of ~~*disease*~~ transmission of *pathogenic agents* and morbidity or mortality of animals not related to *disease*.

Transport of *ornamental aquatic animals* should follow protocols that are appropriate for maintaining the welfare of the species and life stage being transported (e.g. for packaging, water quality, temperature, stocking density, duration). Where existing protocols are not available, they may be developed by considering the factors provided in Chapter 7.2. *Welfare of farmed fish during transport* and should accommodate other requirements during transport, (e.g. the need for inspection and external container repackaging). The International Air Transport Association (IATA) regulations for the transport of live animals should also be taken into account.

Plans~~*Contingency plans*~~ should be developed that identify possible adverse welfare events that may occur during transport, the procedures for managing each event, the actions to be taken and the responsibilities of the parties involved.

———————

Annex 12. – Periods of basic biosecurity conditions and targeted surveillance for disease-specific chapters of the *Aquatic Code*

SECTION 8

DISEASES OF AMPHIBIANS

CHAPTER 8.1.

INFECTION WITH *BATRACHOCHYTRIUM DENDROBATIDIS*

[…]

Article 8.1.5.

Country free from infection with *B. dendrobatidis*

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *B. dendrobatidis*~~none of the *susceptible species* referred to in Article 8.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *B. dendrobatidis* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. dendrobatidis*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of *B. dendrobatidis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of *B. dendrobatidis*; or

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

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

Article 8.1.6.

Zone free from infection with *B. dendrobatidis*

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *B. dendrobatidis*~~none of the *susceptible species* referred to in Article 8.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *B. dendrobatidis* for at least the last ten~~[ten]~~ years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. dendrobatidis*, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of *B. dendrobatidis* and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. dendrobatidis.*~~

i) at least the last two years in wild and farmed *susceptible species* without detection of *B. dendrobatidis*; or

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

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

Article 8.1.7.

Compartment free from infection with *B. dendrobatidis*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *B. dendrobatidis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 8.1.9. and 8.1.10. as appropriate; and

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

[…]

CHAPTER 8.2.

INFECTION WITH *BATRACHOCHYTRIUM SALMANDRIVORANS*

[…]

Article 8.2.5.

Country free from infection with *B. salamandrivorans*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. salamandrivorans* if all shared water bodies are within countries or *zones* declared free from infection with *B. salamandrivorans* (see Article 8.2.6.).

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

1) none of the *susceptible species* referred to in Article 8.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *B. salamandrivorans* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. salamandrivorans*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of *B. salamandrivorans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of *B. salamandrivorans*; or

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

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

Article 8.2.6.

Zone free from infection with *B. salamandrivorans*

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

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

1) none of the *susceptible species* referred to in Article 8.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~six~~] months;

OR

2) there has been no occurrence of infection with *B. salamandrivorans* for at least the last ten[~~ten~~] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. salamandrivorans*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[~~ten~~] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two[~~two~~] years without detection of *B. salamandrivorans* and *basic biosecurity conditions* have been continuously met and have been in place for at least one[~~one~~] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. salamandrivorans.*~~

      i) at least the last two years in wild and farmed *susceptible species* without detection of *B. salamandrivorans*; or

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

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

Article 8.2.7.

Compartment free from infection with *B. salamandrivorans*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *B. salamandrivorans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 8.2.9. and 8.2.10. as appropriate; and

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

[…]

CHAPTER 8.3.

INFECTION WITH *RANAVIRUS* SPECIES

[…]

Article 8.3.5.

Country free from infection with *Ranavirus* species

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *Ranavirus* species if all shared water bodies are within countries or *zones* declared free from infection with *Ranavirus* species (see Article 8.3.6.).

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *Ranavirus* species~~none of the *susceptible species* referred to in Article 8.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *Ranavirus* species for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *Ranavirus* species, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *Ranavirus* species, and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

   a) on detection of *Ranavirus* species, the affected area was declared an *infected zone* and a *protection zone* was established; and

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

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

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

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

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

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

Article 8.3.6.

Zone free from infection with *Ranavirus* species

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *Ranavirus* species~~none of the *susceptible species* referred to in Article 8.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *Ranavirus* species for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *Ranavirus* species, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *Ranavirus* species and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

   a) on detection of *Ranavirus* species, the affected area was declared an *infected zone* and a *protection zone* was established; and

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *Ranavirus* species.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of *Ranavirus* species; or

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

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

Article 8.3.7.

Compartment free from infection with *Ranavirus* species

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *Ranavirus species*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 8.3.9. and 8.3.10. as appropriate; and

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

[…]

SECTION 9

DISEASES OF CRUSTACEANS

CHAPTER 9.1.

ACUTE HEPATOPANCREATIC NECROSIS DISEASE

[…]

Article 9.1.5.

Country free from infection with AHPND

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with AHPND if all shared water bodies are within countries or *zones* declared free from infection with AHPND (see Article 9.1.6.).

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

1) none of the *susceptible species* referred to in Article 9.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with AHPND, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of AHPND, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 9.1.6.

Zone free from infection with AHPND

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

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

1) none of the *susceptible species* referred to in Article 9.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with AHPND, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of AHPND and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of AHPND~~.

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

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

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

Article 9.1.7.

Compartment free from infection with AHPND

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.1.9. and 9.1.10. as appropriate; and

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

[…]

CHAPTER 9.2.

INFECTION WITH *APHANOMYCES ASTACI* (CRAYFISH PLAGUE)

[…]

Article 9.2.5.

Country free from infection with *A. astaci*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *A. astaci* if all shared water bodies are within countries or *zones* declared free from infection with *A. astaci* (see Article 9.2.6.).

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *A. astaci*~~none of the *susceptible species* referred to in Article 9.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *A. astaci* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. astaci*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of *A. astaci*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of *A. astaci*; or

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

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

Article 9.2.6.

Zone free from infection with *A. astaci*

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *A. astaci*~~none of the *susceptible species* referred to in Article 9.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *A. astaci* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. astaci*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) has been in place in the *zone* for at least the last two~~[two]~~ years without detection of *A. astaci* and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:~~ at least the last [two] years without detection of *A. astaci*~~.

      i) at least the last two years in wild and farmed *susceptible species* without detection of *A. astaci*; or

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

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

Article 9.2.7.

Compartment free from infection with *A. astaci*

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.2.9. and 9.2.10. as appropriate; and

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

[…]

CHAPTER 9.3.

INFECTION WITH DECAPOD IRIDESCENT VIRUS 1

[…]

Article 9.3.5.

Country free from infection with DIV1

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with ~~with~~ DIV1 if all shared water bodies are within countries or *zones* declared free from infection with DIV1 (see Article 9.3.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for its entire *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for infection with DIV1~~none of the *susceptible species* referred to in Article 9.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with DIV1 for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with DIV1, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of DIV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 but the following conditions have been met:

   a) on detection of DIV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with DIV1; and

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

      i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of DIV1; or

      ii) at least the last one~~[one]~~ year without detection of DIV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 9.3.6.

Zone free from infection with DIV1

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with DIV1 if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for a *zone* within its *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for infection with DIV1~~none of the *susceptible species* referred to in Article 9.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with DIV1 for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with DIV1, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of DIV1 and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 in the *zone* but the following conditions have been met:

   a) on detection of DIV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with DIV1; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of DIV1.~~

      i) at least the last two years in wild and farmed *susceptible species* without detection of DIV1; or

      ii) at least the last one year without detection of DIV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 9.3.7.

Compartment free from infection with DIV1

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with DIV1 for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of DIV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with DIV1 and subsequently lost its free status due to the detection of DIV1 in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of DIV1, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.3.9. and 9.3.10. as appropriate; and

   c) one survey for infection with DIV1 has been completed at least six months~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~.

[…]

CHAPTER 9.4.

INFECTION WITH *HEPATOBACTER PENAEI* (NECROTISING HEPATOPANCREATITIS)

[…]

Article 9.4.5.

Country free from infection with *H. penaei*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *H. penaei* if all shared water bodies are within countries or *zones* declared free from infection with *H. penaei* (see Article 9.4.6.).

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

1) none of the *susceptible species* referred to in Article 9.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *H. penaei* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *H. penaei*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of *H. penaei*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of *H. penaei*; or

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

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

Article 9.4.6.

Zone free from infection with *H. penaei*

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

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

1) none of the *susceptible species* referred to in Article 9.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~six~~] months;

OR

2) there has been no occurrence of infection with *H. penaei* for at least the last ten[~~ten~~] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *H. penaei*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[~~ten~~] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two[~~two~~] years without detection of *H. penaei* and *basic biosecurity conditions* have been continuously met and have been in place for at least one[~~one~~] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *H. penaei.*~~

      i) at least the last two years in wild and farmed *susceptible species* without detection of *H. penaei*; or

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

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

Article 9.4.7.

Compartment free from infection with *H. penaei*

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.4.9. and 9.4.10. as appropriate; and

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

[…]

CHAPTER 9.5.

INFECTION WITH HYPODERMAL AND HAEMATOPOIETIC NECROSIS VIRUS

[…]

Article 9.5.5.

Country free from infection with IHHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IHHNV if all shared water bodies are within countries or *zones* declared free from infection with IHHNV (see Article 9.5.6.).

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

1) none of the *susceptible species* referred to in Article 9.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHHNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of IHHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 9.5.6.

Zone free from infection with IHHNV

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

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

1) none of the *susceptible species* referred to in Article 9.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHHNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of IHHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:~~ at least the last [two] years without detection of IHHNV~~.

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

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

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

Article 9.5.7.

Compartment free from infection with IHHNV

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one[~~one~~] year without detection of IHHNV~~*H. penaei*~~, and *basic biosecurity conditions* have been continuously met and have been in place for at least one[~~one~~] year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.5.9. and 9.5.10. as appropriate; and

   c) one survey for infection with IHHNV~~*H. penaei*~~ has been completed at least six months[~~six months~~] after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*[~~pathogen~~].

[…]

CHAPTER 9.6.

INFECTION WITH INFECTIOUS MYONECROSIS VIRUS

[…]

Article 9.6.5.

Country free from infection with IMNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IMNV if all shared water bodies are within countries or *zones* declared free from infection with IMNV (see Article 9.6.6.).

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

1) none of the *susceptible species* referred to in Article 9.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IMNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two ~~[two]~~ years without detection of IMNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 9.6.6.

Zone free from infection with IMNV

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

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

1) none of the *susceptible species* referred to in Article 9.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six ~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IMNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of IMNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place: ~~at least the last [two] years without detection of IMNV~~.

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

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

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

Article 9.6.7.

Compartment free from infection with IMNV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.6.9. and 9.6.10. as appropriate; and

   c) one survey for infection with IMNV has been completed at least six months~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the pathogen.

[…]

CHAPTER 9.7.

INFECTION WITH MACROBRACHIUM ROSENBERGII NODAVIRUS (WHITE TAIL DISEASE)

[…]

Article 9.7.5.

Country free from infection with MrNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with MrNV if all shared water bodies are within countries or *zones* declared free from infection with MrNV (see Article 9.7.6.).

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

1) none of the *susceptible species* referred to in Article 9.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with MrNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of MrNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 9.7.6.

Zone free from infection with MrNV

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

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

1) none of the *susceptible species* referred to in Article 9.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~six~~] months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with MrNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[~~ten~~] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two[~~two~~] years without detection of MrNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one[~~one~~] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:~~at least the last [two] years without detection of MrNV~~.

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

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

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

Article 9.7.7.

Compartment free from infection with MrNV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.7.9. and 9.7.10. as appropriate; and

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

[…]

CHAPTER 9.8.

INFECTION WITH TAURA SYNDROME VIRUS

[…]

Article 9.8.5.

Country free from infection with TSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with TSV if all shared water bodies are within countries or *zones* declared free from infection with TSV (see Article 9.8.6.).

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

1) none of the *susceptible species* referred to in Article 9.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TSV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of TSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 9.8.6.

Zone free from infection with TSV

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

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

1) none of the *susceptible species* referred to in Article 9.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TSV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of TSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for :~~at least the last [two] years without detection of TSV.~~

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

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

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

Article 9.8.7.

Compartment free from infection with TSV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.8.9. and 9.8.10. as appropriate; and

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

[…]

CHAPTER 9.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

[…]

Article 9.9.5.

Country free from infection with WSSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with WSSV if all shared water bodies are within countries or *zones* declared free from infection with WSSV (see Article 9.9.6.).

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

1) pathway 1 (absence of susceptible species) not suitable for infection with WSSV~~none of the *susceptible species* referred to in Article 9.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with WSSV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of WSSV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 9.9.6.

Zone free from infection with WSSV

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with WSSV~~none of the *susceptible species* referred to in Article 9.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with WSSV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two [two] years without detection of WSSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one[one] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of WSSV.~~

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

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

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

Article 9.9.7.

Compartment free from infection with WSSV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.9.9. and 9.9.10. as appropriate; and

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

[…]

CHAPTER 9.10.

INFECTION WITH YELLOW HEAD VIRUS GENOTYPE 1

[…]

Article 9.10.5.

Country free from infection with YHV1

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with YHV1 if all shared water bodies are within countries or *zones* declared free from infection with YHV1 (see Article 9.10.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for its entire *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with YHV1 for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with YHV1, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of YHV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 but the following conditions have been met:

   a) on detection of YHV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with YHV1; and

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

      i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of YHV1; or

      ii) at least the last one~~[one]~~ year without detection of YHV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 9.10.6.

Zone free from infection with YHV1

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with YHV1 if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for a *zone* within its *territory* if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 9.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with YHV1 for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with YHV1, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of YHV1 and *basic biosecurity conditions* have been continuously met and have been in place for at least one ~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 in the *zone* but the following conditions have been met:

   a) on detection of YHV1, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with YHV1; and

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of YHV1~~.

      i) at least the last two years in wild and farmed *susceptible species* without detection of YHV1; or

      ii) at least the last one year without detection of YHV1 if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 9.10.7.

Compartment free from infection with YHV1

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with YHV1 for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[one]~~ year without detection of YHV1, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with YHV1 and subsequently lost its free status due to the detection of YHV1 in the *compartment* but the following conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of YHV1, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 9.10.9. and 9.10.10. as appropriate; and

   c) one survey for infection with YHV1 has been completed at least six months~~[six months]~~ after restocking (as described in Article 1.4.14.) without detection of the *pathogenic agent*~~pathogen~~.

[…]

SECTION 10

DISEASES OF FISH

CHAPTER 10.1.

INFECTION WITH EPIZOOTIC HAEMATOPOIETIC NECROSIS VIRUS

[…]

Article 10.1.5.

Country free from infection with EHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with EHNV if all shared water bodies are within countries or *zones* declared free from infection with EHNV (see Article 10.1.6.).

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

1) none of the *susceptible species* referred to in Article 10.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with EHNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of EHNV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 10.1.6.

Zone free from infection with EHNV

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

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

1) none of the *susceptible species* referred to in Article 10.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with EHNV, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of infection with EHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of EHNV~~.

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

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

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

Article 10.1.7.

Compartment free from infection with EHNV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.1.9. and 10.1.10. as appropriate; and

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

[…]

CHAPTER 10.2.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

[…]

Article 10.2.5.

Country free from infection with *A. invadans*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *A. invadans* if all shared water bodies are within countries or *zones* declared free from infection with *A. invadans* (see Article 10.2.6.).

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *A. invadans*~~none of the *susceptible species* referred to in Article 10.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *A. invadans* for at least the last 15~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. invadans*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last 15~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *A. invadans*, and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *A. invadans*; or

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

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

Article 10.2.6.

Zone free from infection with *A. invadans*

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *A. invadans*~~none of the *susceptible species* referred to in Article 10.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *A. invadans* for at least the last 15~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *A. invadans*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last 15~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *A. invadans* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *A. invadans*~~.

      i) at least the last three years in wild and farmed *susceptible species* without detection of *A. invadans*; or

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

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

Article 10.2.7.

Compartment free from infection with *A. invadans*

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.2.9. and 10.2.10. as appropriate; and

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

[…]

CHAPTER 10.3.

INFECTION WITH GYRODACTYLUS SALARIS

[…]

Article 10.3.5.

Country free from infection with *G. salaris*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *G. salaris* if all shared water bodies are within countries or *zones* declared free from infection with *G. salaris* (see Article 10.3.6.).

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

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

OR

2) pathway 2 (historical freedom) is not suitable for infection with *G. salaris;* ~~there has been no occurrence of infection with *G. salaris* for at least the last 15[ten] years, and:~~

   ~~a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *G. salaris*, as described in Article 1.4.8. of Chapter 1.4.the corresponding chapter of the *Aquatic Manual*; and~~

   ~~b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last 15 [ten] years;~~

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *G. salaris*, and *basic biosecurity conditions* have been continuously met and have been in place for at least two ~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *G. salaris*; or

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

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

Article 10.3.6.

Zone free from infection with *G. salaris*

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

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

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

OR

2) pathway 2 (historical freedom) is not suitable for infection with *G. salaris;* ~~there has been no occurrence of infection with *G. salaris* for at least the last 15[ten] years, and:~~

~~a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *G. salaris*, as described in Article 1.4.8. of Chapter 1.4.; and~~

~~b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last 15[ten] years;~~

OR

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

OR

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

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

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

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

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for:. ~~at least the last [two] years without detection of *G. salaris.*~~

i) at least the last three years in wild and farmed *susceptible species* without detection of *G. salaris*; or

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

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

Article 10.3.7.

Compartment free from infection with *G. salaris*

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.3.9. and 10.3.10. as appropriate; and

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

[…]

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

Article 10.4.5.

Country free from infection with ISAV

In this article, all statements referring to a country free from ISAV are for any detectable ISAV, including HPR0 ISAV.

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with ISAV if all shared water bodies are within countries or *zones* declared free from infection with ISAV (see Article 10.4.7.).

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

1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) pathway 2 (historical freedom) is not suitable for infection with ISAV;~~there has been no occurrence of infection with ISAV for at least the last [ten] years, and:~~

   ~~a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with ISAV, as described in the corresponding chapter of the *Aquatic Manual*; and~~

   ~~b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;~~

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~two~~[two] years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~one~~[one] years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

ii) at least the last twoone[one] years without detection of ISAV if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 10.4.6.

Country free from infection with HPR-deleted ISAV

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

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with HPR-deletedHPR0 ISAV if all shared water bodies are within countries or *zones* declared free from infection with HPR-deletedHPR0 ISAV (see Article 10.4.8.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom with HPR-deletedHPR0 ISAV for its entire territory if it can demonstrate that:

1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[six] months;

OR

2) there has been no occurrence of infection with HPR-deletedHPR0 ISAV for at least the last ten[ten] years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with HPR-deletedHPR0 ISAV, as described in Article 1.4.8. of Chapter 1.4.the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two[two] years without detection of HPR-deletedHPR0 ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one[one] year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with HPR-deletedHPR0 ISAV and subsequently lost its free status due to the detection of HPR-deletedHPR0 ISAV but the following conditions have been met:

   a) on detection of HPR-deletedHPR0 ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of HPR-deletedHPR0 ISAV, and the appropriate disinfection procedures (as described in Chapter 4.4.) have been completed followed by fallowing as described in Chapter 4.7.; and

c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with HPR-deleted~~HPR0~~ ISAV; and

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

i) at least the last two~~[two]~~ years in wild and farmed *susceptible species* without detection of HPR-deleted~~0~~ ISAV; or

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

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

Article 10.4.7.

Zone free from infection with ISAV

In this article, all statements referring to a *zone* free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

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

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

1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) pathway 2 (historical freedom) is not suitable for infection with ISAV;~~there has been no occurrence of infection with ISAV for at least the last [ten] years, and:~~

~~a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with ISAV, as described in the corresponding chapter of the *Aquatic Manual*; and~~

~~b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;~~

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~two~~[two] years without detection of ISAV and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~one~~[one] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of ISAV.~~

i) at least the last three~~two~~ years in wild and farmed *susceptible species* without detection of ISAV; or

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

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

Article 10.4.8.

Zone free from infection with HPR-deleted ISAV

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

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

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

1) none of the *susceptible species* referred to in Article 10.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with HPR-deleted ISAV for at least the last ten~~[ten]~~ years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with HPR-deleted ISAV, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

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

OR

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

a) on detection of HPR-deleted ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and

b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of HPR-deleted ISAV, and the appropriate

disinfection procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with HPR-deleted ISAV; and

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of HPR-deleted ISAV.~~

i) at least the last two years in wild and farmed *susceptible species* without detection of HPR-deleted ISAV; or

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

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

Article 10.4.9.

Compartment free from infection with ISAV

In this article, all statements referring to a *compartment* free from infection with ISAV are for any detectable ISAV, including HPR0 ISAV.

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

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

OR

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

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

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

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

Article 10.4.10.

Compartment free from infection with HPR-deleted ISAV

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

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

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

OR

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

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

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

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

[…]

CHAPTER 10.5.

INFECTION WITH INFECTIOUS SALMONID ALPHAVIRUS

[…]

Article 10.5.5.

Country free from infection with SAV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with SAV if all shared water bodies are within countries or *zones* declared free from infection with SAV (see Article 10.5.6.).

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

1) none of the *susceptible species* referred to in Article 10.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last 12~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SAV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of SAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 10.5.6.

Zone free from infection with SAV

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

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

1) none of the *susceptible species* referred to in Article 10.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last 12[~~six~~] months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SAV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[~~ten~~] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two[~~two~~] years without detection of SAV and *basic biosecurity conditions* have been continuously met and have been in place for at least one[~~one~~] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of SAV.~~

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

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

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

Article 10.5.7.

Compartment free from infection with SAV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.5.9. and 10.5.10. as appropriate; and

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

[…]

CHAPTER 10.6.

INFECTION WITH INFECTIOUS HAEMATOPOIETIC NECROSIS VIRUS

[…]

Article 10.6.5.

Country free from infection with IHNV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with IHNV if all shared water bodies are within countries or *zones* declared free from infection with IHNV (see Article 10.6.6.).

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

1) none of the *susceptible species* referred to in Article 10.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHNV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of IHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 10.6.6.

Zone free from infection with IHNV

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

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

1) none of the *susceptible species* referred to in Article 10.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with IHNV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two ~~[two]~~ years without detection of IHNV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place; ~~at least the last [two] years without detection of IHNV.~~

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

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

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

Article 10.6.7.

Compartment free from infection with IHNV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.6.9. and 10.6.10. as appropriate; and

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

[…]

CHAPTER 10.7.

INFECTION WITH KOI HERPESVIRUS

[…]

Article 10.7.5.

Country free from infection with KHV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with KHV if all shared water bodies are within countries or *zones* declared free from infection with KHV (see Article 10.7.6.).

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

1) none of the *susceptible species* referred to in Article 10.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with KHV for at least the last 15~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with KHV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last 15~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of KHV and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 10.7.6.

Zone free from infection with KHV

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

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

1) none of the *susceptible species* referred to in Article 10.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with KHV for at least the last 15~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with KHV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last 15~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of KHV and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of KHV.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of KHV; or

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

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

Article 10.7.7.

Compartment free from infection with KHV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.7.9. and 10.7.10. as appropriate; and

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

[…]

CHAPTER 10.9.

INFECTION WITH SPRING VIRAEMIA OF CARP VIRUS

[…]

Article 10.9.5.

Country free from infection with SVCV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with SVCV if all shared water bodies are within countries or *zones* declared free from infection with SVCV (see Article 10.9.6.).

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

1) none of the *susceptible species* referred to in Article 10.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SVCV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten ~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of SVCV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 10.9.6.

Zone free from infection with SVCV

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

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

1) none of the *susceptible species* referred to in Article 10.9.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with SVCV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of SVCV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of SVCV.~~

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

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

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

Article 10.9.7.

Compartment free from infection with SVCV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.9.9. and 10.9.10. as appropriate; and

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

[…]

CHAPTER 10.10.

INFECTION WITH VIRAL HAEMORRHAGIC SEPTICAEMIA VIRUS

[…]

Article 10.10.5.

Country free from infection with VHSV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with VHSV if all shared water bodies are within countries or *zones* declared free from infection with VHSV (see Article 10.10.6.).

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

1) pathway 1 (absence of susceptible species) not suitable for infection with VHSV~~none of the *susceptible species* referred to in Article 10.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with VHSV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of VHSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 10.10.6.

Zone free from infection with VHSV

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with VHSV~~none of the *susceptible species* referred to in Article 10.10.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with VHSV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of VHSV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of VHSV.~~

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

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

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

Article 10.10.7.

Compartment free from infection with VHSV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.10.9. and 10.10.10. as appropriate; and

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

[…]

CHAPTER 10.11.

INFECTION WITH TILAPIA LAKE VIRUS

[…]

Article 10.11.5.

Country free from infection with TiLV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with TiLV if all shared water bodies are within countries or *zones* declared free from infection with TiLV (see Article 10.11.6.).

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

1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TiLV, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of TiLV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with TILV and subsequently lost its free status due to the detection of TiLV but the following conditions have been met:

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

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

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

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

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

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

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

Article 10.11.6.

Zone free from infection with TILV

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

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

1) none of the *susceptible species* referred to in Article 10.11.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with TiLV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two~~[two]~~ years without detection of TiLV and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of TiLV.~~

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

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

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

Article 10.11.7.

Compartment free from infection with TiLV

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

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

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.11.9. and 10.11.10. as appropriate; and

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

[…]

SECTION 11

DISEASES OF MOLLUSCS

CHAPTER 11.1.

INFECTION WITH ABALONE HERPESVIRUS

[…]

Article 11.1.5.

Country free from infection with abalone herpesvirus

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with abalone herpesvirus if all shared water bodies are within countries or *zones* declared free from infection with abalone herpesvirus (see Article 11.1.6.).

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

1) none of the *susceptible species* referred to in Article 11.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with abalone herpesvirus, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two~~[two]~~ years without detection of AbHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with abalone herpesvirus and subsequently lost its free status due to the detection of AbHV but the following conditions have been met:

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

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

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

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

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

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

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

Article 11.1.6.

Zone free from infection with abalone herpesvirus

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

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

1) none of the *susceptible species* referred to in Article 11.1.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six[~~six~~] months;

OR

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

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with abalone herpesvirus, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten[~~ten~~] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two[~~two~~] years without detection of AbHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one[~~one~~] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of abalone herpesvirus.~~

i) at least the last two years in wild and farmed *susceptible species* without detection of abalone herpesvirus; or

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

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

Article 11.1.7.

Compartment free from infection with abalone herpesvirus

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ years without detection of AbHV, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.1.9. and 11.1.10. as appropriate; and

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

[…]

CHAPTER 11.2.

INFECTION WITH *BONAMIA EXITOSA*

[…]

Article 11.2.5.

Country free from infection with *B. exitiosa*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. exitiosa* if all shared water bodies are within countries or *zones* declared free from infection with *B. exitiosa* (see Article 11.2.6.).

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

1) none of the *susceptible species* referred to in Article 11.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *B. exitiosa* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. exitosa*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *B. exitiosa* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *B. exitiosa*; or

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

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

Article 11.2.6.

Zone free from infection with *B. exitiosa*

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

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

1) none of the *susceptible species* referred to in Article 11.2.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *B. exitiosa* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. exitiosa*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *B. exitiosa* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. exitiosa*.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of *B. exitiosa*; or

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

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

Article 11.2.7.

Compartment free from infection with *B. exitiosa*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *B. exitiosa*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.2.9. and 11.2.10. as appropriate; and

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

[…]

CHAPTER 11.3.

INFECTION WITH *BONAMIA OSTREAE*

[…]

Article 11.3.5.

Country free from infection with *B. ostreae*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *B. ostreae* if all shared water bodies are within countries or *zones* declared free from infection with *B. ostreae* (see Article 11.3.6.).

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

1) none of the *susceptible species* referred to in Article 11.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *B. ostreae* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. ostreae*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *B. ostreae* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *B. ostreae*; or

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

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

Article 11.3.6.

Zone free from infection with *B. ostreae*

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

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

1) none of the *susceptible species* referred to in Article 11.3.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *B. ostreae* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *B. ostreae*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *B. ostreae* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *B. ostreae*.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of *B. ostreae*; or

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

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

Article 11.3.7.

Compartment free from infection with *B. ostreae*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one[two] years without detection of *B. ostreae*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one[one] year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.3.9. and 11.3.10. as appropriate; and

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

[…]

CHAPTER 11.4.

INFECTION WITH *MARTEILIA REFRINGENS*

[…]

Article 11.4.5.

Country free from infection with *M. refringens*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *M. refringens* if all shared water bodies are within countries or *zones* declared free from infection with *M. refringens* (see Article 11.4.6.).

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

1) none of the *susceptible species* referred to in Article 11.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *M. refringens* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. refringens*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *M. refringens* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *M. refringens*; or

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

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

Article 11.4.6.

Zone free from infection with *M. refringens*

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

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

1) none of the *susceptible species* referred to in Article 11.4.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *M. refringens* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. refringens*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *M. refringens* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *M. refringens*.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of *M. refringens*; or

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

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

Article 11.4.7.

Compartment free from infection with *M. refringens*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *M. refringens*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.4.9. and 11.4.10. as appropriate; and

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

[…]

CHAPTER 11.5.

INFECTION WITH *PERKINSUS MARINUS*

[…]

Article 11.5.5.

Country free from infection with *P. marinus*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *P. marinus* if all shared water bodies are within countries or *zones* declared free from infection with *P. marinus* (see Article 11.5.6.).

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

1) none of the *susceptible species* referred to in Article 11.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *P. marinus* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. marinus*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *P. marinus* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *P. marinus*; or

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

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

Article 11.5.6.

Zone free from infection with *P. marinus*

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

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

1) none of the *susceptible species* referred to in Article 11.5.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

2) there has been no occurrence of infection with *P. marinus* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. marinus*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *P. marinus* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *P. marinus*.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of *P. marinus*; or

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

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

Article 11.5.7.

Compartment free from infection with *P. marinus*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one[two] years without detection of *P. marinus*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one[one] year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.5.9. and 11.5.10. as appropriate; and

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

[…]

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

[…]

Article 11.6.5.

Country free from infection with *P.olseni*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *P. olseni* if all shared water bodies are within countries or *zones* declared free from infection with *P. olseni* (see Article 11.6.6.).

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *P. olseni*~~none of the *susceptible species* referred to in Article 11.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *P. olseni* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. olseni*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *P. olseni* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

      i) at least the last three~~[two]~~ years in wild and farmed *susceptible species* without detection of *P. olseni*; or

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

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

Article 11.6.6.

Zone free from infection with *P. olseni*

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

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

1) pathway 1 (absence of susceptible species) not suitable for infection with *P. olseni*~~none of the *susceptible species* referred to in Article 11.6.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months~~;

OR

2) there has been no occurrence of infection with *P. olseni* for at least the last ten~~[ten]~~ years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *P. olseni*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *P. olseni* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *P. olseni*.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of *P. olseni*; or

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

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

Article 11.6.7.

Compartment free from infection with *P. olseni*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *P. olseni*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.6.9. and 11.6.10. as appropriate; and

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

[…]

CHAPTER 11.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

[…]

Article 11.7.5.

Country free from infection with *X. californiensis*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *X. californiensis* if all shared water bodies are within countries or *zones* declared free from infection with *X. californiensis* (see Article 11.7.6.).

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

1) none of the *susceptible species* referred to in Article 11.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *X. californiensis*, as described in Article 1.4.8. of Chapter 1.4.~~the corresponding chapter of the *Aquatic Manual*~~; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last three~~[two]~~ years without detection of *X. californiensis* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

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

Article 11.7.6.

Zone free from infection with *X. californiensis*

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

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

1) none of the *susceptible species* referred to in Article 11.7.2. are present and *basic biosecurity conditions* have been continuously met for at least the last six~~[six]~~ months;

OR

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

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *X. californiensis*, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten~~[ten]~~ years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last three~~[two]~~ years without detection of *X. californiensis* and *basic biosecurity conditions* have been continuously met and have been in place for at least two~~[one]~~ years prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for: ~~at least the last [two] years without detection of *X. californiensis*.~~

      i) at least the last three years in wild and farmed *susceptible species* without detection of *X. californiensis*; or

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

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

Article 11.7.7.

Compartment free from infection with *X. californiensis*

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

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one~~[two]~~ year~~s~~ without detection of *X. californiensis*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one~~[one]~~ year prior to commencement of *targeted surveillance*;

OR

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

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

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 11.7.9. and 11.7.10. as appropriate; and

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

[…]

Annex 13. – Article 9.9.2. of Chapter 9.9. 'Infection with white spot syndrome virus'

CHAPTER 9.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

[…]

Article 9.9.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.~~to all decapod (Order Decapoda) crustaceans from marine, brackish and freshwater sources. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

Family	**Scientific name**	**Common name**
Astacidae	*Austropotamobius pallipes*	white-clawed crayfish
	Pacifastacus leniusculus	signal crayfish
	Pontastacus leptodactylus	Danube crayfish
Calanidae	*Calanus pacificus californicus*	no common name
Cambaridae	*Faxonius limosus*	spinycheek crayfish
	Procambarus clarkii ~~spp.~~ (~~all species~~)	red swamp crawfish ~~N/A~~
	Procambarus zonangulus	no common name
Cancridae	*Cancer pagurus*	edible crab
Nephropidae	*Homarus gammarus*	European lobster
	Nephrops norvegicus	Norway lobster
Nereididae	*Dendronereis sp.*	N/A
Paguridae	*Pagurus benedicti*	no common name
Palaemonidae	*Macrobrachium nipponense*	Oriental river prawn
	Palaemon carinicauda ~~spp.~~ (~~all species~~)	ridgetail prawn ~~N/A~~
	Palaemon orientis	no common name
	Palaemon ritteri	barred grass shrimp
Palinuridae	*Panulirus spp.* (all species)	N/A
Parastacidae	*Cherax quadricarinatus*	red claw crayfish
Penaeidae	all species	N/A
Polybiidae	*Liocarcinus depurator*	blue-leg swimcrab
	Necora puber	velvet swimcrab
Portunidae	all species	N/A
Varunidae	*Eriocheir sinensis*	Chinese mitten crab

[…]

Annex 14.– Articles 10.2.1. and 10.2.2. of Chapter 10.2. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)'

CHAPTER 10.2.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

Article 10.2.1.

For the purposes of the *Aquatic Code*, infection with *Aphanomyces invadans* means *infection* with the *pathogenic agent A. invadans* (syn. *A. piscicida*) of the Genus *Aphanomyces* and Family Leptolegniaceae. The *disease* was previously referred to as epizootic ulcerative syndrome.

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

Article 10.2.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	**Scientific name**	**Common name**
Alosidae	*Alosa sapidissima*	American shad
	Brevoortia tyrannus	Atlantic menhaden
Anabantidae	*Anabas testudineus*	climbing perch
Bagridae	*Mystus cavasius*	gangetic mystus
Centrarchidae	*Lepomis macrochirus*	bluegill
	Micropterus dolomieu	smallmouth bass
	Micropterus salmoides	largemouth black bass
Channidae	*Channa spp.*(all species)	N/A
Cichlidae	*Etroplus suratensis*	pearlspot
Clariidae	*Clarias gariepinus*	North African catfish
Cyprinidae	*Cirrhinus mrigala*	mrigal carp
	Dawkinsia filamentosa	blackspot barb
	Enteromius paludinosus	straightfin barb
	Labeo catla	catla
	Labeo rohita	roho labeo
	Pethia conchonius	rosy barb
Gobiidae	*Glossogobius giuris*	tank goby
Ictaluridae	*Ictalurus punctatus*	channel catfish
Mastacembelidae	*Mastacembelus armatus*	zig-zag eel
Mugilidae	*Mugil cephalus*	flathead grey mullet
Osphronemidae	*Trichogaster fasciata*	banded gourami
Siluridae	*Wallago attu*	wallago

Sparidae	*Archosargus probatocephalus*	sheepshead
Xenocyprididae	*Hypophthalmichthys nobilis*	bighead carp

~~yellowfin seabream *(Acantopagrus australis)*, climbing perch *(Anabas testudineus)*, eels (Anguillidae), bagrid catfishes (Bagridae), silver perch *(Bidyanus bidyanus)*, Atlantic menhaden*(Brevoortia tyrannus)*, jacks (*Caranx* spp.), catla *(Catla catla)*, striped snakehead *(Channa striatus)*, mrigal *(Cirrhinus mrigala)*, torpedo-shaped catfishes (*Clarias* spp.), halfbeaks flying fishes (Exocoetidae), tank goby *(Glossogobius giuris)*, marble goby *(Oxyeleotris marmoratus)*, gobies (Gobiidae), rohu *(Labeo rohita)*, rhinofishes (*Labeo* spp.), barramundi and giant sea perch *(Lates calcarifer)*, striped mullet *(Mugil cephalus)*, mullets (Mugilidae) (*Mugil* spp. and *Liza* spp.), ayu *(Plecoglossus altivelis)*, pool barb *(Puntius sophore)*, barcoo grunter *(Scortum barcoo)*, sand whiting *(Sillago ciliata)*, catfishes (Siluridae spp.), snakeskin gourami *(Trichogaster pectoralis)*, common archer fish *(Toxotes chatareus)*, silver barb *(Puntius gonionotus)*, spotted scat *(Scatophagus argus)*, giant gourami *(Osphronemus goramy)*, dusky flathead *(Platycephalus fuscus)*, spiny turbot (*Psettodes* sp.), Tairiku-baratanago *(Rhodeus ocellatus)*, Keti-Bangladeshi (*Rohtee* sp.), rudd *(Scaridinius erythrophthalmus)*, terapon (*Terapon* sp.) and three-spot gourami *(Trichogaster trichopterus)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

[…]

Annex 15. – Articles 10.4.12. of Chapter 10.4. 'Infection with infectious salmon anaemia virus'

CHAPTER 10.4.

INFECTION WITH INFECTIOUS SALMON ANAEMIA VIRUS

[…]

Article 10.4.12.

Maintenance of free status for infection with HPR-deleted ISAV

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

A country, zone or compartment that is declared free from infection with HPR-deleted~~HPR0~~ ISAV following the provisions of Articles 10.4.6., 10.4.8. and 10.4.10. (as relevant) may maintain its status as free from infection with HPR-deleted~~HPR0~~ ISAV provided that the requirements described in Article 1.4.15. are continuously maintained.

[…]

Annex 16. – Draft new Chapter 10.X. 'Infection with *Megalocytivirus pagrus1*'

CHAPTER 10.X.

INFECTION WITH *MEGALOCYTIVIRUS PAGRUS1*

Article 10.X.1.

For the purposes of the *Aquatic Code*, infection with *Megalocytivirus pagrus1* means *infection* with the *pathogenic agent Megalocytivirus pagrus1* (including the genogroups infectious spleen and kidney necrosis virus, red sea bream iridovirus and turbot reddish body iridovirus) of the Genus *Megalocytivirus* and Family Iridoviridae.

All three genogroups of *M. pagrus1* should be notified in accordance with Chapter 1.1.

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

Article 10.X.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	Species	Common name
Apogonidae	*Pterapogon kauderni*	Banggai cardinalfish
Butidae	*Oxyeleotris marmorata*	marble goby
Carangidae	*Pseudocaranx dentex*	white trevally
	Seriola spp. (all species)	N/A
	Trachinotus spp. (all species)	N/A
	Trachurus japonicus	Japanese jack mackerel
Centrarchidae	*Lepomis macrochirus*	bluegill
Cichlidae	*Astronotus ocellatus*	Oscar
	Etroplus suratensis	pearlspot
	Oreochromis niloticus	Nile tilapia
	Pterophyllum spp. (all species)	N/A
Cyprinidae	*Epalzeorhynchos frenatum*	rainbow sharkminnow
Danionidae	*Danio rerio*	zebrafish
Ephippidae	*Platax orbicularis*	orbiculate batfish
Girellidae	*Girella punctata*	largescale blackfish
Haemulidae	*Parapristipoma trilineatum*	chicken grunt
	Plectorhinchus cinctus	crescent sweetlips
Lateolabracidae	*Lateolabrax japonicus*	Japanese seabass
Latidae	*Lates calcarifer*	barramundi
Lethrinidae	*Lethrinus spp.* (all species)	N/A
Mugilidae	*Mugil cephalus*	flathead grey mullet
Nothobranchiidae	*Aphyosemion gardneri*	steel blue killifish

Oplegnathidae	*Oplegnathus spp.* (all species)	N/A
Osphronemidae	*Macropodus opercularis*	paradise fish
	Osphronemus goramy	giant gourami
	Trichogaster lalius	dwarf gourami
	Trichopodus spp. (all species)	N/A
Paralichthyidae	*Paralichthys olivaceus*	bastard halibut
Percalatidae	*Percalates novemaculeata*	Australian bass
Percichthyidae	*Maccullochella peelii*	Murray cod
Pleuronectidae	*Verasper variegatus*	spotted halibut
Poeciliidae	*Poecilia spp.* (all species)	N/A
	Xiphophorus spp. (all species)	N/A
Procatopodidae	*Poropanchax normani*	Norman's lampeye
Rachycentridae	*Rachycentron canadum*	Cobia
Sciaenidae	*Larimichthys crocea*	large yellow croaker
	Sciaenops ocellatus	red drum
Scombridae	*Scomber japonicus*	chub mackerel
	Scomberomorus niphonius	Japanese Spanish mackerel
	Thunnus orientalis	Pacific bluefin tuna
Scophthalmidae	*Scophthalmus maximus*	turbot
Serranidae	*Epinephelus spp.* (all species)	N/A
Sinipercidae	*Siniperca chuatsi*	Mandarin fish
Sparidae	*Acanthopagrus schlegelii*	blackhead seabream
	Dentex tumifrons	yellowback seabream
	Pagrus major	red sea bream
Stromateidae	*Pampus argenteus*	silver pomfret
Synanceiidae	*Inimicus japonicus*	no common name
Tetraodontidae	*Takifugu rubripes*	tiger pufferfish

Article 10.X.3.

Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with *M. pagrus1* status of the exporting country, zone or compartment

The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to *M. pagrus1*, regardless of the infection with *M. pagrus1* status of the *exporting country*, *zone* or *compartment*:

1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates *M. pagrus1*;

2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates *M. pagrus1*;

3) fish oil;

4) fish skin leather.

Article 10.X.4.

Requirements for self-declaration of freedom from infection with *M. pagrus1*

A Member Country may make a self-declaration of freedom from infection with *M. pagrus1* for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.X.5. to 10.X.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:

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

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

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

Article 10.X.5.

Country free from infection with *M. pagrus1*

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with *M. pagrus1* if all shared water bodies are within countries or *zones* declared free from infection with *M. pagrus1* (see Article 10.X.6.).

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus1* for its entire *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for infection with *M. pagrus1*;

OR

2) there has been no occurrence of infection with *M. pagrus1* for at least the last ten years, and:

   a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. pagrus1*, as described in ~~in~~ Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last ten years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last two years without detection of *M. pagrus1*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom from infection with *M. pagrus1* and subsequently lost its free status due to the detection of *M. pagrus1* but the following conditions have been met:

   a) on detection of *M. pagrus1*, the affected area was declared an *infected zone* and a *protection zone* was established; and

   b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. pagrus1*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

   c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *M. pagrus1*; and

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

i) at least the last two years in wild and farmed *susceptible species* without detection of *M. pagrus1*; or

ii) at least the last one year without detection of *M. pagrus1* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 10.X.6.

Zone free from infection with *M. pagrus1*

If a *zone* extends over the *territory* of more than one country, it can only be declared a *zone* free from infection with *M. pagrus1* if all of the relevant *Competent Authorities* confirm that all relevant conditions have been met.

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus1* for a *zone* within its *territory* if it can demonstrate that:

1) pathway 1 (absence of susceptible species) not suitable for this disease;

OR

2) there has been no occurrence of infection with *M. pagrus1* for at least the last ten years, and:

a) the Member Country can demonstrate that conditions are conducive to the clinical expression of infection with *M. pagrus1*, as described in Article 1.4.8. of Chapter 1.4.; and

b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last ten years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last two years without detection of *M. pagrus1*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one year prior to commencement of *targeted surveillance*;

OR

4) it previously made a self-declaration of freedom for a *zone* from infection with *M. pagrus1* and subsequently lost its free status due to the detection of *M. pagrus1* in the *zone* but the following conditions have been met:

a) on detection of *M. pagrus1*, the affected area was declared an *infected zone* and a *protection zone* was established; and

b) infected populations within the *infected zone* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. pagrus1*, and the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed followed by *fallowing* as described in Chapter 4.7.; and

c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place since eradication of infection with *M. pagrus1*; and

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

i) at least the last two years in wild and farmed *susceptible species* without detection of *M. pagrus1*; or

ii) at least the last one year without detection of *M. pagrus1* if affected *aquaculture establishments* were not epidemiologically connected to wild populations of *susceptible species*.

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

Article 10.X.7.

Compartment free from infection with *M. pagrus1*

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with *M. pagrus1* for a *compartment* within its *territory* if it can demonstrate that:

1) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *compartment* for at least the last one year without detection of *M. pagrus1*, and *basic biosecurity conditions* have been continuously met and have been in place for at least one year prior to commencement of *targeted surveillance*;

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with *M. pagrus1* and subsequently lost its free status due to the detection of *M. pagrus1* in the *compartment* but the *following* conditions have been met:

   a) all *aquatic animals* within the *compartment* have been killed and disposed of by means that minimise the likelihood of further transmission of *M. pagrus1*, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.X.9. and 10.X.10. as appropriate; and

   c) one survey for infection with *M. pagrus1* has been completed at least six months after restocking (as described in Article 1.4.14.) without detection of the pathogen.

Article 10.X.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with *M. pagrus1* following the provisions of Articles 10.X.4. to 10.X.7. (as relevant) may maintain its status as free from infection with *M. pagrus1* provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.X.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with *M. pagrus1*

When importing *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with *M. pagrus1*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.X.5., 10.X.6. or 10.X.7. (as applicable) and 10.X.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with *M. pagrus1*.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.X.3.

Article 10.X.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with *M. pagrus1*

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus1*, the *Competent Authority* of the *importing country* should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.X.3. or other products authorised by the *Competent Authority*; and

   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate *M. pagrus1* in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

   a) In the exporting country:

      i) identify potential source populations and evaluate their *aquatic animal* health records;

      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with *M. pagrus1* .

   b) In the importing country:

      i) import the F-0 population into a *quarantine* facility;

      ii) test the F-0 population for *M. pagrus1* in accordance with Chapter 1.4. to determine their suitability as broodstock;

      iii) produce a first generation (F-1) population in *quarantine*;

      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with *M. pagrus1*, and sample and test for *M. pagrus1* in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter [under study]~~2.3.X.~~ of the *Aquatic Manual*;

      v) if *M. pagrus1* is not detected in the F-1 population, it may be defined as free from infection with *M. pagrus1* and may be released from *quarantine*;

      vi) if *M. pagrus1* is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.X.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with *M. pagrus1*

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with *M. pagrus1*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processing into one of the products referred to in Article 10.X.3. or in point 1 of Article 10.X.14., or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. pagrus1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. pagrus1* or disposed of in a biosecure manner in accordance with Chapters 4.4.and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.X.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with *M. pagrus1*

When importing *aquatic animals* of a species referred to in Article 10.X.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with *M. pagrus1*, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.X.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. pagrus1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of *M. pagrus1* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.X.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with *M. pagrus1*

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus1*, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of *M. pagrus1* or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of *M. pagrus 1* or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

Article 10.X.14.

Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with *M. pagrus1* status of the exporting country, zone or compartment

1) *Competent Authorities* should not require any conditions related to *M. pagrus1* regardless of the infection with *M. pagrus1* status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:

   a) fish fillets or steaks (chilled).

   Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.

   For these *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.

2) When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.X.2. from a country, *zone* or *compartment* not declared free from infection with *M. pagrus1*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Annex 17. – Articles 11.6.1. and 11.6.2. of Chapter 11.6. 'Infection with *P. olseni*'

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

Article 11.6.1.

For the purposes of the *Aquatic Code*, infection with *Perkinsus olseni* means *infection* with the pathogenic agent *P. olseni* of the Family Perkinsidae.

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

Article 11.6.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.: ~~primarily venerid clams (*Austrovenus stutchburyi*, *Venerupis pullastra*, *Venerupis aurea*, *Ruditapes decussatus* and *Ruditapes philippinarum*), abalone (*Haliotis rubra*, *Haliotis laevigata*, *Haliotis Cyclobates* and *Haliotis scalaris*) and other species (*Anadara trapezia*, *Barbatianovaezelandiae*, *Macomonaliliana*, *Paphies australis* and *Crassostrea ariakensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

Family	**Scientific name**	**Common name**
Arcidae	*Anadara kagoshimensis*	half-crenated ark ~~cockle~~
	Anadara trapezia	no common name ~~ark cockle~~
Cardiidae	*Tridacna crocea*	crocus giant clam
Haliotidae	*Haliotis laevigata*	greenlip abalone
	Haliotis rubra	blacklip abalone
	Haliotis iris	black paua
Margaritidae	*Pinctada fucata*	Japanese pearl oyster
Mytilidae	*Mytilus galloprovincialis*	Mediterranean mussel
	Perna canaliculus	New Zealand mussel
Veneridae	*Austrovenus stutchburyi*	Stutchbury's venus ~~clam~~
	Leukoma jedoensis	Jedo venus ~~clam~~
	Paratapes undulatus	undulate venus ~~clam~~
	Protapes gallus	rooster venus ~~clam~~
	Proteopitar patagonicus	no common name
	Ruditapes decussatus	grooved carpet shell
	Ruditapes philippinarum	Japanese carpet shell ~~clam~~

[…]

Annex 18. – Articles 11.7.1. and 11.7.2. of Chapter 11.6. 'Infection with *X. californiensis*'

CHAPTER 11.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Article 11.7.1.

For the purposes of the *Aquatic Code*, infection with *Xenohaliotis californiensis* means *infection* with the pathogenic agent *Candidatus* Xenohaliotis californiensis of the Family Anaplasmataceae ~~*X. californiensis*~~.

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

Article 11.7.2.

Scope

The recommendations in this chapter apply to the following species that meet the criteria for listing as susceptible in accordance with Chapter 1.5.:

Family	**Scientific name**	**Common name**
Haliotidae	*Haliotis corrugata*	pink abalone
	Haliotis cracherodii	black abalone
	Haliotis discus discus	Japanese abalone
	Haliotis diversicolor	small abalone
	Haliotis fulgens	green abalone
	Haliotis kamtschatkana	pinto abalone
	Haliotis rufescens	red abalone
	Haliotis rufescens X *Haliotis discus hannai* hybrid	hybrid red and Japanese abalone
	Haliotis sorenseni	white abalone
	Haliotis tuberculata	tuberculate abalone

~~black abalone *(Haliotis cracherodii)*, white abalone *(Haliotis sorenseni)*, red abalone *(Haliotis rufescens)*, pink abalone *(Haliotis corrugata)*, green abalone (*Haliotis tuberculata* and *Haliotis fulgens*), flat abalone *(Haliotis wallalensis)* and Japanese abalone *(Haliotis discus-hannai)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

[…]

_____

Annex 22. – Sections 2.2.1. and 2.2.2. of Chapter 2.2.9. 'Infection with white spot syndrome virus'

CHAPTER 2.2.9.

INFECTION WITH WHITE SPOT SYNDROME VIRUS

[…]

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Astacidae	*Austropotamobius pallipes*	white-clawed crayfish
	Pacifastacus leniusculus	signal crayfish
	Pontastacus leptodactylus	Danube crayfish
Calanidae	*Calanus pacificus californicus*	no common name
Cambaridae	*Faxonius limosus*	spinycheek crayfish
	Procambarus clarkii ~~*spp.* (all species)~~	red swamp crawfish ~~N/A~~
	Procambarus zonangulus	no common name
Cancridae	*Cancer pagurus*	edible crab
Nephropidae	*Homarus gammarus*	European lobster
	Nephrops norvegicus	Norway lobster
Nereididae	*Dendronereis sp.*	N/A
Paguridae	*Pagurus benedicti*	no common name
Palaemonidae	*Macrobrachium nipponense*	Oriental river prawn
	Palaemon carinicauda ~~*spp.* (all species)~~	ridgetail prawn ~~N/A~~
	Palaemon orientis	no common name
	Palaemon ritteri	barred grass shrimp
Palinuridae	*Panulirus spp.* (all species)	N/A
Parastacidae	*Cherax quadricarinatus*	red claw crayfish
Penaeidae	all species	N/A
Polybiidae	*Liocarcinus depurator*	blue-leg swimcrab
	Necora puber	velvet swimcrab
Portunidae	all species	N/A
Varunidae	*Eriocheir sinensis*	Chinese mitten crab

~~Of all the species that have been tested to date, no decapod (order Decapoda) crustacean from marine, brackish or freshwater sources has been reported to be refractory to infection with WSSV (Flegel, 1997; Lightner, 1996; Lo & Kou, 1998; Maeda *et al.*, 2000; Stentiford *et al.*, 2009).~~

~~[**Note:** an assessment of species that meet the criteria for listing as susceptible to infection with WSSV in accordance with Chapter 1.5. has not yet been completed]~~

2.2.2. Species with incomplete evidence for susceptibility

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with WSSV according to Chapter 1.5. of the *Aquatic Code* are:

Family	Scientific name	Common name
Carcinidae	*Carcinus maenas*	green crab
Ergasilidae	*Ergasilus manicatus*	no common name
Gecarcinucidae	*Spiralothelphusa hydrodroma*	no common name
	Vela pulvinata	no common name
Grapsidae	*Metopograpsus sp.*	N/A
Macrophthalmidae	*Macrophthalmus (Mareotis) japonicus*	no common name
Ocypodidae	*Leptuca pugilator*	Atlantic sand fiddler
Palaemonidae	*Macrobrachium idella*	slender river prawn
	Macrobrachium lamarrei	Kuncho river prawn
	~~*Macrobrachium nipponense*~~	~~Oriental river prawn~~
	Macrobrachium rosenbergii	giant river prawn
	Palaemon adspersus	Baltic prawn
Scyllaridae	*Scyllarus arctus*	lesser slipper lobster
Sergestidae	*Acetes sp.*	N/A
Sesarmidae	*Sesarma sp.*	N/A
Varunidae	*Helice tientsinensis*	N/A
Veneridae	*Meretrix lusoria*	Japanese hard clam

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated:

Family	Scientific name	Common name
Alpheidae	*Alpheus brevicristatus*	teppo snapping shrimp
	Alpheus digitalis	forceps snapping shrimp
	Alpheus japonicus	Japanese snapping shrimp
	Alpheus lobidens	brownbar snapping shrimp
Artemiidae	*Artemia salina*	brine shrimp
	Artemia sp.	~~N/A~~ brine shrimp
	Nitokra sp.	N/A
Astacidae	*Astacus astacus*	noble crayfish
Balanidae	*Belanus sp.*	N/A
Brachionidae	*Brachionus plicatilis*	no common name
	Brachionus urceolaris	no common name
Calappidae	*Calappa lophos*	common box crab
	Calappa philargius	spectacled box crab

Cambaridae	*Faxonius punctimanus*	spothand crayfish
Crangonidae	*Crangon affinis*	Japanese sand shrimp
Cyclopidae	*Apocyclops royi*	no common name
Diogenidae	*Diogenes nitidimanus*	no common name
Dorippidae	*Paradorippe granulata*	granulated mask crab
Epialtidae	*Doclea muricata*	no common name
Eunicidae	*Marphysa gravelyi*	polychaete worm
Euphausiidae	*Euphausia pacifica*	Isada krill
Galenidae	*Halimede ochtodes*	no common name
Grapsidae	*Grapsus albolineatus*	no common name
	Metopograpsus messor	no common name
Hippolytidae	*Latreutes anoplonyx*	medusa shrimp
	Latreutes planirostris	flatnose shrimp
Leucosiidae	*Philyra syndactyla*	no common name
Lithodidae	*Lithodes maja*	stone king crab
Macrophthalmidae	*Macrophthalmus (Macrophthalmus) sulcatus*	no common name
Matutidae	*Ashtoret miersii*	no common name
	Matuta planipes	flower moon crab
Menippidae	*Menippe rumphii*	maroon stone crab
Ocypodidae	*Gelasimus vocans*	orange fiddler crab
	Leptuca panacea	gulf sand fiddler
	Leptuca spinicarpa	spined fiddler
	Minuca longisignalis	gulf marsh fiddler
	Minuca minax	redjointed fiddler
	Minuca rapax	mudflat fiddler
Ostreidae	*Magallana gigas*	Pacific oyster
Paguridae	*Pagurus angustus*	no common name
Palaemonidae	*Palaemon gravieri*	Chinese ditch prawn
	Palaemon macrodactylus	migrant prawn
	Palaemon pandaliformis	potitinga prawn
	Palaemon pugio	daggerblade grass shrimp
	Palaemon serenus	no common name
	Palaemon serrifer	carpenter prawn
Parthenopidae	*Parthenope prensor*	no common name
Pasiphaeidae	*Leptochela gracilis*	lesser glass shrimp
Sergestidae	*Acetes chinensis*	northern mauxia shrimp
Sesarmidae	*Armases cinereum*	squareback marsh crab
	Circulium rotundatum	no common name
Solenoceridae	*Solenocera crassicornis*	coastal mud shrimp

Squillidae	*Squilla mantis*	spottail mantis squillid
Thiaridae	*Melanoides tuberculata*	red-rim melania
Upogebiidae	*Austinogebia edulis*	no common name
Varunidae	*Chhapgarus intermedius*	no common name
	Cyrtograpsus angulatus	no common name
	Helice tridens	no common name
	Neohelice granulata	no common name
Xanthidae	*Atergatis integerrimus*	red egg crab
	Demania splendida	no common name
	Liagore rubronaculata	no common name

~~All life stages are potentially susceptible, from eggs to broodstock (Lightner, 1996; Venegas *et al.*, 1999). WSSV genetic material has been detected in reproductive organs (Lo *et al.*, 1997), but susceptibility of the gametes to WSSV infection has not been determined definitively.~~

[…]

Annex 23. – Sections 2.2.1. and 2.2.2. of Chapter 2.3.1. 'Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)'

CHAPTER 2.3.1.

INFECTION WITH *APHANOMYCES INVADANS* (EPIZOOTIC ULCERATIVE SYNDROME)

[…]

2.2. Host factors

2.2.1. Susceptible host species

~~[Note: an assessment of species that meet the criteria for listing as susceptible to infection with *A. invadans* in accordance with Chapter 1.5. has not been completed]~~ Species that fulfil the criteria for listing as susceptible to infection with *A. invadans* (epizootic ulcerative syndrome) according to Chapter 1.5. of the *Aquatic Animal Health Code* (*Aquatic Code*) are:

~~Table 2.1. Fish species susceptible to infection with *Aphanomyces invadans*~~

Family	Scientific name	Common name
~~Alestidae~~	~~*Brycinus lateralis*~~	~~striped robber~~
	~~*Hydrocynus vittatus*~~	~~tigerfish~~
	~~*Micralestes acutidens*~~	~~silver robber~~
~~Ambassidae~~	~~*Ambassis agassizii*~~	~~chanda perch~~
~~Apogonidae~~	~~*Glossamia aprion*~~	~~mouth almighty~~
~~Ariidae~~	~~*Arius sp.*~~	~~fork-tailed catfish~~
~~Belonidae~~	~~*Strongylura kreffti*~~	~~long tom~~
Alosidae	*Alosa sapidissima*	American shad
	Brevoortia tyrannus	Atlantic menhaden
Anabantidae	*Anabas testudineus*	climbing perch
Bagridae	*Mystus cavasius*	gangetic mystus
Centrarchidae	*Lepomis macrochirus*	bluegill
	Micropterus dolomieu	smallmouth bass
	Micropterus salmoides	largemouth black bass
Channidae	*Channa spp.*(all species) ~~*marulius*~~	N/A ~~great snakehead fish~~
	~~spotted snakehead~~	~~*Channa punctatus*~~
	~~*Channa striatus*~~	~~striped snakehead~~
Cichlidae	*Etroplus suratensis*	pearlspot
	~~*Coptodon rendalli*~~	~~redbreast tilapia~~
	~~*Oreochromis andersoni*~~	~~three-spoted tilapia~~

	~~*Oreochromis machrochir*~~	~~greenhead tilapia~~
	~~*Sargochromis carlottae*~~	~~rainbow bream~~
	~~*Sargochromis codringtonii*~~	~~green bream~~
	~~*Sargochromis giardi*~~	~~pink bream~~
	~~*Serranochromis angusticeps*~~	~~thinface largemouth~~
	~~*Serranochromis robustus*~~	~~Nembwe~~
	~~*Tilapia sparrmanii*~~	~~banded tilapia~~
Clariidae	*Clarias gariepinus*	~~sharptooth~~ North African catfish
	~~*Clarias ngamensis*~~	~~blunt-toothed African catfish~~
	~~*Clarius batrachus*~~	~~walking catfish~~
~~Clupeidae~~	~~*Alosa sapidissima*~~	~~American shad~~
	~~*Brevoortia tyrannus*~~	~~Atlantic menhaden~~
	~~*Nematalosa erebi*~~	~~bony bream~~
Cyprinidae	~~*Barbus paludinosus*~~	~~straightfin barb~~
	~~*Barbus poechii*~~	~~dashtail barb~~
	~~*Barbus thamalakanensis*~~	~~Thamalakane barb~~
	~~*Barbus unitaeniatus*~~	~~longbeard barb~~
	~~*Carassius auratus*~~	~~goldfish~~
	~~*Catla catla*~~	~~Catla~~
	Cirrhinus mrigala	mrigal carp
	Dawkinsia filamentosa	blackspot barb
	Enteromius paludinosus	straightfin barb
	~~*Esomus sp.*~~	~~flying barb~~
	~~*Labeo cylindricus*~~	~~red-eye labeo~~
	~~*Labeo lunatus*~~	~~upper Zambezi labeo~~
	Labeo catla	catla
	Labeo rohita	roho labeo ~~Rohu~~
	Pethia conchonius	rosy barb
	~~*Puntius gonionotus*~~	~~silver barb~~
	~~*Puntius sophore*~~	~~pool barb~~
	~~*Rohtee sp.*~~	~~keti-Bangladeshi~~
~~Eleotridae~~	~~*Oxyeleotris lineolatus*~~	~~sleepy cod~~
	~~*Oxyeleotris marmoratus*~~	~~marble goby~~
Gobiidae	*Glossogobius giuris*	tank goby
Ictaluridae	*Ictalurus punctatus*	channel catfish
Mastacembelidae	*Mastacembelus armatus*	zig-zag eel

Mugilidae	*Mugil cephalus*	flathead grey mullet
Osphronemidae	*Trichogaster fasciata*	banded gourami
Siluridae	*Wallago attu*	wallago
Sparidae	*Archosargus probatocephalus*	sheepshead
Xenocyprididae	*Hypophthalmichthys nobilis*	bighead carp

2.2.2. **Species with incomplete evidence for susceptibility**

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with *A. invadans* according to Chapter 1.5. of the *Aquatic Code* are: ~~[under study]~~

Family	**Scientific name**	**Common name**
Cyprinidae	*Labeo capensis*	orange river mudfish
	Pethia punctata	no common name
	Puntius mahecola	no common name
Elopidae	*Elops machnata*	tenpounder
Epinephelidae	*Epinephelus malabaricus*	Malabar grouper
Ictaluridae	*Ameiurus melas*	black bullhead
	Ameiurus nebulosus	brown bullhead
Mugilidae	*Mugil curema*	white mullet
	Planiliza macrolepis	largescale mullet
	Planiliza parsia	goldspot mullet
Pristolepididae	*Pristolepis malabarica*	no common name
Salmonidae	*Oncorhynchus mykiss*	rainbow trout
Scatophagidae	*Scatophagus argus*	spotted scat
Sciaenidae	*Bairdiella chrysoura*	goldtail croaker
	Pogonias cromis	black drum

[…]

_____

Annex 24. – Chapter 2.4.2. 'Infection with *Bonamia exitiosa*'

CHAPTER 2.4.2.

INFECTION WITH *BONAMIA EXITIOSA*

1. Scope

Infection with *Bonamia exitiosa* means infection with the pathogenic agent *Bonamia exitiosa* of the Family *Haplosporiidae*.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

Bonamia exitiosa is a haplosporidian protozoan parasite (Arzul & Carnegie, 2015; Carnegie & Cochennec-Laureau, 2004) infecting haemocytes of several oyster species, causing disease and mortality (Cranfield *et al.,* 2005; Dinamani *et al.,* 1987). ~~Since the original description of the parasite in New Zealand in the mid-1980s, *B. exitiosa* and *B. exitiosa*-like microcells have been described in various locations globally. Species assignment was based primarily on the sequence of the ITS rDNA locus of the ribosomal DNA gene complex, as the available data on histology ultrastructure and molecular sequences was insufficient to discriminate unequivocally between species (Hill et al. 2010b).~~

2.1.2. Survival and stability in processed or stored samples

No data available

2.1.3. Survival and stability outside the host

No data available.

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Ostreidae	*Crassostrea virginica*	eastern oyster
	Magallana (syn. *Crassostrea*) *ariakensis*	Ariake cupped oyster
	Ostrea angasi	Australian mud oyster
	Ostrea chilensis	Chilean flat oyster
	Ostrea edulis	European flat oyster
	Ostrea equestris	crested oyster
	Ostrea lurida	Olympia oyster
	Ostrea puelchana	Argentinean flat oyster

2.2.2. Species with incomplete evidence for susceptibility

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with *B. exitiosa* according to Chapter 1.5 of the *Aquatic Code* are: ~~dwarf oyster (*Ostrea stentina*).~~

Family	Scientific name	Common name
Ostreidae	*Ostrea stentina*	dwarf oyster

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated:

Family	Scientific name	Common name
Ostreidae	*Magallana* (syn. *Crassostrea*) *gigas*	Pacific cupped oyster
	Saccostrea glomerata	Sydney rock oyster

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

Juveniles and adults are susceptible to infection however, prevalence and infection intensity are generally higher in individuals of 2 years of age. In *O. edulis*, *B. exitiosa* DNA has also been detected in larvae (Arzul *et al.,* ~~2010~~ 2011; Helmer *et al.,* 2020). *Bonamia exitiosa* is particularly pathogenic in young *M. ariakensis*, <50 mm in shell height (Bishop *et al.,* 2006).

2.2.4. Distribution of the pathogen in the host

Bonamia exitiosa is an intrahaemocytic protozoan, but it can be observed extracellularly (Dinamani *et al.,* 1987). Infection is systemic with the protozoan found in several organs and especially in the connective tissues of gills and mantle (Hine, 1991a). In *O. angasi*, the parasite has been observed in the gills, mantle and gonad and particularly in the connective tissue of the digestive gland (Buss *et al.,* 2020a). In *O. edulis*, the parasite is associated with heavy haemocytic infiltration and appears in the connective tissue of various organs mostly within haemocytes, but sometimes outside host cells (Abollo *et al.,* 2008). In *O. stentina*, haemocytosis was not observed in animals found to be infected with the parasite (Hill *et al.,* 2010).

2.2.5. Aquatic animal reservoirs of infection

Susceptible species (see Section 2.2.1) should be considered potential reservoirs.

2.2.6. Vectors

None known.

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Mortality in *O. chilensis* occurs concurrently with the highest infection intensity, particularly in association with high intensity apicomplexan infections (Hine, 2002; Hine & Wesney, 1994). The disease seems to kill more than 80% of the oysters as the wave of infection passes through an oyster bed over a period of 2–3 years (Cranfield *et al.,* 2005). In *O. angasi*, >85% mortality was observed in oysters after 40 days of exposure with infected oysters (Buss *et al.,* 2020a).

Prevalence is variable in *O. chilensis* (from 0% to nearly 80%) (Cranfield *et al.,* 2005). In the Southern Hemisphere, infection with *B. exitiosa* shows the highest prevalence from January to April, with the parasite barely detectable in September and October (Hine, 1991a). Stressors such as exposure to extreme temperatures (below 7°C or above 26°C), high salinity (40 ppt), starvation (prolonged holding in filtered sea water), handling (vigorous stirring four times per day), or heavy infection with an apicomplexan (Hine, 2002), can affect the disease dynamics of *B. exitiosa* in *O. chilensis* (Hine *et al.,* 2002).

Prevalence is variable in *O. edulis* in which co-infection with *B. ostreae* was reported (Abollo *et al.,* 2008). In Galicia (Spain), the maximum reported prevalence of *B. exitiosa* in *O. edulis* was 34% in one batch collected in October (Abollo *et al.,* 2008). Despite some prevalence differences observed between sampling dates, it is not presently possible to determine the annual infection pattern of flat oysters with *B. exitiosa* in Europe.

In *Ostrea angasi*, no clear seasonal pattern was described and prevalence increased over time from 8 to 40% after 3 months to 57 to 88% after 1 year, depending on farming site (Buss *et al.,* 2020c).

2.3.2. Clinical signs, including behavioural changes

Clinical signs include dead or gaping oysters.

2.3.3 Gross pathology

Most live infected oysters appear normal, but sometimes the gills can appear to be eroded (Dinamani *et al*., 1987).

2.3.4. Modes of transmission and life cycle

Transmission by infective stages carried passively on water currents between oyster beds is suspected (Cranfield *et al.,* 2005; Hine, 1996). Studies with *O. chilensis* have shown that transmission of the parasite directly from host to host is possible; Hine (1991a; 1991b) has shown that released infective particles are ingested by oysters and enter the haemolymph from the gut. Infective particles are phagocytosed by agranular haemocytes, and are able to resist lysis within the haemocyte (Hine & Wesney, 1994).

Parasite DNA has been detected in larvae incubated in the palleal cavity of adult oysters suggesting possible transmission between these two age groups. Thus, larvae may contribute to the spread of the parasite during their planktonic life stage (Helmer *et al.,* 2020).

2.3.5. Environmental factors

Experimental studies using variations in temperature and salinity as stressors (Hine *et al.,* 2002) showed that prevalence was higher in oysters kept for a short period (14 days) in warm water (25–26°C for 1 hour daily) or in hypersaline (39–40 ppt) water compared with cold water (7°C for 1 hour daily) and to hyposaline water (15 ppt).

In *O. chilensis*, prevalence shows an annual pattern with two peaks reported in April (early autumn) and August (winter) (Hine, 1991a). The evolution of *B. exitiosa* in *O. edulis* or *O. stentina* according to the season has not been studied.

Increased water temperature increases the risk of death of *O. angasi* due to *B. exitiosa* infection particularly when it is combined with other stressors – both starvation and increased motion (Bradley *et al.,* 2020).

2.3.6. Geographical distribution

Infection with *B. exitiosa* has been reported ~~from~~ in *O. chilensis* in Oceania (Dinamani *et al*., 1987; Doonan *et al.,* 1994); in *O. angasi* in Oceania (Corbeil *et al.,* 2006b; Hine, 1996; Hine & Jones, 1994); in *O. edulis* in Europe (Abollo *et al.,* 2008; Narcisi *et al.,* 2010); and in *O. stentina* in Africa (Hill *et al.,* 2010).

See WAHIS (https://wahis.woah.org/#/home) for recent information on distribution at the country level.

2.4. Biosecurity and disease control strategies

2.4.1. Vaccination

None.

2.4.2. Chemotherapy including blocking agents

None.

2.4.3. Immunostimulation

None.

2.4.4. Breeding resistant strains

None.

2.4.5. Inactivation methods

40,000 ppm chlorine for 10 minutes and 2000 ppm iodine for 1 minute inactivate 100% of *B. exitiosa* isolated from infected oysters (Buss *et al.,* 2020b).

2.4.6. Disinfection of eggs and larvae

No data available.

2.4.7. General husbandry

Development of lighter dredges and less damaging fishing strategies should reduce the chance of disease outbreaks by lowering disturbance (Cranfield *et al.,* 2005). Avoiding stressors such as exposure to extreme temperatures (below 7 or above 26°C) and high salinity (40 ppt), starvation, handling, or heavy infection with other parasites, as well as decreasing stocking density, should mitigate the impact of the disease (Cranfield *et al.,* 2005; Hine *et al.,* 2002).

3. Specimen selection, sample collection, transportation and handling

This section draws on information in Sections 2.2, 2.3 and 2.4 to identify populations, individuals and samples that are most likely to be infected.

3.1. Selection of populations and individual specimens

Gaping or freshly dead individuals (2 or more years old) should be sampled as a priority, to increase the chances of detecting infected oysters. For histology, only live (including moribund) oysters should be sampled.

Sampling should be carried out when prevalence is known to be at a maximum, or during periods of higher water temperature e.g. between January and April in the Southern Hemisphere (Hine, 1991a).

3.2. Selection of organs or tissues

A 3–5 µm thick section of tissue that includes a sample of gills, mantle, gonad~~,~~ and digestive gland, is used for histological examination. Gills or heart are preferred for some tests, including ~~such as~~ imprints and PCR. ~~For PCR in *O. edulis* it is recommended to include gills and gonad.~~ More than 1 organ (including gills, heart and gonad) should be used for PCR-based diagnosis of *B. exitiosa*, to maximise the sensitivity (Ramilo *et al.,* 2014).

3.3. Samples or tissues not suitable for pathogen detection

Tissues other than gills, heart, gonads and mantle are less suitable.

3.4. Non-lethal sampling

None.

3.5. Preservation of samples for submission

For guidance on sample preservation methods for the intended test methods, see Chapter 2.4.0 *General information* (*diseases of molluscs*).

3.5.1. Samples for pathogen isolation

Not applicable.

3.5.2. Preservation of samples for molecular detection

Tissue samples for PCR testing should be preserved in 80% (v/v) analytical-grade ethanol.

Standard sample collection, preservation and processing methods for molecular techniques can be found in Section B.5.5 of Chapter 2.4.0 *General information* (diseases of molluscs).

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

Standard sample collection, preservation and processing methods for histological techniques can be found in Section B.5.3 of Chapter 2.4.0 *General information* (diseases of molluscs).

3.5.4. Samples for other tests

None.

3.6. Pooling of samples

Pooling of samples from more than one individual animal for a given purpose is only recommended where robust supporting data on diagnostic sensitivity and diagnostic specificity have been evaluated and found to be suitable. The effect of pooling on diagnostic sensitivity has not been thoroughly evaluated, therefore larger specimens should be processed and tested individually. Small life stages such as spat can be pooled to obtain the minimum amount of material for molecular detection.

4. Diagnostic methods

The methods currently available for pathogen detection that can be used in i) surveillance of apparently healthy animals, ii) presumptive diagnosis in clinically affected animals and iii) confirmatory diagnostic purposes are listed in Table 4.1. by animal life stage.

Ratings for purposes of use. For each recommended assay a qualitative rating for the purpose of use is provided. The ratings are determined based on multiple performance and operational factors relevant to application of an assay for a defined purpose. These factors include appropriate diagnostic performance characteristics, level of assay validation, availability cost, timeliness, and sample throughput and operability. For a specific purpose of use, assays are rated as:

+++ =	Methods are most suitable with desirable performance and operational characteristics.
++ =	Methods are suitable with acceptable performance and operational characteristics under most circumstances.
+ =	Methods are suitable, but performance or operational characteristics may limit application under some circumstances.
Shaded boxes =	Not appropriate for this purpose.

Validation stage. The validation stage corresponds to the assay development and validation pathway in chapter 1.1.2. The validation stage is specific to each purpose of use. Where available, information on the diagnostic performance of recommended assays is provided in Section 6.3.

WOAH Reference Laboratories welcome feedback on diagnostic performance of recommended assays, in particular PCR methods. Of particular interest are any factors affecting expected assay sensitivity (e.g. tissue components inhibiting amplification) or expected specificity (e.g. failure to detect particular genotypes, detection of homologous sequences within the host genome). These issues should be communicated to the WOAH Reference Laboratories so that advice can be provided to diagnostic laboratories and the standards amended if necessary.

Table 4.1. *WOAH recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals*

Method	A. Surveillance of apparently healthy animals				B. Presumptive diagnosis of clinically affected animals				C. Confirmatory diagnosis[1] of a suspect result from surveillance or presumptive diagnosis			
	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV
Imprints		++	++	2		+++	+++	NA				
Histopathology		++	++	2		+++	+++	2				
Transmission electron microscopy									+	+	+	NA
Real-time PCR	+++	+++	+++	3	+++	+++	+++	2	+++	+++	+++	NA
Conventional PCR	++	++	++	2	+++	+++	+++	NA				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	NA
In-situ hybridisation					+	+	+	1				
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
Other antigen detection methods												

LV = level of validation, refers to the stage of validation in the WOAH Pathway (chapter 1.1.2), Figures brackets mean that partial data are available; NA = not available; PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; Ab- or Ag-ELISA = antibody or antigen enzyme-linked immunosorbent assay, respectively; [1]For confirmatory diagnoses, methods need to be carried out in combination (see Section 6).
[2]Susceptibility of early and juvenile life stages is described in Section 2.2.3.
Shading indicates the test is inappropriate or should not be used for this purpose.

4.1. Imprints

Samples to be taken consist of heart (preferably the ventricle) or gills from fresh, gaping or freshly dead bivalves if they are sufficiently large. If bivalves are too small (such as spat), imprints should be done using the entire individual.

After drying tissues on absorbent paper, several imprints are made on a glass slide. Slides are air-dried, fixed (in methanol or absolute ethanol) and stained using a commercially available blood-staining kit, in accordance with the manufacturer's instructions. After rinsing in tap water and drying, the slides are mounted with a cover-slip using an appropriate synthetic resin. Slides are observed first at ×200 magnification and then under oil immersion at ×1000 magnification.

Infection with *B. exitiosa* is indicated by the presence of small spherical or ovoid organisms (2–5 µm wide) within the haemocytes. However, the parasite might also occur extracellularly. These organisms show a basophilic cytoplasm often containing a lipid vacuole and an eosinophilic nucleus which is rather central unlike the *B. ostreae* nucleus which is rather eccentric (colours of cytoplasm and nucleus may vary with the stain used). Parasitic cells can appear larger on imprints than on histological examination. Multinucleated cells can be observed (Abollo *et al.,* 2008; Hine *et al.,* 2001). The technique is not parasite species specific.

A positive result is indicative of infection with a *Bonamia* sp~~ecies~~.

4.2. Histopathology

Samples to be taken consist of fresh, gaping or freshly dead bivalves.

Sections of tissue that include gills, digestive gland, mantle~~,~~ and gonad should be fixed for 24 hours minimum in a recommended fixative followed by standard processing for histology as described in section 5.3 of Chapter 2.4.0 *General information* (diseases of molluscs). Observations are made at increasing magnifications up to ×1000.

Infection with *B. exitiosa* is indicated by the presence of parasites as small cells (2–5 µm in diameter) within the haemocytes or free in the connective tissue or sinuses of the gills, gonads, digestive gland, gut and mantle. The parasite causes different lesions according to it host. It is often associated with an intense disseminated haemocyte infiltration in *O. chilensis* but intense focal haemocyte infiltration in *O. angasi* in which it is epitheliotrophic (Engelsma & Hine, 2009). In *O. edulis*, it is associated with haemocyte infiltration of the connective tissues surrounding the digestive gland and the mantle (Longshaw *et al.,* 2013). To avoid any doubt, the parasite has to be observed inside the haemocyte for a positive diagnosis.

B. exitiosa is generally larger than *B. ostreae* and often has a central or subcentral nucleus (Lane *et al.,* 2016). Plasmodia stages characterised by irregular shape were noted in the haemocyte cytoplasm but, unlike *B. perspora,* no spore has been described in *B. exitiosa*. The technique is not species-specific.

Positive result is indicative of infection with a *Bonamia* sp~~ecies~~.

4.3. Transmission electron microscopy

Samples to be taken consist of live, gaping or freshly dead bivalves.

A small sized piece of tissue (1–2 mm) should be fixed in an appropriate fixative for at least 1 hour and then processed as described in section 5.4 of Chapter 2.4.0 *General information* (diseases of molluscs).

Infection with *B. exitiosa* is indicated by the presence of parasites within the haemocytes. Different stages, including uninucleated, binucleated and plasmodial stages have been reported; moreover, *B. exitiosa* has a large amoeboid trophic stage, apparently not present in *B. ostreae.* Intracellular structures include mitochondria, haplosporosomes, Golgi apparatus and persistent intranuclear microtubules. In *O. chilensis*, four parasite developmental stages have been described in infected oysters corresponding to dense forms, intermediate forms, plasmodial forms and vacuolated forms (Hill *et al.,* 2010; Hine, 1991b; Hine *et al.,* 2001).

Uninucleated stages of *B. exitiosa* are slightly larger in size in comparison with *B. ostreae* and have more haplosporosomes, mitochondrial profiles and lipoid bodies per ultrastructure section, as well as smaller tubulo-vesicular mitochondria. However, this stage is smaller in comparison with *B. perspora* which has also smaller haplosporosomes (Hine *et al.,* 2001; 2014).

4.4. Nucleic acid amplification

PCR assays should always be run with the controls specified in Section B.5.5 *Molecular methods* Chapter 2.4.0 *General information* (diseases of molluscs). Molluscs are known to potentially contain substances that can inhibit PCR reactions. It is recommended to check for the presence of PCR inhibitors in DNA extracts to avoid false negative results. In case PCR inhibitors are present, DNA samples can be diluted prior to PCR analyses (a 1/10 dilution usually resolves most cases of PCR inhibition). Each sample should be tested in duplicate.

Extraction of nucleic acids

Different kits and procedures can be used for nucleic acid extraction. The quality and concentration of the extracted nucleic acid is important and can be checked using a suitable method as appropriate to the circumstances.

4.4.1. Real-time PCR

Three TaqMan PCR assays are available for the detection of *Bonamia* spp.: one targeting the ITS1 (internal transcribed spacer) region (Corbeil *et al.,* 2006a) and two targeting the 18S (small subunit rDNA) (Canier *et al.,* 2020; Marty *et al.,* 2006). The PCR assay developed by Canier *et al.* (2020) targets the 18S (small subunit rDNA) and allows the concomitant detection of *Bonamia* spp. and *Marteilia refringens* parasites.

Two other real-time PCR protocols have been developed to specifically detect *B. exitiosa*: one SYBR-green PCR assay targeting the 18S-ITS1 region (Ramilo *et al.,* 2013), and a TaqMan PCR protocol targeting the actin gene (https://www.eurl-mollusc.eu/SOPs). These two PCR assays allow the concomitant detection of *B. ostreae* and *B. exitiosa* parasites.

PCR assays are generally more sensitive than histology and/or cytology for the diagnosis of *B. exitiosa* (see Sections 6.1. and 6.2) although Buss *et al.* (2019) found that histology was more sensitive than real-time PCR in farmed populations of *Ostrea angasi*. Real-time PCR assays usually have higher sensitivity than conventional PCR assays (see Sections 6.1. and 6.2).

***Primers and probes* (*sequence*)**

Pathogen/ target gene	**Primer/probe (5'–3')**	**Concentration**	**Cycling parameters[a]**
Method 1: Corbeil *et al.,* 2006a; GenBank Accession No.: DQ312295			
TaqMan® PCR *Bonamia* spp./ITS-1	ITS-For: CCC-TGC-CCT-TTG-TAC-ACA-CC ITS-Rev: TCA-CAA-AGC-TTC-TAA-GAA-CGC-G Probe BonITS: TTA-GGT-GGA-TAA-GAG-CCG-C (FAM MGB-NFQ)	900 nM 900 nM 250 nM	35 cycles of: 95°C/15 sec and 63.6°C/60 sec
Method 2: Marty *et al.,* 2006; GenBank Accession No.: DQ312295			
TaqMan® PCR *Bonamia* spp./18S	Fwd: CCC-GGC-TTC-TTA-GAG-GGA-CTA Rev: ACC-TGT-TAT-TGC-CCC-AAT-CTT-C Probe: CTG-TGT-CTC-CAG-CAG-A (FAM MGB-NFQ)	800 nM 800 nM 250 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 3: Canier *et al.,* 2020; GenBank Accession No.: EU016528			
TaqMan® PCR *Bonamia* spp./18S	Bosp2-18S-F: CAG-GAT-GCC-CTT-AGA-TGC-TC Bosp2-18S-R: GTA-CAA-AGG-GCA-GGG-ACG-TA Probe Bosp-18S-IN: TTG-ACC-CGG-CTT-GAC-AAG-GC (HEX-BHQ1)	300 nM 500 nM 300 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 4: Ramilo *et al.,* 2013; GenBank Accession No: DQ312295			
SYBR Green PCR *B. exitiosa*/18S-ITS	BEXIT-F: GCG-CGT-TCT-TAG-AAG-CTT-TG BEXIT-R: AAG-ATT-GAT-GTC-GGC-ATG-TCT	300 nM 300 nM	35 cycles of: 95°C/30 sec and 58°C/45 sec, 72°C/60 sec Melt curve from 58°C to 95°C with 0.5°C increment/sec
Method 5: EURL for mollusc diseases (2023); GenBank Accession No: KM073106			

TaqMan® PCR *B. exitiosa*/actin	**BEa_F: GAC-TTT-GAC-CAT-CGG-AAA-CG BEa_R: ATC-GAG-TCG-TAC-GCG-AGT-CT BEa_probe GGC-AGC-GAA-TCG-ATG-GGA-AT (FAM-BHQ-1)**	**300 nM 300 nM 200 nM**	**40 cycles of: 95°C/15 sec and 60°C/20 sec**

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

4.4.2. Conventional PCR

Two conventional PCR protocols targeting the 18S (small subunit rDNA) have been developed for the detection of *Bonamia* spp. (Carnegie *et al.,* 2000; Cochennec *et al*., 2000). Conventional PCRs are generally more sensitive than histology or cytology (see Sections 6.1. and 6.2). Under certain circumstances, the Cochennec *et al.* (2000) primers generate a 295 bp non-specific product of approximately the same size as the expected product of 300 bp (Engelsma *et al.,* 2014).

Primer sequences

Pathogen/ target gene	Primer (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Carnegie *et al.,* 2000 modified in Carnegie *et al.,* 2008; amplicon size [760 bp]; GenBank Accession No.: AF262995			
Bonamia spp./18S amplifies most of the identified *Bonamia* spp. including *B. ostreae* and *B. exitiosa*	CF: CGG-GGG-CAT-AAT-TCA-GGA-AC CR: CCA-TCT-GCT-GGA-GAC-ACA-G	250 nM 250 nM	35 cycles of: 95°C/1 min and 59°C/1 min and 72°/1 min
Method 2: Cochennec *et al.,* 2000; amplicon size [304 bp]: GenBank Accession No.: AF192759			
Bonamia spp./18S amplifies all identified *Bonamia* spp. and several members of Haplosporidia	BO: CAT-TTA-ATT-GGT-CGG-GCC-GC BOAS: CTG-ATC-GTC-TTC-GAT-CCC-CC	1 µM 1 µM	30 cycles of: 95°C/60 sec, 55°C/60 sec, 72°C/60 sec
Method 3: Ramilo *et al.,* 2013; amplicon size [246 bp], GenBank Accession No: DQ312295			
***Bonamia exitiosa*/18S-ITS1**	**BEXIT-F GCG-CG-TTC-TTA-GAA-GCT-TTG BEXIT-R AAG-ATT-GAT-GTC-GGC-ATG-TCT**	**0.3 µM 0.3 µM**	**35 cycles of: 94°C/30sec, 58°C/45sec, 72°C/1 min**

[(a)]A denaturation step at 94–95°C prior to cycling and a final elongation step at 72°C (between 5 and 10 minutes) must be included.

The PCR methods 1 and 2 are not specific for *B. ostreae*. Sequence analysis of the amplicons must be used to confirm identity. Amplicons obtained by method 2 can be digested with the *Bgl* I enzyme which allows to distinguish two profiles: *B. ostreae* (two bands of 120 and 180 bp) and *B. exitiosa* (not digested).

4.4.3. Other nucleic acid amplification methods

None available.

4.5. Amplicon sequencing

The size of the PCR amplicon is verified by agarose gel electrophoresis and purified by excision from this gel. Obtained sequences are analysed and compared with published sequences.

Targeted regions are 18S, ITS1 and actin. Although the sequences are available in the public gene banks, it is recommended to refer such cases to the appropriate WOAH Reference Laboratory.

4.6. *In-situ* hybridisation

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

Several *in-situ* hybridisation protocols have been developed, two targeting the 18S and one the ITS1.

The first one (Cochennec *et al*., 2000) allows detection at the *Bonamia* genus level and uses a 300 bp labelled probe produced by PCR.

Two ISH protocols were designed to specifically detect *B. exitiosa* (Hill *et al.,* 2010; Ramilo *et al.,* 2014) but should also detect closely related parasites (belonging to the "clade *B. exitiosa*"). These assays rely on digoxigenin-labelled oligonucleotide probes.

Reference	Pathogen/target	ISH probe type	ISH probe
Method 1 Cochennec *et al.,* 2000	*Bonamia* spp. and several members of Haplosporidia 18S	Labelled BO–BOAS amplicons	BO–BOAS PCR product (300bp)
Method 2: Hill *et al.,* 2010	*Bonamia exitiosa* and closely related *Bonamia* spp. 18S	Three labelled oligonucletotides	CaBon166: CGA-GCA-GGG-TTT-GTC-ACG-TAT CaBon461: TTC-CGA-ATA-GGC-AAC-CGA-AG CaBon1704: CAA-AGC-TTC-TAA-GAA-CGC-GCC
Method 3: Ramilo *et al.,* 2014	*Bonamia exitiosa* and closely related *Bonamia* spp. ITS1	Labelled oligonucletotides	BEX_ITS: CAA-AGA-TTG-ATG-TCG-GCA-TG

Technical procedure

The first steps in the technical procedure follow the recommendations described in chapter 2.4.0.

Subsequent steps concerning Method 1 (Cochennec *et al.,* 2000) are that the probe is produced by PCR using the previously described primer pair Bo–Boas (Section 4.4.2) with digoxigenin incorporation and the PCR is performed as described in the section on PCR except that DIG dUTP 25 mM is added to the reaction mixture. The detection steps are performed according to the manufacturer's instructions. In other protocols, probes consist ~~in~~ of digoxigenin-labelled nucleotides.

Slides are dehydrated by immersion in an ethanol series and air dried. The slides are then covered with hybridisation buffer (4 × SSC [standard saline citrate; 60 mM NaCl, 600 mM NaCl, pH 7], 50% formamide, 1 × Denhardt's solution, 250 µg ml^{-1} yeast tRNA, 10% dextran sulphate) containing approx. 20 ng of the digoxigenin-labelled probe (1–2 µl of the probe produced by PCR, or 1 µl at 100 µm of labelled nucleotides). Sections are covered with *in-situ* plastic cover-slips and placed for 5 minutes at 95°C. Slides are then cooled on ice for 1– 5 minutes before overnight hybridisation at 42°C in a humid chamber Sections are washed twice for 5 minutes in 2 × SSC at room temperature, and once for 10 minutes in 0.4 × SSC at 42°C. The detection steps are performed according to the manufacturer's instructions. The slides are then rinsed with appropriate buffer. The sections are counter-stained with an appropriate stain~~ing~~, rinsed in tap water, immersed in 95% and 100% ethanol for 30 seconds for each, rinsed for 10–30 seconds in xylene and cover-slips are applied using an appropriate mounting medium.

Interpretation of results:

A positive result corresponds to labelled parasites inside the haemocytes, with all negative controls (including non-infected sample and no probe ISH reaction control) negative and all positive controls (including infected sample) positive. In addition, non-specific probe such as SSUrDNA can be used to verify the integrity of DNA in paraffin blocks.

4.7. Immunohistochemistry

Not available.

4.8. Bioassay

Not available.

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

Not available.

4.10. Other methods

Not available.

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

Real-time PCR is recommended for targeted surveillance to declare freedom from infection with *B. exitiosa*. Histology, tissue imprint and conventional PCR can also be used (see Table 4.1).

6. Corroborative diagnostic criteria

This section only addresses the diagnostic test results for detection of infection in the absence (Section 6.1.) or in the presence of clinical signs (Section 6.2.) but does not evaluate whether the infectious agent is the cause of the clinical event.

The case definitions for a suspect and confirmed case have been developed to support decision-making related to trade and confirmation of disease status at the country, zone or compartment level. Case definitions for disease confirmation in endemically affected areas may be less stringent. If a Competent Authority does not have the capability to undertake the necessary diagnostic tests it should seek advice from the appropriate WOAH Reference Laboratory, and if necessary, refer samples to that laboratory for confirmatory testing of samples from the index case in a country, zone or compartment considered free.

6.1. Apparently healthy animals or animals of unknown health status[1]

Apparently healthy populations may fall under suspicion, and therefore be sampled, if there is an epidemiological link(s) to an infected population. Hydrographical proximity to, or movement of animals or animal products or equipment, etc., from a known infected population equate to an epidemiological link. Alternatively, healthy populations are sampled in surveys to demonstrate disease freedom.

6.1.1. Definition of suspect case in apparently healthy animals

The presence of infection with *B. exitiosa* shall be suspected if at least one of the following criteria is met:

i) Observation of parasite cells in tissue imprints

ii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iii) Positive result by conventional PCR

iv) Positive result by real-time PCR

6.1.2. Definition of confirmed case in apparently healthy animals

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

~~i) Positive result by tissue imprints or histology followed by real-time PCR or by conventional PCR and sequencing~~

i) Positive result by real-time PCR and conventional PCR and sequencing

ii) Positive result by real-time PCR and *in-situ* hybridisation

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

6.2 Clinically affected animals

Clinical signs are not pathognomonic for a single disease; however they may narrow the range of possible diagnoses.

6.2.1. Definition of suspect case in clinically affected animals

The presence of infection with *B. exitiosa* shall be suspected if at least one of the following criteria is met:

i) Gross pathology or clinical signs associated with the disease as described in this chapter

[1] For example transboundary commodities.

ii) Observation of parasite cells in tissue imprints

iii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iv) Positive result by real-time PCR

v) Positive result by conventional PCR

vi) Positive result by *in-situ* hybridisation

6.2.2. Definition of confirmed case in clinically affected animals

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

i) Positive result by real-time PCR ~~or~~ and by conventional PCR and sequencing

ii) Positive result by real-time PCR and *in-situ hybridisation*

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

6.3. Diagnostic sensitivity and specificity for diagnostic tests

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with *B. exitiosa* are provided in Tables 6.3.1. and 6.3.2. This information can be used for the design of surveys for infection with *B. exitiosa*, however, it should be noted that diagnostic performance is specific to the circumstances of each diagnostic accuracy study (including the test purpose, source population, tissue sample types and host species) and diagnostic performance may vary under different conditions. Data are only presented where tests are validated to at least level 2 of the validation pathway described in Chapter 1.1.2. and the information is available within published diagnostic accuracy studies.

Data on analytical performances (stage 1 validation) are often missing for diagnostic tests described in this chapter: the limit of detection is rarely available, and the inclusivity of molecular assays is not always fully evaluated (missing information on the detection of *Bonamia* spp. lineages/species other than *B. ostreae* and *B. exitiosa*).

Diagnostic sensitivity (DSe) and specificity (DSp) (stage 2 validation) are available for most diagnostic tests. However, these values depend on the studied mollusc population (host species, prevalence, intensity of infection, etc.), the protocol (tissue analysed, DNA extraction, use of cut-off value for PCR assays, etc.) and test purpose. Additionally, as no gold standard exists for the detection of *B. exitiosa*, several approaches can be used for DSe and DSp estimation, such as the use of a combination of tests to establish reference results or latent class analysis (maximum likelihood or Bayesian method). If Bayesian Latent class is used, the analysis can incorporate prior knowledge about the performance of compared diagnostic tests. The choice of the overall approach used will have an impact on DSe & DSp estimates. It is therefore complex to compare DSe/DSp estimates from different studies.

Real-time PCR is generally considered as the most sensitive method except in some particular cases as for example for the diagnostic of *Bonamia* spp. in a population of farmed *O. angasi* in Australia, where histology was found to be more sensitive (Buss *et al.,* 2019). This population was characterised by a high *Bonamia* prevalence but low intensity of infection with focal lesions. The fact that PCR diagnosis is performed in a small part of tissue could explain this result.

Two real-time PCR (Canier *at al.,* 2020 and EURL, 2023) were evaluated for their reproducibility (stage 3 validation) in the context of interlaboratory comparison tests.

6.3.1. For presumptive diagnosis of clinically affected animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
TaqMan PCR *Bonamia* spp. (Corbeil *et al.,* 2006a) (with epidemiological Ct cut-off)	Diagnosis	Two farms in *B. exitiosa* endemic areas in Australia: a coastal lease with *B. exitiosa* associated mortalities, a land-	Gills	*Ostrea angasi*	93.5% (232)	92.2% (232)	Histology Bayesian latent class analysis	Bradley *et al.*, 2020

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Histology	Diagnosis	based hatchery with no *B. exitiosa* associated mortalities (prevalences ~30 and 60%)	Tissue slide		50.8% (232)	98.2% (232)	Taqman PCR Bayesian latent class analysis	

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction.

6.3.2. For surveillance of apparently healthy animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Histology	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Tissue section	*O. chilensis*	44.4% (28)	100% (28)	Combination conventional PCR and ISH (DSe & DSp: 100%)	Diggles *et al.,* 2003
	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA, where *B. ostreae* is endemic). Low prevalence populations	Tissue section	*Ostrea edulis* (1–2.5 years)	56% (607)	100% (607)	Combination histology and real-time PCR (DSe: 88%, DSp: 99%)	Marty *et al.,* 2006
	Surveillance	Flat oysters produced in hatchery derived from five origins, deployed in the field, in a *B. ostreae & B. exitiosa* endemic area (Galicia, Spain). High prevalence populations	Tissue section	*Ostrea edulis* (2–3 years)	54% (137)	96% (137)	Real-time PCR (DSe: 100%, DSp: 77%) and conventional PCR. Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2013
	Surveillance	30 flat oysters from an area affected by *B. ostreae* and *B. exitiosa* in Galicia, Spain. High prevalence populations	Tissue section	*Ostrea edulis*	63% (30)	88% (30)	ISH (DSe: 82%, DSp:88%), PCR-RFLP (DSe 91%, DSp 100%), real-time PCR (DSe 100%, DSp 75%). Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2014
	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Tissue section	*Ostrea angasi*	76% (400)	93% (400)	Real-time PCR (DSe: 69%, DSp:93%) and heart imprint (DSe: 61%, DSp: 60%). Bayesian latent class analysis	Buss *et al.,* 2019
Cytology	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Heart imprints	*Ostrea angasi*	61% (400)	60% (400)	Histology (DSe: 76%, DSp: 93%) and real-time PCR (DSe: 69%, DSp:93%) Bayesian latent class analysis	Buss *et al.,* 2019
	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Heart imprints	*O. chilensis*	59.3% (28)	100% (28)	Combination conventional PCR	Diggles *et al.,* 2003

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
							and ISH (DSe & DSp: 100%)	
In situ hybridisation (Cochennec *et al.,* 2000)	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Tissue section	*O. chilensis*	100% (28)	27.3% (28)	Combination heart imprint and histology (DSe & DSp: 100%)	Diggles *et al.,* 2003
Conventional PCR *Bonamia* spp. (Cochennec *et al.,* 2000)	Surveillance	28 flat oysters from one site in New Zealand (high prevalence 60–96%)	Gonad and digestive gland	*O. chilensis*	88.2% (28)	36.4% (28)	Combination heart imprint and histology (DSe & DSp: 100%)	Diggles *et al.,* 2003
	~~Surveillance~~	~~Eight batches of 30 flat oysters, Spain (tested by two laboratories) (total prevalence 10–30%)~~	~~NA~~	~~*Ostrea edulis*~~	~~93% (240)~~	~~85-90% (240)~~	~~Combination histology and gill imprints (DSe: 64-69%, DSp: 97.5%)~~	~~Balseiro *et al.,* 2006~~
	Surveillance	30 flat oysters from an area affected by *B. ostreae* and *B. exitiosa* in Galicia, Spain	Gills	*Ostrea edulis*	91% (30)	100% (30)	ISH (DSe: 82%, DSp:88%), Histology (Des 63%, DSp 88%), and real-time PCR (DSe 100%, DSp 75%) Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2014
	Surveillance	Flat oysters from the three main production sites in France representative of three different levels of *B. ostreae* prevalence (very low, low, high)	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	82.8% (349)	98.7% (349)	Real-time PCR (DSe: 77.5%, DSp: 98.4%) Bayesian latent class analysis	Canier *et al.*, 2020
TaqMan real-time PCR *Bonamia* spp.	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA, where *B. ostreae* is endemic). Low prevalence populations	Heart	*Ostrea edulis* (1–2.5 years)	88% (607)	99% (607)	Combination histology and real-time PCR; histology (DSe: 56%, DSp: 100%)	Marty *et al.,* 2006
TaqMan real-time PCR *Bonamia* spp. (Corbeil *et al.,* 2006a),	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Mantle, gill, heart (DNA tested pure and 1/10 diluted)	*Ostrea angasi*	69% (400)	93% (400)	Histology (DSe: 76%, DSp: 93%) and heart imprint (DSe: 61%, DSp: 60%) Bayesian latent class analysis	Buss *et al.,* 2019
TaqMan real-time PCR *Bonamia* spp.	Surveillance	Flat oysters from the three main production sites in France representative of three different levels of *B. ostreae* prevalence (very low, low, high)	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	77.5% (349)	98.4% (349)	Conventional PCR (DSe: 82.8%, DSp: 98.7%) Bayesian latent class analysis	Canier *et al.,* 2020
SYBR Green real-time PCR *B. exitiosa*	Surveillance	Flat oysters produced in hatchery derived from 5 origins, deployed in the field, in a *B. ostreae &*	Gills	*Ostrea edulis* (2–3 years)	100% (137)	77% (137)	Histology (DSe: 54%, DSp: 96%) and conventional PCR. Maximum	Ramilo *et al.,* 2013

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
(Ramilo *et al.,* 2013)		*B. exitiosa* endemic area (Galicia, Spain). High prevalence populations					likelihood latent class analysis (TAGS)	
	Surveillance	30 flat oysters from an area affected by *B. ostreae* and *B. exitiosa* in Galicia, Spain	Gills	*Ostrea edulis*	100% (30)	75% (30)	ISH (DSe: 82%, DSp:88%), histology (DSe 63%, DSp 88%), and PCR-RFLP (DSe 91%, DSp 100%). Maximum likelihood latent class analysis, (TAGS)	Ramilo *et al.,* 2014

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction.

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* *

NB: There is a WOAH Reference Laboratory for infection with *Bonamia exitiosa*
(please consult the WOAH web site:
https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3).
Please contact WOAH Reference Laboratories for any further information on infection with *Bonamia exitiosa*

NB: FIRST ADOPTED IN 1995 AS BONAMIOSIS. MOST RECENT UPDATES ADOPTED IN 2022 (SECTIONS 2.2.1 AND 2.2.2).

Annex 25. – Chapter 2.4.2. 'Infection with *Bonamia ostreae*

CHAPTER 2.4.3.

INFECTION WITH *BONAMIA OSTREAE*

1. Scope

Infection with *Bonamia ostreae* means infection with the pathogenic agent *Bonamia ostreae* of the Family Haplosporiidae.

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent

Bonamia ostreae is a haplosporidian protozoan parasite (Arzul & Carnegie, 2015; Carnegie & Cochennec-Laureau, 2004) infecting haemocytes of ~~flat oysters, *Ostrea edulis*~~ several oysters species, and causing disease and mortality (Grizel, 1985).

2.1.2. Survival and stability in processed or stored samples

No data available.

2.1.3. Survival and stability outside the host

After its release from *Ostrea edulis*, *B. ostreae* can survive at least 4 days in seawater, however more than 90% of shed parasites are no longer detected after 2 days outside the oysters (Mérou *et al.,* 2020). Up to 58% of parasites isolated from highly infected oysters seem to survive after 48 hours ~~1 week~~ in seabed bore water at 15°C (Arzul *et al.,* 2009).

For inactivation methods, see Section 2.4.5.

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Ostreidae	*Magallana* (syn. *Crassostrea*) *ariakensis*	Ariake cupped oyster
	Ostrea chilensis	Chilean flat oyster
	Ostrea edulis	European flat oyster

2.2.2. Species with incomplete evidence for susceptibility

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with *B. ostreae* according to Chapter 1.5 of the *Aquatic Code* are:

Family	Scientific name	Common name
Ostreidae	*Ostrea puelchana* ~~s~~	Argentinean flat oyster

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated:

Family	Scientific name	Common name
Actiniidae	*Actinia equina*	beadlet anemone
Ascidiidae	*Ascidiella aspersa*	European sea squirt
Ophiotrichidae	*Ophiothrix fragilis*	brittle star
Ostreidae	*Magallana* (syn. *Crassostrea*) gigas	Pacific cupped oyster
N/A	grouped zooplankton	zooplankton

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

All ages of oysters appear susceptible to *B. ostreae* including larvae and spat (Arzul *et al.,* ~~2010~~ 2011), however, prevalence and infection intensity are generally higher in individuals of 2 years of age or more particularly post-spawning (Culloty & Mulcahy, 1996).

2.2.4. Distribution of the pathogen in the host

Bonamia ostreae is an intrahaemocytic protozoan (Comps *et al*., 1980; Pichot *et al*., 1979) but it can be observed extracellularly between epithelial or interstitial cells in the gills and stomach or in necrotic connective tissue areas. Intraepithelial localisation has also been reported in gills (Montes *et al*., 1994). The parasite was also reported in ovarian tissue (van Banning, 1990). Advanced infections become systemic. In larvae, the parasite was observed in the epithelium surrounding the visceral cavity (Arzul *et al.,* ~~2010~~ 2011).

2.2.5. Aquatic animal reservoirs of infection

Any susceptible species (see Section 2.2.1) and any species with incomplete evidence for susceptibility (see Section 2.2.2.) should be considered as potential reservoir. In addition, the observation of parasites presumably *B. ostreae* in *Ostrea angasi* displayed in a zone infected with *B. ostreae*, suggests that this species could also be a reservoir for *B. ostreae* (Bougrier *et al.,* 1986).

2.2.6. Vectors

The possible role of benthic macroinvertebrates and zooplankton in the life cycle of *B. ostreae* was investigated. The brittle star *Ophiothrix fragilis* was identified as a possible vector for the parasite (Lynch *et al.,* 2006).

2.3. Disease pattern

2.3.1. Mortality, morbidity and prevalence

Infection of wild and cultured flat oysters is often lethal, and death usually occurs concurrently with the highest intensity of infection.

Prevalence is variable (from 0% to 80%) and is higher in individuals older than 2 years. The disease occurs and can be transmitted throughout the year, but there is a seasonal variation in infection with *B. ostreae,* with prevalence of infection increasing from autumn and showing a peak in late winter/early spring (Arzul *et al.,* 2006; Culloty & Mulcahy, 1996; Engelsma *et al.,* 2010; Grizel, 1985; Mérou *et al.,* 2023).

2.3.2. Clinical signs, including behavioural changes

Clinical signs include dead or gaping oysters.

2.3.3 Gross pathology

Gross pathology includes occasional yellow discoloration, extensive lesions including perforated ulcers in the connective tissues of the gills, mantle and digestive gland (Comps *et al*., 1980). These gross signs are not pathognomonic for infection with *B. ostreae* and most infected oysters appear normal.

2.3.4. Modes of transmission and life cycle

Direct transmission from host to host is possible. Transmission of the parasite directly from host to host by cohabitation or by inoculation of purified parasites has been demonstrated experimentally (Hervio *et al.,* 1995), suggesting that no intermediate host is needed. This is supported by the correlation between oyster density and prevalence of bonamiosis (Grizel, 1985).

The observation of parasites in the epithelium of palleal organs including gills suggests that the parasite enters into and is released from the oysters through these organs.

Moreover, the parasite was observed in larvae incubated in the pallial cavity of adult oysters suggesting possible transmission between these two age groups. Thus, larvae may contribute to the spread of the parasite during their planktonic life stage (Arzul *et al.,* ~~2010~~ 2011).

A lag time of at least 3 months is generally observed before detecting the parasite in disease free batches moved into infected areas (Montes, 1991).

2.3.5. Environmental factors

Survival of parasites purified and maintained in sea water is lower at 25°C than at 4°C or 15°C (Arzul *et al.,* 2009). High salinities (35, 40 and 45 ppt) appear to favour parasite survival (Arzul *et al.,* 2009). Prevalence shows an annual pattern that may differ according to areas. Prevalence of infection increases from autumn and shows a peak in late winter/early spring. Two peaks generally occurring in winter/spring and in autumn have been reported (Arzul *et al.,* 2006; Culloty & Mulcahy, 1996; Mérou *et al.,* 2023). Lower summer temperatures and higher summer salinities induce higher prevalence the following winter (Arzul *et al.,* 2006). *Ostrea edulis* appears to be more susceptible to *B. ostreae* following a period of lower food availability and lower salinities (Engelsma *et al.,* 2010).

2.3.6. Geographical distribution

Infection with *B. ostreae* has been found in Europe, North America (Carnegie & Cochennec-Laureau, 2004) and Oceania (Lane *et al.,* 2016).

See WAHIS (https://wahis.woah.org/#/home) for recent information on distribution at the country level.

2.4. Biosecurity and disease control strategies

2.4.1. Vaccination

None.

2.4.2. Chemotherapy including blocking agents

None.

2.4.3. Immunostimulation

None.

2.4.4. Breeding resistant strains

Selective breeding has been shown to be effective in reducing susceptibility and mortality caused by *B. ostreae* (Lynch *et al.,* 2014; Naciri-Graven *et al.,* 1998).

2.4.5. Inactivation methods

Peracetic acid bath (0.001% and 0.005%) has been shown to reduce contamination of oysters by *B. ostreae* (Grizel, 1985). Bench scale experiment showed that a 94 mJ/cm^2 UV C exposure inactivates up to 40% of *B. ostreae* isolated from infected oysters (Fernandez-Boo *et al.,* 2021).

2.4.6. Disinfection of eggs and larvae

No data available.

2.4.7. General husbandry

Mortalities caused by bonamiosis can be reduced using suspension culture, lower stocking densities or by culturing *Ostrea edulis* with *Magallana* (*Crassostrea) gigas,* which are not naturally susceptible to infection (Carnegie & Cochennec-Laureau, 2004). Oyster seed from hatcheries are preferred to seed from natural settlements which appears to have higher levels of parasites (Conchas *et al*., 2003). In an infected zone, harvesting larger oysters should allow reducing the parasite load in the population.

3. Specimen selection, sample collection, transportation and handling

This section draws on information in Sections 2.2, 2.3 and 2.4 to identify populations, individuals and samples that are most likely to be infected.

3.1. Selection of populations and individual specimens

Gaping or freshly dead individuals (2 or more years old) should be sampled by priority, to increase the chances of detecting infected oysters. For histology, only live (including moribund) oysters should be sampled.

Sampling of bivalves should be carried out when prevalence is known to be at a maximum. When such data are not available in a particular ecosystem, sampling should preferably be carried out in late winter-early spring (Arzul *et al.,* 2006; Culloty & Mulcahy, 1996; Engelsma *et al.,* 2010).

3.2. Selection of organs or tissues

A 3–5 µm thick section of tissues including gills, mantle, gonad, and digestive gland, is used for diagnosis of *B. ostreae* by histology. Gills or heart are preferred for some tests, including imprints and PCR.

3.3. Samples or tissues not suitable for pathogen detection

Tissues other than gills, heart and mantle are less suitable.

3.4. Non-lethal sampling

No difference was observed between results obtained using real-time PCR from a mix of gill, mantle and digestive gland tissues and using real-time PCR from a biopsy of gills collected on anaesthetised oysters (Kamermans *et al.,* 2023).

Environmental DNA- and RNA-based approaches have been successfully developed allowing the detection of parasite DNA or RNA in sea water (Mérou *et al.,* 2020; von Gersdorff Jorgensen *et al.,* 2020). Although these methods allow detection in experimental conditions, their application in the field has not been validated (Mérou *et al.,* 2023).

3.5. Preservation of samples for submission

For guidance on sample preservation methods for the intended test methods, see Chapter 2.4.0 *General information* (*diseases of molluscs*).

3.5.1. Samples for pathogen isolation

Not applicable.

3.5.2. Preservation of samples for molecular detection

Tissue samples for PCR testing should be preserved in ~~70–100~~ 80% (v/v) analytical-grade ethanol.

Standard sample collection, preservation and processing methods for molecular techniques can be found in Section B.5.5 of Chapter 2.4.0 *General information* (diseases of molluscs).

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

Standard sample collection, preservation and processing methods for histological techniques can be found in Section B.5.3 of Chapter 2.4.0 *General information* (diseases of molluscs).

3.5.4. Samples for other tests

None.

3.6. Pooling of samples

Pooling of samples from more than one individual animal for a given purpose is only recommended where robust supporting data on diagnostic sensitivity and diagnostic specificity have been evaluated and found to be suitable. The effect of pooling on diagnostic sensitivity has not been thoroughly evaluated, therefore larger specimens should be processed and tested individually. Small life stages such as spat can be pooled to obtain the minimum amount of material for molecular detection.

Performances of diagnostic methods applied on pools have not been evaluated. However, the detection of *B. ostreae* DNA was found similar between individuals and pools of five individuals when using a real-time PCR assay targeting the multiple copy 18S gene (Lane *et al.,* 2017).

4. Diagnostic methods

The methods currently available for pathogen detection that can be used in i) surveillance of apparently healthy animals, ii) presumptive diagnosis in clinically affected animals and iii) confirmatory diagnostic purposes are listed in Table 4.1. by animal life stage.

Ratings for purposes of use. For each recommended assay a qualitative rating for the purpose of use is provided. The ratings are determined based on multiple performance and operational factors relevant to application of an assay for a defined purpose. These factors include appropriate diagnostic performance characteristics, level of assay validation, availability cost, timeliness, and sample throughput and operability. For a specific purpose of use, assays are rated as:

+++ =	Methods are most suitable with desirable performance and operational characteristics.
++ =	Methods are suitable with acceptable performance and operational characteristics under most circumstances.
+ =	Methods are suitable, but performance or operational characteristics may limit application under some circumstances.
Shaded boxes =	Not appropriate for this purpose.

Validation stage. The validation stage corresponds to the assay development and validation pathway in chapter 1.1.2. The validation stage is specific to each purpose of use. Where available, information on the diagnostic performance of recommended assays is provided in Section 6.3.

WOAH Reference Laboratories welcome feedback on diagnostic performance of recommended assays, in particular PCR methods. Of particular interest are any factors affecting expected assay sensitivity (e.g. tissue components inhibiting amplification) or expected specificity (e.g. failure to detect particular genotypes, detection of homologous sequences within the host genome). These issues should be communicated to the WOAH Reference Laboratories so that advice can be provided to diagnostic laboratories and the standards amended if necessary.

Table 4.1. *WOAH recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals*

Method	A. Surveillance of apparently healthy animals				B. Presumptive diagnosis of clinically affected animals				C. Confirmatory diagnosis[1] of a suspect result from surveillance or presumptive diagnosis			
	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV	Early life stages[2]	Juveniles[2]	Adults	LV
Imprints		++	++	2		+++	+++	NA				
Histopathology		++	++	2		+++	+++	NA				
Transmission electron microscopy									+	+	+	NA
Real-time PCR	+++	+++	+++	3	+++	+++	+++	NA	+++	+++	+++	NA
Conventional PCR	++	++	++	3	+++	+++	+++	NA				
Conventional PCR followed by amplicon sequencing									+++	+++	+++	NA
In-situ hybridisation									++	++	++	NA
Bioassay												
LAMP												
Ab-ELISA												
Ag-ELISA												
Other antigen detection methods												

LV = level of validation, refers to the stage of validation in the WOAH Pathway (chapter 1.1.2), Figures in brackets mean that partial data are available; NA = not available; PCR = polymerase chain reaction; LAMP = loop-mediated isothermal amplification; Ab- or Ag-ELISA = antibody or antigen enzyme-linked immunosorbent assay, respectively;

[1]For confirmatory diagnoses, methods need to be carried out in combination (see Section 6). [2]Susceptibility of early and juvenile life stages is described in Section 2.2.3.

[3]Specify the test used. Shading indicates the test is inappropriate or should not be used for this purpose.

4.1. Imprints

Samples to be taken consist of heart (preferably the ventricle) or gills from fresh, gaping or freshly dead bivalves if they are sufficiently large. If bivalves are too small (as spat), imprints should be done using the entire individual.

After drying tissues on absorbent paper, several imprints are made on a glass slide. Slides are air-dried, fixed and stained using a commercially available blood-staining kit, in accordance with the manufacturer's instructions. Fixation can be done using methanol or absolute ethanol. After rinsing in tap water and drying, the slides are mounted with a cover-slip using an appropriate synthetic resin. Slides are observed first at ×200 magnification and then under oil immersion at ×1000 magnification.

Imprints are generally less sensitive than PCR methods (see Sections 6.1. and 6.2).

Infection with *B. ostreae* is indicated by the presence of small spherical or ovoid organisms (2–5 µm wide) within haemocytes. However, the parasite might also occur extracellularly. These organisms show a basophilic cytoplasm often containing a lipid vacuole and an eosinophilic nucleus which is rather eccentric in the case of *B. ostreae* and rather centred in the case of *B. exitiosa* (colours of cytoplasm and nucleus may vary with the stain used). Parasitic cells can appear wider on imprints than on histological examination. Multinucleated cells can be observed (Balouet *et al.,* 1983; Bucke, 1988). The technique is not parasite species specific.

A positive result is indicative of infection with a *Bonamia* sp~~ecies~~.

4.2. Histopathology

Samples to be taken consist of fresh, gaping or freshly dead bivalves.

Sections of tissue that include gills, digestive gland, mantle, and gonad should be fixed for 24 hours minimum in a recommended fixative followed by standard processing for histology as described in section 5.3 of Chapter 2.4.0 *General information* (diseases of molluscs). Observations are made at increasing magnifications up to ×1000.

Histology is generally less sensitive than PCR methods (see Sections 6.1. and 6.2).

Infection with *Bonamia ostreae* is indicated by the presence of small cells of 2–5 µm wide within the haemocytes or free in the connective tissue or sinuses of gills, gut, digestive gland, gonad and mantle, often associated with an intense inflammatory reaction. Parasite cells could be observed in some epithelia including stomach or mantle epithelia (Balouet *et al.,* 1983). To avoid any doubt, the parasite has to be observed inside the haemocyte for a positive diagnosis. Although *B. ostreae* is slightly smaller than *B. exitiosa* and usually presents an eccentric nucleus, both species are difficult to distinguish in histology. No spore has been described in *B. ostreae* unlike *B. perspora* which has also a central to slightly eccentric nucleus. The technique is not species specific.

A positive result is indicative of infection with a *Bonamia* sp~~ecies~~.

4.3. Transmission electron microscopy

Samples to be taken consist of live, gaping or freshly dead bivalves.

A small sized piece of tissue (1–2 mm) should be fixed in an appropriate fixative for at least 1 hour and then processed as described in section 5.4 of Chapter 2.4.0 *General information* (diseases of molluscs).

Infection with *B. ostreae* is indicated by the presence of parasites within the haemocytes. Different stages, including uninucleated, and rarely binucleated and plasmodial stages have been reported (Montes *et al*., 1994; Pichot *et al*., 1979). Intracellular structures include mitochondria, haplosporosomes, Golgi apparatus and persistent intranuclear microtubules. Two forms were described including a dense form rich in ribosomes and haplosporosomes and a light form, slightly larger with less dense cytoplasm and a nucleus showing a large nucleolus (Bucke, 1988; Pichot *et al.,* 1979).

Uninucleated *B. ostreae* stages are smaller than *B. exitiosa* or *B. perspora* ones and have larger haplosporosomes than other *Bonamia* spp. (Hine *et al.,* 2014). They are also denser and have fewer lipoid bodies than other *Bonamia* spp. (Hine *et al.,* 2001).

4.4. Nucleic acid amplification

PCR assays should always be run with the controls specified in Section B.5.5 *Molecular methods* Chapter 2.4.0 *General information* (diseases of molluscs). Molluscs are known to potentially contain substances that can inhibit PCR reactions. It is recommended to check for the presence of PCR inhibitors in DNA extracts to avoid false negative results. In case PCR inhibitors are present, DNA sample can be diluted prior to PCR analyses (a 1/10 dilution ~~allows to~~ resolves most cases of PCR inhibition). Each sample should be tested in duplicate.

Extraction of nucleic acids

Different kits and procedures can be used for nucleic acid extraction. The quality and concentration of the extracted nucleic acid is important and can be checked using a suitable method as appropriate to the circumstances.

4.4.1. Real-time PCR

Three TaqMan PCR assays are available for the detection of *Bonamia* spp.: one targeting the ITS1 (internal transcribed spacer) region (Corbeil *et al.,* 2006) and two targeting the 18S (small subunit rDNA) (Canier *et al.,* 2020; Marty *et al.,* 2006). The PCR assay developed by Canier *et al.* (2020) targets the 18S (small subunit rDNA) and allows the concomitant detection of *Bonamia* spp. and *Marteilia refringens* parasites.

~~Two~~ Three other real-time PCR protocols have been developed to specifically detect *B. ostreae*: ~~one~~ two SYBR-green PCR assays targeting the actin 1 gene (Robert *et al.,* 2009) and the 18S-ITS1 region, (Ramilo *et al.,* 2013), and a TaqMan PCR assay targeting the actin gene (https://www.eurl-mollusc.eu/SOPs). These PCR assays allow the concomitant detection of *B. ostreae* and *B. exitiosa* parasites.

PCR assays are generally more sensitive than histology or cytology for the diagnosis of *B. ostreae* (see Sections 6.1. and 6.2). Real-time PCR usually have a better sensitivity than conventional PCR (see Sections 6.1. and 6.2).

***Primers and probes* (*sequences*)**

Pathogen/ target gene	Primer/probe (5'–3')	Concentration	Cycling parameters[a]
Method 1: Corbeil *et al.,* 2006; GenBank Accession No.: JN040831			
TaqMan® PCR *Bonamia* spp./ITS-1	ITS-For: CCC-TGC-CCT-TTG-TAC-ACA-CC ITS-Rev: TCA-CAA-AGC-TTC-TAA-GAA-CGC-G Probe Bon ITS: TTA-GGT-GGA-TAA-GAG-CCG-C (FAM MGB-NFQ)	900 nM 900 nM 250 nM	35 cycles of: 95°C/15 sec and 63.6°C/60 sec
Method 2: Marty *et al.,* 2006; GenBank Accession No.: AF192759			
TaqMan® PCR *Bonamia* spp./18S	Fwd: CCC-GGC-TTC-TTA-GAG-GGA-CTA Rev: ACC-TGT-TAT-TGC-CCC-AAT-CTT-C Probe: CTG-TGT-CTC-CAG-CAG-A (FAM MGB-NFQ)	800 nM 800 nM 250 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 3: Canier *et al.,* 2020; GenBank Accession No. AF192759			
TaqMan® PCR *Bonamia* spp./18S	Bosp2-18S-F: CAG-GAT-GCC-CTT-AGA-TGC-TC Bosp2-18S-R: GTA-CAA-AGG-GCA-GGG-ACG-TA Probe Bosp-18S-IN: TTG-ACC-CGG-CTT-GAC-AAG-GC (HEX-BHQ1)	300 nM 500 nM 300 nM	40 cycles of: 95°C/15 sec and 60°C/60 sec
Method 4: Ramilo *et al.,* 2013; GenBank Accession No. AF262995			
SYBR Green PCR *B. ostreae*/18S-ITS	BOSTRE-F: TTA-CGT-CCC-TGC-CCT-TTG-TA BOSTRE-R: TCG-CGG-TTG-AAT-TTT-ATC-GT	300 nM 300 nM	35 cycles of: 95°C/30 sec and 55°C/45 sec, 72°C/60 sec Melt curve from 55°C to 95°C with 0.5°C increment/sec
Method 5: EURL for mollusc diseases; GenBank Accession No: AF192759			
TaqMan® PCR *B. ostreae/* actin	BO2_F: AAA-TGG-CCT-CTT-CCC-AAT-CT BO2_R: CCG-ATC-AAA-CTA-GGC-TGG-AA BO2 probe: TGA-CGA-TCG-GGA-ATG-AAC-GC (HEX BHQ1)	300 nM 300 nM 200 nM	40 cycles of: 95°C/15 sec and 60°C/20 sec
Method 6: Robert *et al.,* 2009; GenBank Accession No: AM410919, AM410920, AM410921			

SYBR Green PCR ***B. Ostreae*/actin 1**	**Bo A1F: GCT-TCG-ACC-GAA-AGT-TCC-G** **Bo A2R: GGC-GAA-GAG-GTC-TTT-TCT-GA**	**2400 nM** **1200 nM**	**40 Cycles of: 95°C/30 sec and 60°C/1 min, 72°C/30 sec Melt curve from 60°C to 95°C with 0.5°C increment/sec**

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

4.4.2. Conventional PCR

Three conventional PCR protocols targeting the 18S (small subunit rDNA) have been developed for the detection of *Bonamia* spp. (Carnegie *et al.,* 2000; Cochennec *et al*., 2000) or *B. ostreae* (Engelsma *et al.,* 2010).

The PCR assay described by Carnegie *et al.* (2000) amplifies most of the identified *Bonamia* spp. including *B. ostreae* and *B. exitiosa*, while the Cochennec *et al.* (2000) PCR amplifies *Bonamia* spp. and several members of Haplosporidia. The Engelsma *et al.* (2010) PCR was shown not to detect *B. exitiosa* and *Haplosporidium armoricanum.*

Conventional PCR assays were generally more sensitive than histology or cytology (see Sections 6.1. and 6.2) although Lynch *et al.* (2008) found that heart imprint was more sensitive than the conventional PCR from Cochennec *et al.* (2000). Under certain circumstances, the primers from Cochennec *et al.* (2000) can generate a 295 bp non-specific product (Engelsma *et al.,* 2014).

Primer sequences

Pathogen / target gene	Primer (5'–3')	Concentration	Cycling parameters[(a)]
Method 1: Carnegie *et al.,* 2000 modified in Carnegie *et al.,* 2008; amplicon size [760 bp]; GenBank Accession No.: AF262995			
Bonamia spp./18S amplifies most of the identified *Bonamia* spp. including *B. ostreae* and *B. exitiosa*	CF: CGG-GGG-CAT-AAT-TCA-GGA-AC CR: CCA-TCT-GC-TGGA-GAC-ACA-G	250 nM 250 nM	35 cycles of: 95°C/1min and 59°C/1 min and 72°/1min
Method 2: Cochennec *et al.,* 2000; amplicon size [300 bp]; GenBank Accession No.: AF192759			
Bonamia spp./18S amplifies all identified *Bonamia* spp. and several members of Haplosporidia	BO: CAT-TTA-ATT-GGT-CGG-GCC-GC BOAS: CTG-ATC-GTC-TTC-GAT-CCC-CC	1 µM 1 µM	30 cycles of: 95°C/60 sec, 55°C/60 sec, 72°C/60 sec
Method 3: Engelsma *et al.,* 2010; amplicon size [352 bp]; GenBank Accession No.: KM073106			
***B. ostreae*/18S**	**BoosF03: CAA-TGG-TGC-GTT-CAA-CGA-GT** **BoosR03: GGG-TTC-GCG-GTT-GAATTT-TA**	**400 nM** **400 nM**	**40 cycles of: 95°C/30 sec, 58°C/30 sec, 72°C, 45 sec**

[(a)]A denaturation step at 94-95°C prior to cycling and a final elongation step at 72°C (between 5 and 10 minutes) must be included.

The PCR methods 1 and 2 are not specific for *B. ostreae*. Sequence analysis of the amplicons must be used to confirm identity. Amplicons obtained by method 2 can be digested with the *Bgl* I enzyme which allows to distinguish two profiles: *B. ostreae* (two bands of 120 and 180 bp) and *B. exitiosa* (not digested).

4.4.3. Other nucleic acid amplification methods

None available.

4.5. Amplicon sequencing

The size of the PCR amplicon is verified by agarose gel electrophoresis and purified by excision from this gel. Obtained sequences are analysed and compared with published sequences.

Sequencing is recommended as one of the final steps for confirmatory diagnosis. Targeted regions are 18S, ITS1 and actin. Although the sequences are available in the public gene banks, it is recommended to refer such cases to the appropriate WOAH Reference Laboratory.

4.6. *In-situ* hybridisation

Samples to be taken: live or freshly dead oysters.

Several *in situ* hybridisation (ISH) protocols targeting the 18S have been developed.

The first one (Cochennec *et al*., 2000) allows a detection at the *Bonamia* genus level and uses a 300 bp labelled probe produced by PCR.

Two ISH protocols were designed to specifically detect *B. ostreae* (Carnegie *et al.,* 2003; Hill *et al.,* 2014), and rely on labelled oligonucleotide probes. However, the ISH protocol from Carnegie *et al.* (2003) should also detect *B. exitiosa* according to probe sequence analysis.

Reference	Pathogen/target	ISH probe type	ISH probe
Method 1 Cochennec *et al.,* 2000	*Bonamia* spp. and several members of Haplosporidia 18S	Labelled BO–BOAS amplicons	BO–BOAS PCR product (300bp)
Method 2: Carnegie *et al.,* 2003	*B. ostreae*, and *B. exitiosa* 18S	Labelled oligonucleotides	UME-BO-1: CGA-GGC-AGG-GTT-TGT; UME-BO-2: GGG-TCA-AAC-TCG-TTG-AAC UME-BO-3: CGC-TCT-TAT-CCA-CCT-AAT
Method 3 Hill *et al.,* 2014	*B. ostreae* 18S	Labelled oligonucleotides	Bost171: CCG-CCG-AGG-CAG-GGT-TTG-T

Technical procedure

The first steps in the technical procedure follow the recommendations described in chapter 2.4.0.

Subsequent steps concerning Method 1 (Cochennec *et al.,* 2000) are that the probe is produced by PCR using the previously described primer pair Bo–Boas (Section 4.4.2) with digoxigenin incorporation and the PCR is performed as described in the section on PCR except that DIG dUTP 25 mM is added to the reaction mixture. The detection steps are performed according to the manufacturer's instructions. In other protocols, probes consist in digoxigenin-labelled nucleotides.

Slides are dehydrated by immersion in an ethanol series and air dried. The slides are then covered with hybridisation buffer (4 × SSC [standard saline citrate; 60 mM NaCl, 600 mM NaCl, pH 7], 50% formamide, 1 × Denhardt's solution, 250 µg ml^{-1} yeast tRNA, 10% dextran sulphate) containing approx. 20 ng of the digoxigenin-labelled probe (1–2 µl of the probe produced by PCR, or 1 µl at 100 µm of labelled nucleotides). Sections are covered with *in-situ* plastic cover-slips and placed for 5 minutes at 95°C. Slides are then cooled on ice for 1– 5 minutes before overnight hybridisation at 42°C in a humid chamber Sections are washed twice for 5 minutes in 2 × SSC at room temperature, and once for 10 minutes in 0.4 × SSC at 42°C. The detection steps are performed according to the manufacturer's instructions. The slides are then rinsed with appropriate buffer. The sections are counter-stained with an appropriate staining, rinsed in tap water, immersed in 95% and 100% ethanol for 30 seconds for each, rinsed for 10–30 seconds in xylene and cover-slips are applied using an appropriate mounting medium.

In Carnegie et al. (2003)after proteinase K treatment, slides are washed in several baths including PBS plus 0.2% glycine for 5 minutes, acetylated using 5% anhydrous acetic in 0.1 M triethanolamine/HCl (pH 8), for 10 minutes at room temperature, washed again in PBS for 10 minutes and lastly equilibrated in 5 × SET (750 mM NaCl, 6.4 mM EDTA, 100 mM Tris Base) for 10 minutes at room temperature. Slides are then covered with 200 µl of prehybridisation buffer (5 × SET, 0.02% bovine serum albumin, 0.025% sodium dodecyl sulphate [SDS]) for 30 minutes at 45°C. Prehybridisation buffer is replaced with 10 to 12 µl of the prehybridisation buffer containing 2–10 ng μl^{-1} of the oligonucleotides and slides are incubated overnight in a humid chamber at 45°C. Slides are then washed three times in 0.2 × SET for 5 minutes at 42°C, air dried and mounted before being examined using an epifluorescence microscope at ×600–1000.

Interpretation of results:

A positive result corresponds to labelled parasites inside the haemocytes, with all negative controls (including non-infected sample and no probe ISH reaction control) negative and all positive controls (including infected sample) positive. In addition, non-specific probe such as SSUrDNA can be used to verify the integrity of DNA in paraffin blocks.

4.7. Immunohistochemistry

Not available.

4.8. Bioassay

Not available.

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

Although an immunofluorescent technique based on monoclonal antibodies was developed It has never been validated and it is no longer available (Carnegie & Cochennec-Laureau, 2004).

4.10. Other methods: agent purification

Bonamia ostreae can be purified from highly infected oysters (Mialhe *et al.,* 1988). All organs are homogenised except the adductor muscle, and parasites are concentrated by differential centrifugation on sucrose gradients and then purified by isopycnic centrifugation on a Percoll gradient.

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

Real-time PCR is recommended for targeted surveillance to declare freedom from infection with *B. ostreae*. Histology, tissue imprint and conventional PCR can also be used (see Table 4.1)

6. Corroborative diagnostic criteria

This section only addresses the diagnostic test results for detection of infection in the absence (Section 6.1.) or in the presence of clinical signs (Section 6.2.) but does not evaluate whether the infectious agent is the cause of the clinical event.

The case definitions for a suspect and confirmed case have been developed to support decision making related to trade and confirmation of disease status at the country, zone or compartment level. Case definitions for disease confirmation in endemically affected areas may be less stringent. If a Competent Authority does not have the capability to undertake the necessary diagnostic tests it should seek advice from the appropriate WOAH Reference Laboratory, and if necessary, refer samples to that laboratory for confirmatory testing of samples from the index case in a country, zone or compartment considered free.

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

Apparently healthy populations may fall under suspicion, and therefore be sampled, if there is an epidemiological link(s) to an infected population. Hydrographical proximity to, or movement of animals or animal products or equipment, etc., from a known infected population equate to an epidemiological link. Alternatively, healthy populations are sampled in surveys to demonstrate disease freedom.

6.1.1. Definition of suspect case in apparently healthy animals

The presence of infection with *B. ostreae* shall be suspected if at least one of the following criteria is met:

i) Observation of parasite cells in tissue imprints

ii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iii) Positive result by conventional PCR

iv) Positive result by real-time PCR

[2] For example transboundary commodities.

6.1.2. Definition of confirmed case in apparently healthy animals

The presence of infection with *B. ostreae* is considered to be confirmed if the following criterion is met:

~~i) Positive result by tissue imprints or histology followed by real-time PCR or by conventional PCR and sequencing or by species-specific in-situ hybridisation~~

i) Positive result by real-time PCR and conventional PCR and sequencing

ii) Positive result by real-time PCR and *in-situ* hybridisation

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

6.2 Clinically affected animals

Clinical signs are not pathognomonic for a single disease; however they may narrow the range of possible diagnoses.

6.2.1. Definition of suspect case in clinically affected animals

The presence of infection with *B. ostreae* shall be suspected if at least one of the following criteria is met:

i) Gross pathology or clinical signs associated with the disease as described in this chapter

ii) Observation of parasite cells in tissue imprints

iii) Observation of parasite cells in tissue sections with or without histopathology characteristic of the pathogen

iv) Positive result by real-time PCR

v) Positive result by conventional PCR

6.2.2. Definition of confirmed case in clinically affected animals

The presence of infection with *B. ostreae* is considered to be confirmed if the following criterion is met:

i) Positive result by real-time PCR or and ~~by~~ conventional PCR and sequencing ~~or by species-specific *in-situ* hybridisation~~

ii) Positive result by real-time PCR and *in-situ* hybridisation

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

6.3. Diagnostic sensitivity and specificity for diagnostic tests

The diagnostic performance of tests recommended for surveillance or diagnosis of infection with *B. ostreae* are provided in Tables 6.3.1. (no data are currently available) and 6.3.2. This information can be used for the design of surveys for infection with *B. ostreae*, however, it should be noted that diagnostic performance is specific to the circumstances of each diagnostic accuracy study (including the test purpose, source population, tissue sample types and host species) and diagnostic performance may vary under different conditions. Data are only presented where tests are validated to at least level 2 of the validation pathway described in Chapter 1.1.2. and the information is available within published diagnostic accuracy studies.

Data on analytical performances (stage 1 validation) are often missing for diagnostic tests described in this chapter: the limit of detection is rarely available, and the inclusivity of molecular assays is not fully evaluated (missing information on the detection of *Bonamia* spp. lineages/species other than *B. ostreae* and *B. exitiosa*).

Diagnostic sensitivity (DSe) and specificity (DSp) (stage 2 validation) are available for most diagnostic tests. However, these values depend on the studied mollusc population (host species, prevalence, intensity of infection, etc.), the protocol (tissue analysed, DNA extraction, use of cut-off value for PCR assays, etc.) and test purpose. Additionally, as no gold standard exists for the detection of *B. ostreae*, several approaches can be used for DSe and DSp estimation, such as the use of a combination of tests to establish reference results or latent class analysis (maximum likelihood or Bayesian method). If Bayesian latent class is used, the analysis can incorporate prior knowledge about the performance of compared diagnostic tests. The choice of the overall approach used will have an impact on DSe & DSp estimates. It is therefore complex to compare DSe/DSp estimates from different studies.

Few assays were evaluated for their reproducibility (stage 3 validation). Two real-time PCR (Canier *et al.,* 2020, and EURL, 2023) were evaluated in the context of interlaboratory comparison tests. Additionally, a study comparing conventional PCR, ISH, heart imprint and histology in three laboratories showed that conventional PCR produces the highest rate of positive *B. ostreae* detection but also had the lowest agreement amongst laboratories (Flannery *et al.,* 2014).

6.3.1. For presumptive diagnosis of clinically affected animals (no data are currently available)

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study, PCR: = polymerase chain reaction.

6.3.2. For surveillance of apparently healthy animals

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
Histology	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA, where *B. ostreae* is endemic). Low prevalence populations	Tissue section	*Ostrea edulis* (1–2.5 years)	56% (607)	100% (607)	Combination histology and real-time PCR (DSe: 56%, DSp: 100%)	Marty *et al.,* 2006
	Surveillance	Flat oysters produced in hatchery derived from five origins, deployed in the field, in a *B. ostreae* & *B. exitiosa* endemic area (Galicia, Spain). High prevalence populations	Tissue section	*Ostrea edulis* (2–3 years)	64% (137)	98% (137)	Real-time (DSe 99%, DSp 72%) and conventional PCR Maximum likelihood latent class analysis (TAGS)	Ramilo *et al.,* 2013
	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Tissue section	*Ostrea angasi*	76% (400)	93% (400)	Real-time PCR Corbeil *et al.,* 2006 (DSe: 69%, DSp: 93%) and Heart imprint (DSe 61%, DSp 60%) Bayesian latent class analysis	Buss *et al.,* 2019
Tissue imprints	Surveillance	Flat oysters from 3 farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Heart	*Ostrea angasi*	61% (400)	60% (400)	Histology (DSe: 76%, DSp: 93%) and real-time PCR Corbeil *et al.,* 2006 (DSe: 69%, DSp: 93%). Bayesian latent class analysis	Buss *et al.,* 2019
Conventional PCR *Bonamia* spp. (Cochennec *et al.,* 2020)	Surveillance	Eight batches of 30 flat oysters, Spain (tested by two laboratories) (total prevalence 10–30%)	NA	*Ostrea edulis*	93% (240)	85–90% (240)	Combination histology and gill imprints (DSe: 64-69%, DSp: 97.5%)	Balseiro *et al.,* 2006
	Surveillance	Flat oysters from the 3 main production sites in France representative of three different levels of *B.*	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	82.8% (349)	98.7% (349)	Real-time PCR (DSe 77.5%, DSp 98.4%). Bayesian latent class analysis	Canier *et al.,* 2020

Test type	Test purpose	Source populations	Tissue or sample types	Species	DSe (*n*)	DSp (*n*)	Reference test	Citation
		ostreae prevalence (very low, low, high)						
TaqMan® real-time PCR *Bonamia* spp.	Surveillance	Flat oysters from three farms in western Canada (spats sourced from Washington, USA, where *B. ostreae* is endemic). Low prevalence populations	Heart	*Ostrea edulis* (1-2.5 years)	88% (607)	99% (607)	Combination histology and real-time PCR. Histology (DSe: 56%, DSp: 100%)	Marty *et al.,* 2006
TaqMan® real-time PCR *Bonamia* spp. (Corbeil *et al.,* 2006)	Surveillance	Flat oysters from three farms in South Australia (high prevalence populations 60–90%, but low intensity of infection)	Mantle, gill, heart (DNA tested pure and 1/10 diluted)	*Ostrea angasi*	69% (400)	93% (400)	Histology (DSe: 76%, DSp: 93%) and heart smear (DSe: 61%, DSp: 60%). Bayesian latent class analysis	Buss *et al.,* 2019
TaqMan® real-time PCR *Bonamia* spp.	Surveillance	Flat oysters from the three main production sites in France representative of three different levels of *B. ostreae* prevalence (very low, low, high)	Gills and digestive gland tissues	*Ostrea edulis* (1–3 years)	77.5% (349)	98.4% (349)	Conventional PCR (DSe: 82.8%, DSp: 98.7%). Bayesian latent class analysis	Canier *et al.,* 2020
SYBR Green real-time PCR *B. ostreae*	Surveillance	Flat oysters produced in hatchery derived from five origins, deployed in the field, in a *B. ostreae* & *B. exitiosa* endemic area (Galicia, Spain). High prevalence populations	Gills tissues	*Ostrea edulis* (2–3 years)	99% (137)	72% (137)	Histology (DSe: 64%, DSp: 98%) and conventional PCR). Maximum likelihood latent class (TAGS)	Ramilo *et al.,* 2013

DSe = diagnostic sensitivity, DSp = diagnostic specificity, *n* = number of animals used in the validation study,
PCR: = polymerase chain reaction.
(TAGS programme, Pouillot *et al.,* 2002)

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* *

NB: There is a WOAH Reference Laboratory for infection with *Bonamia ostreae*
(please consult the WOAH web site:
https://www.woah.org/en/what-we-offer/expertise-network/reference-laboratories/#ui-id-3).
Please contact WOAH Reference Laboratories for any further information on infection with *Bonamia ostreae*

NB: FIRST ADOPTED IN 1995 AS BONAMIOSIS. MOST RECENT UPDATES ADOPTED IN 2021 (SECTIONS 2.2.1 AND 2.2.2).

Annex 26. – Sections 2.2.1. and 2.2.2. of Chapter 2.4.6. 'Infection with *P. olseni*'

CHAPTER 2.4.6.

INFECTION WITH *PERKINSUS OLSENI*

[…]

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Arcidae	*Anadara kagoshimensis*	half-crenated ark ~~cockle~~
	Anadara trapezia	no common name ~~ark cockle~~
Cardiidae	*Tridacna crocea*	crocus giant clam
Haliotidae	*Haliotis laevigata*	greenlip abalone
	Haliotis rubra	blacklip abalone
	Haliotis iris	black paua
Margaritidae	*Pinctada fucata*	Japanese pearl oyster
Mytilidae	*Mytilus galloprovincialis*	Mediterranean mussel
	Perna canaliculus	New Zealand mussel
Veneridae	*Austrovenus stutchburyi*	Stutchbury's venus ~~clam~~
	Leukoma jedoensis	Jedo venus ~~clam~~
	Paratapes undulatus	undulate venus ~~clam~~
	Protapes gallus	rooster venus ~~clam~~
	Proteopitar patagonicus	no common name
	Ruditapes decussatus	grooved carpet shell
	Ruditapes philippinarum	Japanese carpet shell ~~clam~~

~~*Perkinsus olseni* has an extremely wide host range. Known hosts include the clams *Anadara trapezia*, *Austrovenus stutchburyi*, *Ruditapes decussatus*, *R. philippinarum, Tridacna maxima, T. crocea, Protothaca jedoensis* and *Pitar rostrata* (Cremonte *et al.*, 2005; Goggin & Lester, 1995; Park *et al.*, 2006; Sheppard & Phillips, 2008; Villalba *et al.*, 2004;); oysters *Crassostrea gigas*, *C. ariakensis*, and *C. sikamea* (Villalba *et al.*, 2004); pearl oysters *Pinctada margaritifera, P. martensii*, and *P. fucata* (Goggin & Lester, 1995; Sanil *et al.*, 2010); abalone *Haliotis rubra, H. laevigata, H. scalaris,* and *H. cyclobates* (Goggin & Lester, 1995). Other bivalve and gastropod species might be susceptible to this parasite, especially in the known geographical range. Members of the families Arcidae, Malleidae, Isognomonidae, Chamidae and Veneridae are particularly susceptible, and their selective sampling may reveal the presence of *P. olseni* when only light infections occur in other families in the same habitat.~~

2.2.2. ~~Susceptible stages of the host~~ Species with incomplete evidence for susceptibility

~~All stages after settlement are susceptible.~~

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with *P. olseni* according to Chapter 1.5. of the *Aquatic Code* are:

Family	Scientific name	Common name
Cardiidae	*Cerastoderma edule*	common edible cockle
Mytilidae	*Mytilus chilensis*	Chilean mussel
Ostreidae	*Crassostrea gasar*	gasar cupped oyster
	Ostrea angasi	Australian mud oyster
Pectinidae	*Pecten novaezelandiae*	New Zealand scallop
Psammobiidae	*Hiatula acuta*	no common name
Veneridae	*Venerupis corrugata*	corrugated venus clam

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated:

Family	Scientific name	Common name
Cardiidae	*Cerastoderma glaucum*	olive green cockle
Chamidae	*Chama pacifica*	reflexed jewel box
Haliotidae	*Haliotis diversicolor*	small abalone
Isognomonidae	*Isognomon alatus*	flat tree oyster
	Isognomon sp.	N/A
Margaritidae	*Pinctada imbricata*	Atlantic pearl oyster
Ostreidae	*Crassostrea rhizophorae*	mangrove cupped oyster
	Dendostrea frons	Frons oyster
	Magallana [syn. *Crassostrea*] *gigas*	Pacific oyster
	Magallana [syn. *Crassostrea*] *hongkongensis*	no common name
	Saccostrea sp.	N/A
Pectinidae	*Mimachlamys crassicostata*	noble scallop
Pharidae	*Sinonovacula constricta*	constricted tagelus clam
Veneridae	*Meretrix lyrata*	lyrate hard clam
	Polititapes aureus	golden carpet shell
	Venus verrucosa	warty venus ~~clam~~

[…]

Annex 27. – Sections 2.2.1. and 2.2.2. of Chapter 2.4.7. 'Infection with *X. californiensis*'

CHAPTER 2.4.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

[…]

2.2. Host factors

2.2.1. Susceptible host species

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

Family	Scientific name	Common name
Haliotidae	*Haliotis corrugata*	pink abalone
	Haliotis cracherodii	black abalone
	Haliotis discus discus	Japanese abalone
	Haliotis diversicolor	small abalone
	Haliotis fulgens	green abalone
	Haliotis kamtschatkana	pinto abalone
	Haliotis rufescens	red abalone
	Haliotis rufescens X *Haliotis discus hannai* hybrid	hybrid red and Japanese abalone
	Haliotis sorenseni	white abalone
	Haliotis tuberculata	tuberculate abalone

~~*Xenohaliotis californiensis* infects members of the genus *Haliotis* and natural infections have been observed in black abalones (*H. cracherodii*), white abalones (*H. sorenseni*), red abalones (*H. rufescens*), pink abalones (*H. corrugata*), green abalones (*H. fulgens*), the small abalone (*H. diversicolor supertexta;* (Wetchateng, 2008; Wetchateng *et al*., 2010), the European abalone (*H. tuberculata*) (Balseiro *et al*., 2006) in the wild or culture facilities, as well as flat (*H. wallalensis*) and Japanese abalones (*H. discus hannai*) in laboratory challenges (Friedman, unpublished observations). Other abalone species have not been tested. Temperature is important in both pathogen transmission and disease expression (Braid *et al*., 2005; Friedman *et al*., 1997; Raimondi *et al*., 2002; Rosenblum *et al*., 2008).~~

2.2.2. ~~Susceptible stages of the host~~ Species with incomplete evidence for susceptibility

Species for which there is incomplete evidence to fulfil the criteria for listing as susceptible to infection with *X. californiensis* according to Chapter 1.5. of the *Aquatic Code* are: *Haliotis gigantea*

In addition, pathogen-specific positive polymerase chain reaction (PCR) results have been reported in the following species, but no active infection has been demonstrated: *Haliotis discus hannai*

~~While all post-larval life stages have been demonstrated susceptible to infection with *X. californiensis*, clinical disease is typically observed in animals >1 years of age in farmed abalones (Friedman, unpublished observations) and all abalone size classes observed in wild populations surveyed to date (e.g. Balseiro *et al*., 2006; Braid *et al*., 2005; Friedman *et al*., 1997; Haaker *et al*., 1992; Steinbeck *et al*., 1992; Van Blaricom *et al*., 1993).~~

[…]

Annex 30. – Deletion of Chapter 4.6. 'Contingency Planning'

~~CHAPTER 4.6.~~

~~CONTINGENCY PLANNING~~

~~Article 4.6.1.~~

~~A number of *diseases* are regarded as posing a potential threat to *aquaculture* as well as to wild stocks of *aquatic animals* world-wide. The introduction of such *diseases* into countries recognised to be free from these *diseases* or into countries with an established control system and eradication programme for such *diseases*, may result in significant losses. In order to diminish such losses, the *Competent Authority* responsible for *aquatic animal* health may need to act quickly and should develop a *contingency plan(s)* before such events occur.~~

~~Article 4.6.2.~~

~~**Legal powers**~~

~~Countries must establish the necessary legal provisions that are needed for the implementation of a *contingency plan(s)*. Such legal powers must include provisions for establishing a list of *diseases* for which action is needed, definitions of how such *diseases* should be managed if detected, provisions for access to infected/suspected sites, and other legal provisions, as needed.~~

~~Article 4.6.3.~~

~~**Crises centre(s)**~~

~~Countries must establish specified crises centre(s) (*disease* control centre[s]) that shall have the responsibility for the co-ordination of all control measures to be carried out. Such centres could either be located centrally or locally, depending on the infrastructure in a given country. A list of the crises centre(s) that has(have) the necessary facilities to carry out *disease* control measures should be made widely available.~~

~~The *contingency plan(s)* should also state that the crises centre(s) has(have) the authority to act rapidly to bring a given *disease* situation under control by contacting the personnel, organisations, *aquaculture establishments*, etc., that are involved directly or indirectly in managing an *outbreak* of a *disease*.~~

~~Article 4.6.4.~~

~~**Personnel**~~

~~The *contingency plan(s)* should provide information on the staff required to undertake the control measures, their responsibilities, and instructions on the chain of command.~~

~~Article 4.6.5.~~

~~**Instructions**~~

~~Countries establishing a *contingency plan(s)* should provide a detailed set of instructions on actions to be taken when a specified *aquatic animal disease* is suspected or confirmed. These could include:~~

~~1) diagnostic procedures in national reference laboratories;~~

~~2) confirmation of *diagnosis*, if necessary, at a WOAH Reference Laboratory;~~

~~3) standing instructions to *aquatic animal* health personnel in the field;~~

4) instructions for handling/disposal of dead *aquatic animals* at an *aquaculture establishment*;

5) instructions for sanitary slaughtering;

6) instructions for *disease* control at the local level;

7) instructions for the establishment of *quarantine* areas and observation (*surveillance*) zones;

8) provisions for controlling movements of *aquatic animals* in established zones;

9) *disinfection* procedures;

10) *fallowing* procedures;

11) *surveillance* methods for establishing successful eradication;

12) re-stocking procedures;

13) compensation issues;

14) reporting procedures;

15) provisions for raising public awareness of *aquatic animal disease*.

Article 4.6.6.

Diagnostic laboratories

Countries establishing a *contingency plan(s)* should establish national reference laboratories having the necessary facilities for diagnostic work on *aquatic animal diseases* that can be carried out rapidly. The national laboratory(ies) must also have established a set of instructions as regards rapid transportation of samples, and established protocols for quality assurance and diagnostic procedures to be used.

Article 4.6.7.

Training programmes

Countries establishing a *contingency plan(s)* must establish necessary training programmes to ensure that skills in field, administrative and diagnostic procedures are maintained. Announced and unannounced field exercises for administrators and *aquatic animal* personnel should be carried out to maintain the state of readiness.

Annex 31. – Deletion of Chapter 10.8. 'Infection with red sea bream iridovirus'

~~CHAPTER 10.8.~~

~~INFECTION WITH RED SEA BREAM IRIDOVIRUS~~

~~Article 10.8.1.~~

~~For the purposes of the *Aquatic Code*, infection with red sea bream iridovirus means *infection* with the *pathogenic agent* red sea bream iridovirus (RSIV) of the Genus *Megalocytivirus* and Family *Iridoviridae*.~~

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

~~Article 10.8.2.~~

~~**Scope**~~

~~The recommendations in this chapter apply to: red sea bream *(Pagrus major)*, yellowtail *(Seriola quinqueradiata)*, amberjack *(Seriola dumerili)*, sea bass (*Lateolabrax* sp. and *Lates calcarifer*), Albacore *(Thunnus thynnus)*, Japanese parrotfish *(Oplegnathus fasciatus)*, striped jack *(Caranx delicatissimus)*, mandarin fish *(Siniperca chuatsi)*, red drum *(Sciaenops ocellatus)*, mullet *(Mugil cephalus)* and groupers (*Epinephelus* spp.). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.~~

~~Article 10.8.3.~~

~~**Measures for the importation or transit of aquatic animal products for any purpose regardless of the infection with RSIV status of the exporting country, zone or compartment**~~

~~The *aquatic animal products* listed below have been assessed as meeting the criteria for safety of *aquatic animal products* in accordance with Article 5.4.1. When authorising the importation or transit of these *aquatic animal products*, *Competent Authorities* should not require any *sanitary measures* related to RSIV, regardless of the infection with RSIV status of the *exporting country*, *zone* or *compartment*:~~

~~1) *aquatic animal products* that have been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates RSIV;~~

~~2) fish *meal* that has been subjected to a heat treatment sufficient to attain a core temperature of at least 56°C for at least 30 minutes, or a time/temperature equivalent that inactivates RSIV;~~

~~3) fish oil;~~

~~4) fish skin leather.~~

~~Article 10.8.4~~

~~**Requirements for self-declaration of freedom from infection with RSIV**~~

~~A Member Country may make a self-declaration of freedom from infection with RSIV for the entire country, a *zone* or a *compartment* in accordance with the provisions of Articles 10.8.5. to 10.8.8., as relevant. The self-declaration of freedom must be made in accordance with other relevant requirements of the *Aquatic Code* including that the Member Country meet the following conditions:~~

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

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

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

Article 10.8.5.

Country free from infection with RSIV

If a country shares water bodies with other countries, it can only make a self-declaration of freedom from infection with RSIV if all shared water bodies are within countries or *zones* declared free from infection with RSIV (see Article 10.8.6.).

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

1) none of the *susceptible species* referred to in Article 10.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with RSIV 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 RSIV, as described in the corresponding chapter of the *Aquatic Manual*; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of RSIV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

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

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

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

In the meantime, the part of the country outside the *infected zone* and *protection zone* may be declared a *free*

zone as described in Article 1.4.4.

Article 10.8.6.

Zone free from infection with RSIV

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

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

1) none of the *susceptible species* referred to in Article 10.8.2. are present and *basic biosecurity conditions* have been continuously met for at least the last [six] months;

OR

2) there has been no occurrence of infection with RSIV 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 RSIV, as described in Article 1.4.8. of Chapter 1.4.; and

   b) *basic biosecurity conditions* as described in Chapter 1.4. have been continuously met for the *zone* for at least the last [ten] years;

OR

3) *targeted surveillance*, as described in Chapter 1.4., has been in place in the *zone* for at least the last [two] years without detection of RSIV, and *basic biosecurity conditions* have been continuously met and have been in place for at least [one] year prior to commencement of *targeted surveillance*;

OR

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

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

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

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

   d) *targeted surveillance*, as described in Chapter 1.4., has been in place for at least the last [two] years without detection of RSIV.

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

Article 10.8.7.

Compartment free from infection with RSIV

As described in Article 1.4.4., a Member Country may make a self-declaration of freedom from infection with RSIV

for a *compartment* within its *territory* if it can demonstrate that:

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

OR

2) it previously made a self-declaration of freedom for a *compartment* from infection with RSIV and subsequently lost its free status due to the detection of RSIV 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 RSIV, the appropriate *disinfection* procedures (as described in Chapter 4.4.) have been completed, and the *compartment* has been fallowed as described in Chapter 4.7.; and

   b) previously existing *basic biosecurity conditions*, including the *compartment biosecurity plan*, have been reviewed and modified as necessary and have continuously been in place from the time of restocking with *aquatic animals* from an approved pathogen free source in accordance with the requirements of Articles 10.8.9. and 10.8.10. as appropriate; and

   c) one survey for infection with RSIV has been completed at least [six months] after restocking (as described in Article 1.4.14.) without detection of the pathogen

Article 10.8.8.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from infection with RSIV following the provisions of Articles 10.8.4. to 10.8.7. (as relevant) may maintain its status as free from infection with RSIV provided that the requirements described in Article 1.4.15. are continuously maintained.

Article 10.8.9.

Importation of aquatic animals or aquatic animal products from a country, zone or compartment declared free from infection with RSIV

When importing *aquatic animals* of a species referred to in Article 10.8.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* declared free from infection with RSIV, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country*. The *international aquatic animal health certificate* should state that, on the basis of the procedures described in Articles 10.8.5., 10.8.6. or 10.8.7. (as applicable) and 10.8.8., the place of production of the *aquatic animals* or *aquatic animal products* is a country, *zone* or *compartment* declared free from infection with RSIV.

The *international aquatic animal health certificate* should be in accordance with the Model Certificate in Chapter 5.11.

This article does not apply to *aquatic animal products* listed in Article 10.8.3.

Article 10.8.10.

Importation of aquatic animals for aquaculture from a country, zone or compartment not declared free from infection with RSIV

When importing, for *aquaculture*, *aquatic animals* of a species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country*

should assess the *risk* in accordance with Chapter 2.1. and consider the *risk* mitigation measures in points 1 and 2 below.

1) If the intention is to grow out and harvest the imported *aquatic animals*, consider applying the following:

   a) the direct delivery to and lifelong holding of the imported *aquatic animals* in a *quarantine* facility; and

   b) before leaving *quarantine* (either in the original facility or following biosecure transport to another *quarantine* facility) the *aquatic animals* are killed and processed into one or more of the *aquatic animal products* referred to in Article 10.8.3. or other products authorised by the *Competent Authority*; and

   c) the treatment of all transport water, equipment, effluent and waste materials to inactivate RSIV in accordance with Chapters 4.4., 4.8. and 5.5.

OR

2) If the intention is to establish a new stock for *aquaculture*, consider applying the following:

   a) In the *exporting country*:

      i) identify potential source populations and evaluate their *aquatic animal* health records;

      ii) test source populations in accordance with Chapter 1.4. and select a founder population (F-0) of *aquatic animals* with a high health status for infection with RSIV.

   b) In the *importing country*:

      i) import the F-0 population into a *quarantine* facility;

      ii) test the F-0 population for RSIV in accordance with Chapter 1.4. to determine their suitability as broodstock;

      iii) produce a first generation (F-1) population in *quarantine*;

      iv) culture the F-1 population in *quarantine* for a duration sufficient for, and under conditions that are conducive to, the clinical expression of infection with RSIV, and sample and test for RSIV in accordance with Chapter 1.4. of the *Aquatic Code* and Chapter 2.3.8. of the *Aquatic Manual*;

      v) if RSIV is not detected in the F-1 population, it may be defined as free from infection with RSIV and may be released from *quarantine*;

      vi) if RSIV is detected in the F-1 population, those animals should not be released from *quarantine* and should be killed and disposed of in a biosecure manner in accordance with Chapter 4.8.

Article 10.8.11.

Importation of aquatic animals or aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from infection with RSIV

When importing, for processing for human consumption, *aquatic animals* of a species referred to in Article 10.8.2., or *aquatic animal products* derived thereof, from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processing into one of the products referred to in Article 10.8.3. or in point 1 of Article 10.8.14., or other products authorised

by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4.and 4.8.

For these *aquatic animals* or *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal* or *aquatic animal product* being used for any purpose other than for human consumption.

Article 10.8.12.

Importation of aquatic animals or aquatic animal products intended for uses other than human consumption, including animal feed and agricultural, industrial, research or pharmaceutical use, from a country, zone or compartment not declared free from infection with RSIV

When importing *aquatic animals* of a species referred to in Article 10.8.2., or *aquatic animal products* derived thereof, intended for uses other than human consumption, including animal *feed* and agricultural, industrial, research or pharmaceutical use, from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should require that:

1) the consignment is delivered directly to, and held in, *quarantine* or containment facilities until processed into one of the products referred to in Article 10.8.3. or other products authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.

Article 10.8.13.

Importation of aquatic animals intended for use in laboratories or zoos from a country, zone or compartment not declared free from infection with RSIV

When importing, for use in laboratories or zoos, *aquatic animals* of a species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should ensure:

1) the consignment is delivered directly to, and held in, *quarantine* facilities authorised by the *Competent Authority*; and

2) all water (including ice), equipment, *containers* and packaging material used in transport are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4., 4.8. and 5.5.; and

3) all effluent and waste materials from the *quarantine* facilities in the laboratories or zoos are treated to ensure inactivation of RSIV or disposed of in a biosecure manner in accordance with Chapters 4.4. and 4.8.; and

4) the carcasses are disposed of in accordance with Chapter 4.8.

~~Article 10.8.14.~~

~~Importation or transit of aquatic animal products for retail trade for human consumption regardless of the infection with RSIV status of the exporting country, zone or compartment~~

1) ~~*Competent Authorities* should not require any conditions related to RSIV regardless of the infection with RSIV status of the *exporting country*, *zone* or *compartment*, when authorising the importation or transit of the following *aquatic animal products* that have been prepared and packaged for retail trade and comply with Article 5.4.2.:~~

   a) ~~fish fillets or steaks (chilled).~~

   ~~Certain assumptions have been made in assessing the safety of the *aquatic animal products* mentioned above. Member Countries should refer to these assumptions at Article 5.4.2. and consider whether the assumptions apply to their conditions.~~

   ~~For these *aquatic animal products* Member Countries may wish to consider introducing internal measures to address the *risks* associated with the *aquatic animal product* being used for any purpose other than for human consumption.~~

2) ~~When importing *aquatic animal products*, other than those referred to in point 1 above, derived from a species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from infection with RSIV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.~~