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**REPORT OF THE MEETING
OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 5–9 January 2004**

The OIE Aquatic Animal Health Standards Commission (in brief, Aquatic Animals Commission) met at the OIE headquarters from 5 to 9 January 2004. The meeting was chaired by Dr Eva-Maria Bernoth, President of the Commission, and Dr Ricardo Enriquez, Secretary General, acted as Rapporteur. The Commission was welcomed by Dr Bernard Vallat, Director General of the OIE, who pointed out the need to reinforce harmonisation between approaches in the *Terrestrial Animal Health Code (Terrestrial Code)* and the *Aquatic Animal Health Code (Aquatic Code)*. He mentioned two main topics in this context: the revision of the disease listing and notification criteria, and the reduction of adverse effects on trade of commodities without increasing risk. He also mentioned the success of the report on the Technical Item on aquatic animal health issues given by Dr Bernoth at the Conference of the Regional Commission for Asia, the Far East and Oceania in Nouméa, New Caladonia, in November 2003, and that he would support similar presentations on aquatic animal health by Members of the Aquatic Animals Commission at Conferences of the other Regional Commissions.

The Agenda and List of Participants are given at Appendices I and II, respectively.

1. Member Country comments on the report of the previous meeting (October 2003)

The Commission considered the Member Country comments in detail. Most comments relate to the appendices and responses are given below. Some general comments were also received.

Australia made a general comment that the Commission should consider developing a strategy for countries to establish and justify freedom of, and protection from, diseases not listed in the *Aquatic Code*. The Commission discussed this proposal and noted that there are general principles outlined in Part 1 and Part 5 of the *Aquatic Code* and Chapter 1.1.4. in the *Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual)* that Member Countries should follow for all diseases.

The United States of America (USA) proposed that the term ‘basic disease security conditions’ be replaced by ‘basic biosecurity requirements’. The Commission accepted to replace ‘disease security’ with ‘biosecurity’ but decided to retain the term ‘conditions’ because it better reflects the intent of the definition. The Commission acknowledges that the meaning of biosecurity is evolving and will keep the matter under review.

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Australia queried whether the occurrence of polymerase chain reaction (PCR) signals in the absence of any other signs of infection is sufficient to meet the definition of *infection* and consequently of *disease*. The Commission agreed that this matter is of some concern. In the Commission's view, a PCR signal alone does not provide confirmation of the presence of viable and transmissible agents. For the purpose of declaration of freedom from infection, the new template for chapters in the *Aquatic Manual* will clarify the use of PCR in the context of presumptive and confirmatory diagnosis (see item 3.1.2.).

Comments from the European Union (EU) on the definition of crustaceans led to a review and revision of several definitions (see [Appendix III](#), on which Member Countries are invited to send comments by **23 April 2004**).

The EU commented on Article 1.5.2.2. (Appendix VI), regarding the movement of aquatic animals or eggs or gametes from an infected aquaculture establishment or zone. The Commission agreed that a commodity-based approach to the risk of movement would clarify this issue (see item 2.4 below).

The EU also queried the justification for the deletion of point 3 of Article 1.5.5.1 (Appendix VII). The Commission's reason for removal of this point is that the *Aquatic Code* makes reference only to the aquatic animal health situation in the exporting country (see Guide to the use of the *Aquatic Animal Health Code*, Section A. Introduction, item 3).

Comments were received from the USA on the reverse-transcription PCR diagnostic test for spring viraemia of carp (SVC). Due to the highly technical nature of the comments, the Commission referred the item to the OIE Reference Laboratory for SVC. A revised description of the test is presented at [Appendix XI](#), on which Member Countries are invited to send comments by **23 April 2004**).

Australia had pointed out a lack of clarity on the timing and frequency of testing for targeted surveillance. The Commission agreed that disease-specific testing and surveillance requirements for declaration of freedom will be developed for the next edition of the *Aquatic Manual*.

2. Planning the seventh edition of the *Aquatic Animal Health Code*

2.1. Revision of the relative contents of the *Aquatic Code* and *Aquatic Manual*

It was brought to the Commission's attention that the contents and nature of information in the *Aquatic Code* and *Aquatic Manual* are not always consistent with those for the terrestrial standards. To date, the Aquatic Animals Commission's approach has been to include principles of aquatic animal health management in the *Aquatic Code* while technical procedures, such as diagnostic methods and details on surveillance, disinfection etc., were included in the *Aquatic Manual*. How to better harmonise the relative contents of the aquatic and terrestrial documents will be discussed at a joint meeting between the two Commissions in January 2005.

2.2. Revision of the disease listing and notification criteria

The Commission received comments from a few Member Countries on the disease listing and notification criteria. The Commission considered these suggestions and made amendments to the criteria (see [Appendix IV](#), on which Member Countries are invited to send comments by **23 April 2004**). The amended set of criteria will be submitted for adoption by the International Committee at the General Session in May 2004.

The EU proposed that in criterion 1 'significant' should be changed to '5% of the value of production in that area'. The Commission did not accept this suggestion because for some industries, e.g. pearl oyster or tuna farming, 5% of the value of production would be too great a loss, while in others, e.g. shrimp farming, greater than 5% production loss is common. The Commission considers that any figure would be arbitrary and not reflect the specifics of the host species, culture system and the disease in question. However, the Commission agreed some amendments to the wording to refine the criterion (see [Appendix IV](#)).

The EU also proposed to qualify criterion 6 to add the requirement that ‘the disease is difficult to contain at a farm level without exceptional control measures’. The Commission did not feel that this comment was relevant to criterion 6, which relates to international spread of a disease.

Prof. Hill, Vice-President of the Aquatic Animals Commission, will meet with the Ad hoc Group on Animal Disease Notification convened by the OIE Animal Health Information Department to facilitate consistency between the approaches taken by the OIE Terrestrial Animal Health Standards Commission (Code Commission) and the Aquatic Animals Commission. New Zealand had suggested that the aquatic animal disease listing and notification criteria should more clearly stem from the OIE risk analysis guidelines. This issue will be brought to the attention of the Ad hoc Group.

2.3. Revision of the list of diseases; review of names of crustacean diseases

The EU and Australia questioned the inconsistency in the naming of diseases of molluscs, crustaceans and fish, respectively. They proposed to have a uniform approach to the naming the different diseases. The Commission reminds Member Countries that recent changes to the names of mollusc diseases resulted from a revision of the taxonomy of the causative agents. Therefore, the mollusc diseases were renamed ‘Infection with PATHOGEN NAME’ for clarity and to reflect the most recent taxonomic position. These changes have been incorporated into the sixth edition of the *Aquatic Code*, and will be adopted in the fifth edition of the *Aquatic Manual*. Regarding the naming of fish and crustacean diseases, the Commission is not aware of such major taxonomic changes. Moreover there does not appear to be confusion with regard to most of the currently used disease names. Where exceptions exist, these will be addressed on a case by case basis (see below for epizootic haematopoietic necrosis [EHN] as an example).

The Commission received comments from several Member Countries on the revised list of diseases. Some concern was expressed at the lack of transparency in the reasoning behind the Commission’s judgement on which criteria were met by the individual diseases. Other Member Countries had provided, as requested, supporting evidence to justify retaining certain diseases on the list that the Commission had initially proposed to remove. The Commission agreed it would improve transparency in the process by providing documented, scientific justification for any changes to the list.

These documents will be prepared by the Commission with the assistance of an Ad hoc Group following the format developed for this purpose for terrestrial animal diseases. These documents will be prepared on the basis of the amended set of listing and notification criteria pending their adoption at the General Session in 2004 (see item 2.2).

The Reference Laboratory for epizootic haematopoietic necrosis (EHN) pointed out that an error had occurred in the October 2003 report regarding the causative agents of EHN. The correct advice by the Reference Laboratory is that European sheatfish virus (ESV) and European catfish virus (ECV) cannot be separated at this point in time, and that a split of the EHN chapter should be into EHN and ESV/ECV. Furthermore, the Reference Laboratory advised that the recognition of ESV/ECV and EHN as two distinct species has now been accepted by the International Committee for Taxonomy of Viruses. The Commission noted this and will henceforth refer to ESV/ECV and EHN as different disease agents.

2.4. New finfish, mollusc and crustacean disease chapters, based on new drafts

Comments from Member Countries on the draft disease chapters were considered.

The USA queried the choice of 25 years, 10 years and 2 years for obtaining disease-free status as arbitrary time periods and suggested that measures, such as generation lengths or other scientifically validated periods of time be used instead. The Commission is aware that these figures are arbitrary, but notes that they were chosen as an interim measure consistent with the *Terrestrial Code* until aquatic animal disease-specific periods of time can be defined (see below). The Commission draws Member Countries attention to *Aquatic Manual* Chapter 1.1.4 Requirements for surveillance for international recognition of freedom from infection.

Several Member Countries (Chile, EU, Norway, USA) objected to the proposed removal of disease free aquaculture establishments as a distinct category. The intent of that proposal had been to include disease free aquaculture establishments in the concept and requirements of disease free zones. Accepting the utility of the specific identification of an aquaculture establishment as a management unit for certain diseases, the Commission discussed this concern with the President of the Code Commission. In the *Terrestrial Code*, some disease chapters currently make reference to herds, flocks or farms, where appropriate for the disease. For the future, the Code Commission is proposing to refine the concept of compartments, which would cover a variety of establishments under a common bio security management system. Compartmentalisation applies to a population when management criteria are applied, while zoning applies when a population is defined on a geographical basis. A compartment may comprise one or more aquaculture establishments. The Code Commission will develop separate requirements for each disease for which the application of zoning or compartmentalisation is appropriate. The Aquatic Animals Commission concluded that this approach could be usefully applied to the aquatic animal sector and resolve concerns by those Member Countries that wished to see aquaculture establishments reincorporated. A modified definition for compartment for inclusion in the *Aquatic Code* is proposed (see [Appendix III](#), on which Member Countries are invited to send comments by **23 April 2004**).

The President of the Code Commission reiterated the comment made by the Director General, i.e. to introduce into the disease chapters of the *Aquatic* and *Terrestrial Codes* the concept of identifying those commodities that can be traded safely – regardless of animal health status in the exporting country – and grading levels of risk for other commodities. This would bring more balance to the chapters by moving the focus from achieving free status to facilitating the trade in safe commodities. It also reflects the wide variety of traded commodities. Previously, the Commission had explored the concept of susceptible, carrier and vector species in order to address the different levels of risks in trade in aquatic animals. The Commission is of the view that following the commodity-based approach would adequately address these different risk levels.

The Commission has introduced the concepts of compartment and commodities into the new draft templates for chapters for fish, molluscs and crustaceans (see [Appendices V to VII](#), on which Member Countries are invited to send comments by **23 April 2004**; **NB**: these draft chapters are to demonstrate the newly introduced concepts of compartmentalisation and commodities. Member Countries should focus their comments on the applicability of these concepts. If the final templates (i.e. including amendments made on the basis of Member Country comments) are adopted by the International Committee in May 2004, the Commission will convene Ad hoc Groups of experts to elaborate the individual disease chapters. For purposes of clarity, marked drafts as well as consolidated versions of these three documents are provided). In addition, the adoption of this concept would address some of the points made by some Member Countries regarding susceptible, carrier and vector species.

Introducing the concepts of compartmentalisation and commodities required modification of several definitions (see [Appendix III](#)).

2.5. New model aquatic animal health certificates

Australia had commented that aquatic animal health certificates based on the model certificates in the *Aquatic Code* could be forged. The Commission acknowledges that forgery of health certificates is a growing problem and will bring this issue to the attention of the Ad hoc Group for model health certificates (see item 4.4.).

Chile suggested certain changes regarding model aquatic animal health certificates for dead fish. The Commission agreed that a commodity-based approach to the risk of movement would clarify this issue (see item 2.4 above).

The Commission noted the comments received from the EU and Norway and will refer them to the Ad hoc Group (see item 4.4.).

The Commission would like to draw attention to the fact that new model aquatic animal health certificates will only be required once new disease chapters for the *Aquatic Code* have been adopted by the International Committee at the General Session. As explained in item 2.4 above, at the General Session in 2004, the International Committee will be asked to adopt only the template for new disease chapters (one example each for fish, mollusc and crustacean diseases). This means that the seventh edition (2004) of the *Aquatic Code* will not contain new disease chapters. The Commission will resume work on the model certificates after May 2004 in parallel with the new disease chapters in preparation for the eighth edition (2005) of the *Aquatic Code* taking into consideration the conclusions of the Ad hoc Group (see item 4.4.). **The changes proposed in Appendix XIII of the October 2003 report are therefore withdrawn.** Some of the changes previously proposed in the June 2003 report, on the other hand, will be submitted for adoption by the International Committee at this year's General Session, because these changes will bring the model health certificates into line with the wording of the disease chapters in the current sixth (2003) edition and the pending seventh (2004) edition of the *Aquatic Code*. These proposed amendments are presented at Appendix VIII, on which Member Countries are invited to send comments by **23 April 2004**.

2.6. New Appendix on General recommendations on disinfection

The Commission completed the new draft Appendix 5.2.1. General recommendations on disinfection of the *Aquatic Code*. This document is appended to this report at Appendix IX, on which Member Countries are invited to send comments by **23 April 2004**. The Commission also suggested to move the current Appendix 5.2.1. Disinfection of fish eggs to the *Aquatic Manual* by incorporating it into Chapter 1.1.5., which will then be titled 'Methods for inactivation of pathogens'. For consistency, the title of Section 5.2. in the *Aquatic Code* will be changed from 'Destruction of pathogens' to 'Inactivation of pathogens'.

2.7. Revision of chapter on measures concerning international transport of aquatic animal disease agents and pathological material

Although the revised chapter had been prepared, the Commission was advised of ongoing deliberations for revision of the International Air Transport Association regulations and therefore decided to postpone proposal of the amended chapter for comment.

3. Planning the fifth edition of the *Manual of Diagnostic Tests for Aquatic Animals*

3.1. Revision of the relative contents of the *Aquatic Code* and *Aquatic Manual*

See item 2.1 above

3.2. New template for disease chapters (to provide information underpinning the *Aquatic Code* chapters, summary tables on diagnostic methods, and disease-specific requirements for sampling and surveillance)

In the past, some Member Countries had expressed concern that for certain diseases, the *Aquatic Manual* focuses on pathogen identification for disease diagnosis, whilst for others, the whole range of diagnostic approaches (including clinical, pathological, histopathological and pathogen identification techniques) is presented. They had also suggested that summary tables of diagnostic methods (such as currently provided for some diseases) should be a standard item in each disease chapter. With the adoption of the new *Aquatic Manual* Chapter 1.1.4 (Requirements for surveillance for international recognition of freedom from infection) by the International Committee in May 2003, there is now also the need to provide disease-specific information to underpin sampling and surveillance schemes and consequently the provisions for declaration of freedom from listed diseases. The Commission therefore prepared a new draft template for disease chapters for the *Aquatic Manual* (see Appendix X, on which Member Countries are invited to send comments by **23 April 2004**).

3.3. Revision of *Aquatic Manual* chapter on disinfection

See item 2.6.

4. Joint meeting with the Central Bureau/Terrestrial Animal Health Standards Commission

The Aquatic Animals Commission was joined by Dr David Wilson, Head of the International Trade Department, Dr Alejandro Thiermann, President of the OIE Terrestrial Animal Health Standards Commission, and Dr Karim Ben Jebara, Head, Animal Health Information Department.

4.1. Update on implementation of new disease list (target date January 2005)

Dr Ben Jebara informed the Commission that the Ad hoc Group on Animal Disease Notification has drafted new criteria for listing a terrestrial animal disease in the *Terrestrial Code*, taking into consideration the criteria for aquatic animal diseases already adopted by the International Committee in May 2003. The Aquatic Animals Commission agreed to be represented at the next meeting of this Group, scheduled for February 2004, to facilitate further harmonisation between aquatic and terrestrial listing and notification criteria. The new criteria for listing a terrestrial animal disease are to be presented to the International Committee in May 2004. Following adoption, both Commissions will advance in applying the new criteria to the currently listed aquatic and terrestrial animal diseases.

4.2. OIE Working Group on Animal Welfare

Dr Wilson informed the Commission that the Global Conference on Animal Welfare, to be held in February 2004, is expected to attract 450 participants. Professor Tore Håstein, Member of the OIE Working Group on Animal Welfare, will present an overview of aquatic animal welfare.

4.3. Development of guiding principles for the listing of closely related disease agents

Dr Wilson informed the Commission that this issue is not currently a problem for terrestrial agents, but it will be addressed when the Code Commission revises chapters on the basis of disease or pathogen.

4.4. Continuing work on harmonisation of horizontal chapters in both *Aquatic* and *Terrestrial Codes*

The Commission compared the general chapters and appendices, including the model certificates, of both *Codes* and identified those items suitable for harmonisation. These will be some of the topics for a joint meeting between the two Commissions in January 2005. An Ad hoc Group will be formed to review the model health certificates.

5. OIE Aquatic animal disease information system

5.1. Disease reporting

For this agenda item, the Aquatic Animals Commission was joined again by Dr Karim Ben Jebara, Head, Animal Health Information Department.

Dr Ben Jebara informed the Commission about the plans to improve disease reporting to the OIE. This includes the development of new standardised forms for electronic disease reporting. The Commission welcomed the initiative and would provide comments on the draft new accompanying *Manual for Aquatic Animal Disease Reporting to the OIE*. The purpose of this *Manual* is to assist Member Countries in accurate and timely disease reporting.

The Commission fully supports the Department of Animal Health Information's initiative to harmonise regionally produced disease information with that collated by the Central Bureau in order to make better use of the information sent by the Member Countries.

6. The role and activities of the OIE in the field of aquatic animals

6.1. Presentations at international meetings and workshops

6.1.1. Asia Regional Advisory Group for Aquatic Animal Health, Bangkok, Thailand, 10–12 November 2003

Dr Bernoth represented the Aquatic Animals Commission at the above-named meeting and presented her report. The Commission agreed that these meetings are very successful for exchange of information on aquatic animal disease occurrences and streamlining of approaches to aquatic animal health. It remains important for OIE to engage in aquatic animal health in the region and to continue to have formal and effective links with organisations such as NACA¹.

6.1.2. International Symposium on Veterinary Epidemiology and Economics (ISVEE 10, Viña del Mar, Chile, 17–21 November 2003)

Dr Enriquez represented the Aquatic Animals Commission at this symposium and presented his mission report. The Commission appreciated the initiative of the ISVEE Organising Committee to attach more importance to aquatic animal disease epidemiology. ISVEE proposes expanding the aquatic component at the 11th Symposium, to be held in Cairns, Australia, 2006, through a 3-day satellite meeting.

6.1.3. 23rd Conference of the OIE Regional Commission for Asia, the Far East and Oceania, Noumea, New Caledonia, 25–28 November 2003

Dr Bernoth attended the OIE Regional Conference as a speaker on a Technical Item. The Conference endorsed a set of recommendations that include action items for OIE as well as for Member Countries, and that are aimed at improving cooperation between veterinary and fisheries authorities, better engagement of Member Countries with the OIE, and improved disease reporting. Notably, the recommendations suggest the nomination by Delegates of an 'aquatic national focal point' as a parallel recipient of Aquatic Animals Commission reports, with the aim to significantly improve dissemination of these reports to relevant experts within Member Countries. This, in turn, will hopefully improve engagement of Member Countries with the OIE regarding draft texts for the *Aquatic Code* and *Aquatic Manual*. Another recommendation suggests the Director General remind Delegates of their responsibility for aquatic animal disease reporting to the OIE. Furthermore, some discrete steps are recommended to heighten awareness of aquatic animal health issues within Member Countries.

6.2. Future international meetings and workshops

6.2.1. Future Conferences of the OIE Regional Commissions

Following the success of the President's participation at the Regional Conference for Asia, the Far East and Oceania (see item 6.1.3) and the Director General's view that the Commission's participation at other Regional Commission Conferences would be useful for raising awareness of aquatic animal health issues and improving disease reporting, the Commission reviewed the OIE Regional Commissions' Conference schedule. The Commission proposes that Prof. Donald Lightner attend the 17th Conference of the OIE Regional Commission for the Americas, to be held in Panama 16–19 March 2004, to give a presentation on the activities of the Aquatic Animals Commission and the importance of aquatic animal production in the region. The Commission further proposes that Prof. Hill attend the 21st Conference of the OIE Regional Commission for Europe, to be held in Avila, Spain, 28 September – 1 October 2004, to give similar presentations.

1 NACA: Network of Aquaculture Centers in Asia-Pacific

For the 16th Conference of the OIE Regional Commission for Africa, to be held in Khartoum, Sudan, in January 2005, the Aquatic Animals Commission has proposed to the Director General that there should be a Technical Item on aquatic animal health similar to that presented in New Caledonia (see item 6.1.3). This Item would be presented by Prof. Eli Katunguka-Rwakishaya.

6.2.2. Aquaculture Biosecurity: Approaches to the Prevention, Control, and Eradication of Aquatic Animal Disease (Special Session of World Aquaculture Society Triennial Conference, 'Aquaculture 2004'), Hawaii, 1–5 March 2004

The President of the Commission will represent the Aquatic Animals Commission at this Conference. Profs Hill and Lightner will also attend, and contribute to increasing awareness of the work of the Aquatic Animals Commission.

7. OIE Reference Laboratory activities

7.1. Updating the list of OIE Reference Laboratories

The Commission recommends acceptance of the following two new applications for OIE Reference Laboratory status:

Infectious salmon anaemia

Atlantic Veterinary College, Department of Pathology and Microbiology, Faculty of Veterinary Medicine, University of Prince Edward Island, 550 University Avenue, Charlottetown, Prince Edward Island, C1A 4P3 Canada; Tel.: (1-902) 566.09.67; Fax: (1-902) 566.08.51; E-mail: kibenge@upe.ca
Designated Reference Expert: Dr Frederick Kibenge

White spot disease and Penaeus monodon-type baculovirus

Department & Institute of Zoology, National Taiwan University, 1, Sec. 4, Roosevelt Rd., Taipei China. Tel: (+886-2) 23.63.02.31/22.62; Fax: (+886-2) 23.63.68.37; E-mail: gracelow@ccms.ntu.edu.tw
Designated Reference Expert: Dr Grace Lo

The Commission had received a resignation from the Dr Jo-Ann Leong from one of the two Reference Laboratories for infectious haematopoietic necrosis in the USA. Recognising that there is thus a need for a replacement Reference Laboratory, the Commission would welcome applications from OIE Member Countries.

8. Any other business

8.1. Cooperation and partnership with other international and regional organisations

8.1.1. Cooperation between veterinary and fisheries authorities

The Commission is pleased to note that there are encouraging signs of improving cooperation between veterinary and fisheries authorities. Through the recommendations prepared at the Conference of the Regional Commission for Asia, the Far East and Oceania (see item 6.1.3), a number of initiatives have been identified to improve cooperation between veterinary and fisheries authorities, especially in those Member Countries where the veterinary authority does not have official responsibility for aquatic animal health. For example, fisheries authorities could be invited to attend OIE-sponsored conferences or workshops that have an aquatic theme, and Member Countries themselves could request their veterinary services to improve the communication and cooperation with fisheries authorities, especially regarding disease reporting and disease emergency responses.

The Commission suggested that the national coordinators already active in the NACA aquatic animal health programme could be candidates for the aquatic national focal points suggested in the recommendations from the OIE Regional Conference (see item 6.1.3).

8.1.2. FAO², NACA, SEAFDEC³ and other international organisations

The Commission considered the revised document entitled 'Surveillance and Zoning for Aquatic Animal Diseases', which is the output of the FAO/DFO Canada⁴/OIE Expert Consultation on Surveillance and Zonation for Responsible Movement of Live Aquatic Animals: A Framework for Reducing the Risk of Trans-Boundary Spread of Aquatic Animal Diseases, which was held from 14 to 18 October 2002 in Rome, Italy, and was pleased to note that the comments made on the previous version had all been addressed. Due to the time lapse since the expert consultation, the contents of the report do not now reflect the current OIE Standards on surveillance and monitoring, which have changed in the interim. It is suggested that they should be referred to by means of footnotes and appendices, etc. Subject to these final amendments, the Commission is pleased to endorse the report.

8.1.3. Emergency Preparedness and Response to Aquatic Animal Diseases in Asia, a Workshop to be held in Jakarta, Indonesia, in August 2004

Dr Vallat had received a letter from the FAO Fisheries Department inviting the OIE to co-sponsor and co-organise a Workshop on Emergency Preparedness and Response to Aquatic Animal Diseases in Asia, to be held in Jakarta, Indonesia, in August 2004. The Workshop is intended to assist Indonesia and countries in the Asian region in identifying actions to reduce the impact of koi herpesvirus on aquaculture and small scale fisheries and in strengthening preparedness and response to serious aquatic animal disease emergencies. The Commission welcomes this initiative in principle, however it feels that the time frame is too short and the focus and topic are too narrow to warrant a co-sponsoring and co-organising role for the OIE.

The Commission feels strongly that there is a need for such initiatives, as suggested by FAO, but that this is a global issue and OIE, in partnership with other international organisations, should organise a global conference on aquatic animal disease emergencies. This conference should have invited speakers from the terrestrial animal sectors in order to share their experiences and be briefed on their current programmes.

8.1.4. Mollusc Diseases Training - Phase III

In response to the lack of information and knowledge on mollusc diseases in the Asian region, FAO and NACA initiated in 1999 a three-tier regional programme on mollusc health management. OIE has contributed to this programme by supporting Dr Franck Berthe's participation as a training expert to the first two phases, which took place at SEAFDEC (Iloilo, Philippines, November 1999) and University of Queensland (Brisbane, Australia, December 2002). The Phase III is planned for 2004 and will be hosted by the National Fisheries Research and Development Institute, Pusan, Korea (Rep. of). Activities during this third and last phase will include training in level III diagnostics (immunoassays, PCR, transmission electron microscopy) for mollusc diseases, inter-calibration exercises and presentation of country-specific survey results. NACA has requested that OIE contribute to Phase III as it did to Phases I and II. The Commission acknowledges improvements in the situation already obtained in the frame of this programme and supports the initiative.

8.1.5. International Symposium on Koi Herpesvirus Disease Control, Japan, March 2004

Dr Vallat had received a letter from the Regional Representation for Asia and the Pacific, regarding an International Symposium on Koi Herpesvirus Disease Control, to be held in Japan, in March 2004. The letter included a request for participation by the Aquatic Animals Commission, and Dr Vallat sought advice from the Commission on this issue. Due to the short notice and other commitments, none of the Commission Members is available to participate at the Symposium. Prof. Hill informed the meeting that an international workshop on koi herpesvirus disease will be held in London, United Kingdom (UK), in February 2004. The Commission awaits the outcome of both meetings with interest.

2 FAO: Food and Agriculture Organization of the United Nations

3 SEAFDEC: South-East Asia Fisheries Development Centre

4 DFO: Federal Department of Fisheries and Oceans (Canada)

8.2. Amphibian disease issues

Prof. Hill reported on continuing efforts to obtain data on international trade in farmed and wild amphibians. A search of the literature had provided information on diseases of wild and farmed amphibians and its link to population declines in various countries. Some of the viral pathogens infect both amphibians and fish, including ornamental fish species, such that either host type can be a vector for disease of the other. This potential risk of international spread of disease has been recognised by the European Commission, which is planning to fund research to assess the risk to the EU. The findings of this research will provide further information for the Aquatic Animals Commission to consider whether it is time to include amphibian disease within its remit.

8.3 Freshwater crayfish disease issues

The Commission received a request from an Australian researcher to increase the attention paid to the disease risks associated with international trade in freshwater crayfish. He also deplored the lack of knowledge of crayfish pathology and suggested that a histology/pathology atlas would contribute to improving this situation. He noted that a similar atlas had previously been co-published by the OIE on the histology and cytology of marine bivalve molluscs. The Commission acknowledges this concern about lack of skills and knowledge of crayfish pathology, but feels that rather than responding to individual requests, it would be more appropriate to develop a generic policy for consideration of such proposals.

8.4 Status of Aquatic Animals Commission Internet activities

Prof. Hill reported that the Commission's web pages are being continually updated, particularly with regard to providing information on new disease developments. He has been informed by Ms Caroline Malotaux that the Commission's web pages are in the process of being re-designed by the Central Bureau to make them consistent with the design of the main OIE web site. The newly designed pages will be submitted to the Commission for comments before being made live.

8.5 Second OIE/FAO/IAEA Consultants Meeting on 'OIE Validation and Certification of Diagnostic Assays for Infectious Animal Diseases' – Specific procedures for OIE to validate and approve diagnostic tests, organised by the OIE Collaborating Centre for ELISA and Molecular Techniques in Animal Disease Diagnosis, IAEA, Vienna, Austria, 9–12 December 2003

The Commission noted that this meeting had taken place. The principles outlined at this meeting will be applicable to aquatic animal diseases. The Commission awaits the final report.

8.6 OIE Strategic Plan for 2005–2010

The Commission noted the draft of the fourth OIE Strategic Plan 2005–2010. When revising its work plan for the coming years, the Commission will take into account the policy directions of the Strategic Plan. The draft fourth OIE Strategic Plan 2005–2010 will be presented to the International Committee for adoption in May 2005.

8.7 Review of Aquatic Animals Commission work plan for 2004

The Commission reviewed its work plan for 2004, which is presented at [Appendix XII](#) for information.

8.8. Dates of next meetings

The Bureau of the Commission will hold a meeting in July 2004 to discuss the outcomes of the General Session. The next full meeting of the Aquatic Animals Commission will be from 20 to 25 January 2005.

.../Appendices

MEETING OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5–9 January 2004

Provisional Agenda

- 1. Member Country comments on the report of the previous meeting (October 2003)**
- 2. Planning of seventh edition of the *Aquatic Animal Health Code***
 - 2.1. Revision of the relative contents of the *Aquatic Code* and *Aquatic Manual*
 - 2.2. Revision of disease listing and notification criteria
 - 2.3. Revision of the list of diseases; review of names of crustacean diseases
 - 2.4. New finfish, mollusc and crustacean disease chapters, based on new drafts
 - 2.5. New model aquatic animal health certificates
 - 2.6. New Appendix on General recommendations on disinfection
 - 2.7. Revision of chapter on measures concerning international transport of aquatic animal disease agents and pathological material
- 3. Planning of fifth edition of the *Manual of Diagnostic Tests for Aquatic Animals***
 - 3.1. Revision of the relative contents of the *Aquatic Code* and *Aquatic Manual*
 - 3.2. New template for disease chapters (to provide information underpinning the *Aquatic Code* chapters, summary tables on diagnostic methods, and disease-specific requirements for sampling and surveillance)
 - 3.3. Revision of *Aquatic Manual* chapters on disinfection of fish and of mollusc aquaculture establishments
- 4. Joint meeting with the Central Bureau/Terrestrial Animal Health Standards Commission**
 - 4.1. Update on implementation of new disease lists (target date January 2005)
 - 4.2. OIE Working Group on Animal Welfare
 - 4.3. Development of guiding principles for the listing of closely related disease agents
 - 4.4. Continuing work on harmonisation of horizontal chapters in both *Aquatic* and *Terrestrial Codes*
- 5. OIE Aquatic animal disease information system**
 - 5.1. Disease reporting
- 6. The role and activities of the OIE in the field of aquatic animals**
 - 6.1. Presentations at international meetings and workshops
 - 6.1.1. Asia Regional Advisory Group for Aquatic Animal Health, Bangkok, Thailand, 10–12 November 2003
 - 6.1.2. International Symposium on Veterinary Epidemiology and Economics (ISVEE 10, Viña del Mar, Chile, 17–21 November 2003)
 - 6.1.3. 23rd Conference of the OIE Regional Commission for Asia, the Far East and Oceania, Noumea, New Caledonia, 25–28 November 2003

6.2. Future international meetings and workshops

6.2.1. Future Conferences of OIE Regional Commissions

6.2.2. Aquaculture Biosecurity: Approaches to the Prevention, Control, and Eradication of Aquatic Animal Disease (Special Session of World Aquaculture Society Triennial Conference, 'Aquaculture 2004'), Hawaii, 1–5 March 2004

7. Annual reports of OIE Reference Laboratory activities

7.1. Updating the list of OIE Reference Laboratories

8. Any other business

8.1. Cooperation and partnership with other international and regional organisations

8.1.1. Cooperation between veterinary and fisheries authorities

8.1.2. FAO⁵, NACA⁶, SEAFDEC⁷ and other international organisations

8.1.3. Emergency Preparedness and Response to Aquatic Animal Diseases in Asia, a Workshop to be held in Jakarta, Indonesia, in August 2004

8.1.4. Mollusc Diseases Training - Phase III

8.1.5. International Symposium on Koi Herpesvirus Disease Control, Japan, March 2004

8.2. Amphibian disease issues

8.3. Freshwater crayfish disease issues

8.4. Status of Aquatic Animals Commission Internet activities

8.5. Second OIE/FAO/IAEA Consultants Meeting on 'OIE Validation and Certification of Diagnostic Assays for Infectious Animal Diseases' – Specific procedures for OIE to validate and approve diagnostic tests, organised by the OIE Collaborating Centre for ELISA and Molecular Techniques in Animal Disease Diagnosis, IAEA, Vienna, Austria, 9–12 December 2003

8.6. OIE Strategic Plan for 2005–2010

8.7. Review of Aquatic Animals Commission work plan for 2004

8.8. Dates of next meetings

5 FAO: Food and Agriculture Organization of the United Nations

6 NACA: Network of Aquaculture Centers in Asia-Pacific

7 SEAFDEC: South-East Asia Fisheries Development Centre

MEETING OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 5–9 January 2004

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SECTION 1.1.
GENERAL DEFINITIONS

CHAPTER 1.1.1.
DEFINITIONS

Article 1.1.1.1.

For the purpose of this *Aquatic Code*:⁸

[Affected establishment

means any *aquaculture establishment* in which a *disease* included in this *Aquatic Code* has been diagnosed.]

Aquatic animal products

means products from *aquatic animals* (fish, molluscs, crustaceans) whether they are intended for farming (eggs, gametes, larvae, etc.), for human consumption, for use in animal feeding or for pharmaceutical, biological, or industrial uses.

Aquatic animals

means all life stages (including eggs and gametes), of live fish, molluscs and crustaceans from *aquaculture establishments* or ~~*aquatic animals*~~ removed from the wild, for farming purposes or for release into the aquatic environment. Other water-living animals are not covered by the *Aquatic Code*. The definition does not cover water-living amphibia, reptiles, birds or mammals.

Basic biosecurity disease security conditions

means a set of conditions applying to a particular *disease*, and a particular *zone* or country, required to ensure adequate disease security, such as:

- a) the *disease*, including suspicion of the *disease*, is compulsorily notifiable to the *Competent Authority*; and
- b) an *early detection system* is in place within the *zone* or country; and
- c) import requirements to prevent the introduction of *disease* into the country or *zone*, as outlined in the *Aquatic Code*, are in place.

Commodity

means *aquatic animals*, *aquatic animal products*, ~~*aquatic animal genetic material*~~, ~~feedstuffs~~, *biological products* and *pathological material*.

8 For this report, all the new proposed changes are highlighted: proposed new text is double underlined, proposed deletions are crossed out. Any text that is not highlighted, but that is marked, is text that was proposed in October 2003, which has been left as it was presented then: proposed new text is double underlined, proposed deletions are between square brackets and in a smaller font size. All other text that is neither highlighted nor marked, is text that currently exists in the *Aquatic Code*.

Compartment

means one or more *aquaculture establishments* under a common biosecurity management system containing an aquatic animal population with a distinct health status with respect to a specific *disease* for which required surveillance, control and biosecurity measures are applied for the purpose of *international trade*. Such *compartments* must be clearly documented.

Crustaceans

means all life stages of aquatic animals belonging to the phylum Arthropoda, a large class of *aquatic animals* characterised by their chitinous exoskeleton and jointed appendages, e.g. crabs, lobsters, crayfish, shrimps, brine shrimp, prawns, isopods, ostracods and amphipods.

Early detection system

means an efficient system for ensuring the rapid recognition of signs that are suspicious of a *listed disease*, or an *emerging disease* situation, or unexplained mortality, in *aquatic animals* in an *aquaculture establishment* or in the wild, and the rapid communication of the event to the *Competent Authority*, with the aim to activate diagnostic investigation with minimal delay. Such a system will include the following characteristics:

- a) broad awareness, e.g. among the personnel employed at *aquaculture establishments* or involved in *processing*, of the characteristic signs of the *listed diseases*;
- b) veterinarians or aquatic animal health specialists trained in recognising and reporting suspicious disease occurrence;
- c) ability of the *Competent Authority* to undertake rapid and effective disease investigation;
- d) access by the *Competent Authority* to laboratories with the facilities for diagnosing and differentiating *listed* and *emerging diseases*.

Fish

means fresh or salt water finfish of any age.

Infected aquaculture establishment

means an *aquaculture establishment* in which a *disease* listed in this *Aquatic Code* has been diagnosed.

Molluses

means aquatic organisms belonging to the phylum Mollusca in the subkingdom Metazoa characterised by soft unsegmented bodies. Most forms are enclosed in a calcareous shell. The different development stages of *molluscs* are termed larvae, postlarvae, spat, juvenile and adult.

Self official declaration of freedom from disease

means declaration by that the *Competent Authority* of the country concerned has formally declared that the country or a *zone* of the country is to be free from a *listed disease* based on implementation of the provisions of the *Aquatic Code* and *Aquatic Manual*. The country may wish to transmit this information to the OIE *Central Bureau*, which may publish the information.

Subclinical

means without clinical manifestations, for example a stage of *infection* at which signs are not apparent or detectable by clinical examination.

Susceptible species

means a species of *aquatic animal* that is capable of being infected by a given *disease agent*.

Zone

means a portion of one or more countries comprising an entire catchment area from the source of a waterway to the estuary, more than one catchment area, part of a catchment area from the source of a waterway to a barrier, or a part of the coastal area, or an estuary with a precise geographical delimitation, that consists of a homogeneous hydrological system. Such *zones* must be clearly delineated on a map of the *territory* of the country(ies) concerned by the *Competent Authority*.

CHAPTER 1.1.2.

DISEASE LISTING AND NOTIFICATION CRITERIA

Article 1.1.2.1.

Criteria for listing an aquatic animal disease

Diseases proposed for listing must meet all of the relevant parameters set for each of the criteria, namely A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a *disease* must have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8.

No.	Criteria (A/ C)	Parameters that support a listing	Explanatory notes
A. Consequences			
1.		Where it occurs, the disease has been shown to cause significant production losses due to morbidity ⁹ and or mortality <u>or product quality</u> at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in <i>susceptible</i> ¹⁰ species, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. <u>The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.</u>
2.	Or	The disease has been shown to, or is strongly suspected to, negatively affect wild aquatic animal populations that are shown to be an asset worth protecting <u>for economic or other reasons, including ecological concerns.</u>	<u>Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, the asset could be ecological or environmental in nature, for example, if the population consists of an endangered species of aquatic animal.</u> See above
3.	Or	The agent is of public health concern.	
And			
B. Spread			
4.		Infectious aetiology of the disease is proven.	

⁹ 'morbidity' includes, for example, loss of production due to spawning failure

¹⁰ 'susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to subclinical infections'

No.	Criteria (A/ C)	Parameters that support a listing	Explanatory notes
5.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
6.	And	Potential for international spread, including via live animals, their products and inanimate objects.	<u>International trade in aquatic animal species susceptible to the disease exists or is likely to develop and,</u> under international trading practices, the entry and establishment of the disease is a likely risk.
7.	And	Several countries <u>or countries with zones</u> [are] <u>may be officially declared free</u> of the disease based on the [recommendations of the <i>Aquatic Animal Health Code</i> and <i>Manual of Diagnostic Tests for Aquatic Animals</i>] <u>general surveillance principles outlined in Chapter 1.1.4 of the <i>Aquatic Manual</i>.</u>	<i>Free countries/zones</i> could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible, however, individual countries that run a control programme on such a disease can demand its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of <i>broodstock</i> from widespread diseases, or the protection of the last remaining <i>free zones</i> from a widespread disease.
And C. Diagnosis			
8.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see <i>OIE Manual of Diagnostic Tests for Aquatic Animals</i>).

...

[] deleted

CHAPTER 2.1.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

Article 2.1.1.1.

For the purposes of this *Aquatic Code*, [the disease agents of] epizootic haematopoietic necrosis (EHN) [are: EHN virus (EHNV), European sheatfish virus (ESV) and European catfish virus (ECV)] means infection with EHN virus (EHNV).

[Provisions for recognition of freedom from EHN means that the conditions as outlined below are met for all of the agents listed above.]

Article 2.1.1.2.

Susceptible species

- 1) For the purpose of this *Aquatic Code*, Naturally susceptible species in which clinical signs of for EHN[V infection] are known to develop are: redfin perch (*Perca fluviatilis*), rainbow trout (*Oncorhynchus mykiss*), Macquarie perch (*Macquaria australasica*), silver perch (*Bidyannus bidyanus*), mountain galaxias (*Galaxias olidus*), mosquito fish (*Gambusia affinis*) and other species belonging to the family Poeciliidae. [The diseases agents listed in Article 2.1.1.1.] EHN[V can also cause [asymptomatic] *subclinical* infection in [their respective susceptible species listed in Article 2.1.1.2] these species.
- 2) Experimental EHN[V infections have been reported in Macquarie perch (*Macquaria australasica*), silver perch (*Bidyannus bidyanus*), mountain galaxias (*Galaxias olidus*), [and] mosquito fish (*Gambusia affinis*) and other species belonging to the family Poeciliidae.
- 2) The following commodities can be traded safely without EHN-related restrictions and regardless of the EHN status of the exporting country, zone or compartment:
 - a) Leather made from fish skin;
 - b) Fish by-products, such as flame-dried or sun-dried meals, and ensilaged fish;
 - c) Fertilised eggs that have been disinfected according to the procedures described in Chapter 1.1.5. of the *Aquatic Manual*;
 - d) Processed filets (chilled, smoked or frozen);
 - e) Dead eviscerated fish (chilled, sun-dried, smoked or frozen);
- 3) The following other commodities may pose a risk, but can be traded safely subject to the conditions prescribed in Articles 2.1.1.9 or 2.1.1.12, as applicable, relating to the EHN status of the fish in the exporting country, zone or compartment:
 - a) Dead uneviscerated fish of the species listed above.
 - b) Live fish of the species listed above (any life stage, including eyed eggs, fry, fingerlings, broodstock, etc.);
- 4) For fish commodities of unknown risk e. g. semen, refer to Articles 2.1.1.10, 2.1.1.11, 2.1.1.13 and 2.1.1.14.

Appendix V (contd)

[Naturally susceptible species in which clinical signs of ESV infection are known to develop are: sheatfish (*Silurus glanis*).

Naturally susceptible species in which clinical signs of ECV infection are known to develop are: catfish (*Ictalurus melas*).

Article 2.1.1.3.

The disease agents listed in Article 2.1.1.1] can cause asymptomatic infection in their respective susceptible species listed in Article 2.1.1.2.

Article 2.1.1.4.

Experimental EHNV infections have been reported in Macquarie perch (*Macquaria australasica*), silver perch (*Bidyanus bidyanus*), mountain galaxias (*Galaxias olidus*), and mosquito fish (*Gambusia affinis*) and other species belonging to the family Poeciliidae.]

Article 2.1.1.[5]3.

Suspect cases of natural infection with [any of the agents listed in Article 2.1.1.1] EHN in species other than those listed in Article[s] 2.1.1.2 [and 2.1.1.3] should be referred immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article 2.1.1.[6]4.

Methods for surveillance, diagnosis and confirmatory identification of the disease agents are provided in the *Aquatic Manual*.

Article 2.1.1.[7]5.

EHN free country

A country may declare itself be [considered] officially declared free from EHN if it meets the conditions in [Articles 2.1.1.8 or 2.1.1.9] point 1) or 2) below.

If a country shares a water catchment area with one or more other countries, it can only declare itself be declared an EHN free country if all the shared water catchment areas are declared EHN free zones [(see Articles 2.1.1.10 to 2.1.1.12)] (see Article 2.1.1.6).

[Article 2.1.1.8]

1) A country where none of the species listed in Article[s] 2.1.1.2 [and 2.1.1.3] is present or where these species are present but there has never been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 2.1.1 of the Aquatic Manual, may declare itself be officially declared [considered] free from EHN when [prescribed biosecurity] basic biosecurity disease security conditions have been in place continuously in the country for at least the previous [2] 10 years and infection is not known to be established in wild populations [as follows:

- a) EHN is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- b) an *early detection system* is in place within the country enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and training of veterinarians or fish health specialists in detecting and reporting unusual disease occurrence; and
- c) infection is not known to be established in wild populations; and
- d) conditions applied to imports to prevent the introduction of EHN into the country are in place (see Section 1.4)].

[Article 2.1.1.9]

OR

- 2) A country where the last known clinical occurrence was within the past 25 years or where the infection status prior to targeted surveillance was [previously] unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.1.1 of the Aquatic Manual, may declare itself be officially declared [considered] free from EHN when:
- it meets [the prescribed biosecurity] basic biosecurity disease security conditions [detailed in Article 2.1.1.8]; and
 - targeted surveillance as described in Chapters 1.1.4 and 2.1.1 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the species listed in Article[s] 2.1.1.2 [and 2.1.1.3] without detection of [the disease agent listed in Article 2.1.1.1] EHN. If there are areas of the country in which there are no such aquaculture establishments but in which there are wild populations of any of the species listed in Article[s] 2.1.1.2 [and 2.1.1.3], those populations must be included in the *targeted surveillance*.

Article 2.1.1.[10]6.

EHN free zone or free compartment

A *zone or compartment* free from EHN may be established within the *territory* of one or more countries of infected or unknown status for EHN and officially declared free by the Competent Authority(ies) of the country(ies) concerned, if the *zone or compartment* meets the conditions referred to in [Articles 2.1.1.11 or 2.1.1.12] point 1) or 2) below.

Such EHN free *zones* must comprise: one or more entire water catchment area(s) from the sources of the waterways to the sea, or part of a catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of fish from lower stretches of the waterway. Such *zones* must be clearly delineated on a map of the *territory* of the country(ies) concerned by the *Competent Authority*.

If a *zone or compartment* extends over more than one country, it can only be declared an EHN free *zone or compartment* if the conditions outlined below apply to all [shared] areas of the *zone or compartment*.

[Article 2.1.1.11]

- 1) In a country of unknown status for EHN, a *zone or compartment* where none of the species listed in Article[s] 2.1.1.2 [and 2.1.1.3] is present or where these species are present but there has never been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 2.1.1 of the Aquatic Manual, may declare itself be officially declared [considered] free from EHN when [prescribed biosecurity] basic biosecurity disease security conditions have been in place continuously in the *zone or compartment* for at least the previous [2] 10 years and infection is not known to be established in wild populations. [as follows:
- EHN is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
 - an *early detection system* is in place within the *zone* enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and veterinarians or fish health specialists are trained in detecting and reporting unusual disease occurrence; and
 - infection is not known to be established in wild populations; and
 - official control measures to prevent the introduction of EHN into the *zone* are in place.]

[Article 2.1.1.12]

OR

- 2) A *zone or compartment* where the last known clinical occurrence was within the previous 25 years or where the infection status prior to targeted surveillance was [previously] unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.1.1 of the *Aquatic Manual*, may declare itself be [considered] officially declared free from EHN when:
- a) it meets [the prescribed biosecurity] basic biosecurity disease security conditions [detailed in Article 2.1.1.11]; and
 - b) *targeted surveillance* as described in Chapters 1.4 and 2.1.1 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the species listed in Article[s] 2.1.1.2 [and 2.1.1.3] without detection of [the disease agents listed in Article 2.1.1.1] EHN. If there are areas of the *zone or compartment* in which there are no such *aquaculture establishments* but in which there are wild populations of any of the species listed in Article[s] 2.1.1.2 [and 2.1.1.3], those populations must be included in the *targeted surveillance*.

These provisions also apply if the *zone or compartment* to be officially declared free lies in an EHN-infected country.

[Article 2.1.1.13.

EHN free aquaculture establishment

An EHN free *aquaculture establishment* may be located within an EHN infected country or zone or within a country or zone of unknown status with respect to EHN if it meets the conditions referred to in Articles 2.1.1.14 or 2.1.1.15. Such EHN free *aquaculture establishments* must be supplied by a contained water source only (e.g. a spring, well, borehole, rain catchment, etc.) and be free from stocks of wild *fish* of the susceptible species listed in Articles 2.1.1.2 and 2.1.1.3, and there must be a natural or artificial barrier that prevents the migration of *fish* from lower stretches of the waterway into the *aquaculture establishment* or its water supply.

Article 2.1.1.14.

An *aquaculture establishment* where none of the species listed in Articles 2.1.1.2 and 2.1.1.3 is present or where there has never been any observed occurrence of the disease despite conditions that are conducive to its clinical expression may be considered free from EHN when *prescribed biosecurity conditions* have been in place continuously in the *aquaculture establishment* for at least the previous 2 years as follows:

- 1) EHN is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) the *aquaculture establishment* complies with an *early detection system* enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and the staff are trained in detecting and reporting unusual disease occurrence; and
- 3) official control measures to prevent the introduction of EHN into the *aquaculture establishment* are in place.

Article 2.1.1.15.

An *aquaculture establishment* where the last known occurrence of EHN was within the previous 25 years or the infection status was previously unknown, for example because of the absence of conditions conducive to clinical expression, may be considered free from EHN when:

- 1) it meets the *prescribed biosecurity conditions* detailed in Article 2.1.1.14; and
- 2) *targeted surveillance* as described in chapters 1.4 and 2.1.1 in the *Aquatic Manual* has been in place for at least the past 2 years without detection of the disease agents listed in Article 2.1.1.1.
 - b) *targeted surveillance* as described in chapters 1.4 and 2.1.1 in the *Aquatic Manual* has been in place for at least the past 2 years without detection of the disease agents listed in Article 2.1.1.1.]

Article 2.1.1.[16]Z.

Maintenance of free status

A country or zone or compartment [or *aquaculture establishment*] that is [considered] officially declared free from EHN following the provisions of [Articles 2.1.1.8, 2.1.1.11 and 2.1.1.14] point 1) of Articles 2.1.1.5 or 2.1.1.6, respectively, may maintain its status as EHN free provided that [the prescribed biosecurity] basic biosecurity disease security conditions are continuously maintained.

A country or zone or compartment [or *aquaculture establishment*] that is [considered] officially declared free from EHN following the provisions of [Articles 2.1.1.9, 2.1.1.12 and 2.1.1.15] point 2) of Articles 2.1.1.5 or 2.1.1.6, respectively, may discontinue *targeted surveillance* and maintain its status as EHN free provided that conditions that are conducive to clinical expression of EHN, as described in Chapter 2.1.1 of the Aquatic Manual, exist and [the prescribed biosecurity] basic biosecurity disease security conditions are continuously maintained.

However, for officially declared free zones or compartment in infected countries and in all cases where conditions are not conducive to clinical expression of EHN, *targeted surveillance* will need to be continued, but at a level commensurate with the degree of risk assessed by the *Competent Authority*.

Article 2.1.1.[17]8.

Suspension and restoration of free status

If a *Competent Authority* has reason to believe that any of the conditions for [recognition of] maintaining its status as an EHN free country or zone or compartment [or *aquaculture establishment* freedom] has been breached, the *Competent Authority* should immediately suspend the free status, implement any necessary containment measures and conduct an investigation.

If the investigation confirms that the suspected breach has not taken place, free status may be restored.

If the investigation confirms that the suspected breach has taken place, suspension of free status is continued. The *Competent Authority* should carry out an epizootiological investigation to determine the likelihood of EHN infection having occurred disease entry and establishment [and re-establish the conditions in Articles 2.1.1.7 to 2.1.1.9, 2.1.1.10 to 2.1.1.12, or 2.1.1.13 to 2.1.1.15 if free status is to be restored]. If this investigation concludes that infection disease entry and establishment have has not occurred, free status may be restored.

If the investigation confirms a significant likelihood that infection has disease entry and establishment have occurred, the *Competent Authority* must declare that the free status is lost. In order to restore free status, the conditions in Articles 2.1.1.5 or 2.1.1.6 must be complied with again in full. Steps leading to re-establishment of free status may require depopulation, *fallowing*, *disinfection* and other measures, as described in Section 1.6, as well as zoning as described in Section 1.4.

Article 2.1.1.[18]9.

When importing live fish of the species listed in Article 2.1.1.2, or their *sexual products*, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of [a surveillance scheme conducted according to the procedures described above and detailed in the *Aquatic Manual*, whether or not the place of production of the consignment is a country, *zone* or *aquaculture establishment* officially declared EHN free] the procedures described in Articles 2.1.1.5 or 2.1.1.6 (as

applicable), whether or not the place of production of the consignment is a country, ~~or zone or compartment~~ officially declared free from EHN.

The certificate shall be in accordance with Model Certificate No. 1 given in Part 6 of this *Aquatic Code*. This certificate may not be required for commodities that can be traded safely (see Article 2.1.1.2).

Article 2.1.1.[19]10.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 2.1.1.9, or cannot certify that the consignment originates from a country, zone or compartment the place of production of the consignment as being free from EHN, the *importing country* should assess the risk[s] of introduction and establishment of EHN associated with the importation of live fish of the species listed in Article 2.1.1.2, or their *sexual products*, from the exporting country, or seek assurance from the exporting country that basic biosecurity disease security conditions are met, prior to a decision on whether to authorise an importation. The importing country should also consider applying risk management measures. This assessment should be made available to the exporting country.

Article 2.1.1.11.

When importing live fish of species other than those listed in Article 2.1.1.2, or their sexual products, the Competent Authority of the importing country should assess the risk of introduction and establishment of EHN associated with the importation prior to a decision on whether to authorise the importation, taking into account, for example, whether there is evidence for or against the presence of EHN in the place of origin. The importing country should also consider applying risk management measures. This assessment should be made available to the exporting country.

Article 2.1.1.[20]12.

When importing dead fish of the *species* listed in Article[s] 2.1.1.2, [and 2.1.1.3] 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of [a surveillance scheme conducted according to the procedures described above and detailed in the *Aquatic Manual*, whether or not the place of production of the consignment is a country, *zone* or *aquaculture establishment* officially declared EHN free] the procedures described in Articles 2.1.1.5 or 2.1.1.6 (as applicable), whether or not the place of production of the consignment is a country, zone or compartment officially declared free from EHN.

The certificate shall be in accordance with Model Certificate No. 2 given in Part 6 of this *Aquatic Code*. This certificate may not be required for commodities that can be traded safely (see Article 2.1.1.2).

Article 2.1.1.[21]13.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred in Article 2.1.1.12, or cannot certify that the consignment originates from a country, zone or compartment the place of production of the consignment as being free from EHN, the *importing country* should assess the risk[s] of introduction and establishment of EHN associated with the importation from the exporting country of dead unviscerated fish of the [susceptible] species listed in Article[s] 2.1.1.2 [and 2.1.1.3], including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the exporting country.

Article 2.1.1.14.Risk management

If a commodity is not listed as one that can be traded safely (see Article 2.1.1.2), or if the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Articles 2.1.1.9 and 2.1.1.12, or cannot certify the place of origin of the consignment as being free from EHN or if the *exporting country* is infected with EHN, or if the *commodity* is of unknown risk, the *importing country* should assess the risk of introduction and establishment of EHN associated with the importation from the *exporting country* including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these risks, if the consignment is:

- 1) for direct human consumption, or
- 2) live fish for human consumption with storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of EHN, or
- 3) has been processed, e.g. cooked, such that EHN – if present – is inactivated.

Article 2.1.1.[22]15.

The *Competent Authorities* of *exporting countries* should not authorise the exportation of live fish or dead *uneviscerated fish* from populations known to be infected with EHN without the [full] prior agreement of the *importing country*.

[] deleted

CHAPTER 2.1.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

Article 2.1.1.1.

For the purposes of this *Aquatic Code*, epizootic haematopoietic necrosis (EHN) means infection with EHN virus (EHNV).

Article 2.1.1.2.

- 1) For the purpose of this *Aquatic Code*, *susceptible species* for EHN are: redfin perch (*Perca fluviatilis*), rainbow trout (*Oncorhynchus mykiss*), Macquarie perch (*Macquaria australasica*), silver perch (*Bidyanus bidyanus*), mountain galaxias (*Galaxias olidus*), mosquito fish (*Gambusia affinis*) and other species belonging to the family Poeciliidae. EHNV can also cause *subclinical* infection in these species.
- 2) The following *commodities* can be traded safely without EHN-related restrictions and regardless of the EHN status of the *exporting country, zone or compartment*:
 - a) Leather made from fish skin;
 - b) Fish by-products, such as flame-dried or sun-dried meals, and ensilaged fish;
 - c) Fertilised eggs that have been disinfected according to the procedures described in Chapter 1.1.5. of the *Aquatic Manual*;
 - d) Processed filets (chilled, smoked or frozen);
 - e) Dead eviscerated fish (chilled, sun-dried, smoked or frozen);
- 3) The following other *commodities* may pose a risk, but can be traded safely subject to the conditions prescribed in Articles 2.1.1.9 or 2.1.1.12, as applicable, relating to the EHN status of the fish in the *exporting country, zone or compartment*:
 - a) Dead uneviscerated fish of the species listed above.
 - b) Live fish of the species listed above (any life stage, including eyed eggs, fry, fingerlings, broodstock, etc.);
- 4) For fish *commodities* of unknown risk e. g. semen, refer to Articles 2.1.1.10, 2.1.1.11, 2.1.1.13 and 2.1.1.14.

Article 2.1.1.3.

Suspect cases of natural infection with EHNV in species other than those listed in Article 2.1.1.2 should be referred immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article 2.1.1.4.

Methods for surveillance, diagnosis and confirmatory identification of the disease agents are provided in the *Aquatic Manual*.

Article 2.1.1.5.

EHN free country

A country may *declare* itself *free* from EHN if it meets the conditions in point 1) or 2) below.

If a country shares a water catchment area with one or more other countries, it can only *declare* itself an EHN free country if all the shared water catchment areas are *declared* EHN free *zones* (see Article 2.1.1.6).

- 1) A country where none of the species listed in Article 2.1.1.2 is present or where these species are present but there has never been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 2.1.1 of the *Aquatic Manual*, may *declare* itself free from EHN when *basic biosecurity conditions* have been in place continuously in the country for at least the previous 10 years and infection is not known to be established in wild populations .

OR

- 2) A country where the last known clinical occurrence was within the past 25 years or where the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.1.1 of the *Aquatic Manual*, may *declare* itself free from EHN when:
 - a) it meets *basic biosecurity conditions* ; and
 - b) *targeted surveillance* as described in Chapters 1.1.4 and 2.1.1 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the species listed in Article 2.1.1.2 without detection of EHN. If there are areas of the country in which there are no such aquaculture establishments but in which there are wild populations of any of the species listed in Article 2.1.1.2 , those populations must be included in the *targeted surveillance*.

Article 2.1.1.6.

EHN free zone or free compartment

A *zone* or *compartment* free from EHN may be established within the *territory* of one or more countries of infected or unknown status for EHN and *declared free* by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in point 1) or 2) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared an EHN free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

- 1) In a country of unknown status for EHN, a *zone* or *compartment* where none of the species listed in Article 2.1.1.2 is present or where these species are present but there has never been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 2.1.1 of the *Aquatic Manual*, may *declare* itself free from EHN when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the previous 10 years and infection is not known to be established in wild populations.

OR

- 2) A *zone* or *compartment* where the last known clinical occurrence was within the previous 25 years or where the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 2.1.1 of the *Aquatic Manual*, may *declare* itself free from EHN when:

Appendix V (contd)

- a) it meets *basic biosecurity conditions* ; and
- b) *targeted surveillance* as described in Chapters 1.1.4 and 2.1.1 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the species listed in Article 2.1.1.2 without detection of EHN. If there are areas of the *zone* or *compartment* in which there are no such *aquaculture establishments* but in which there are wild populations of any of the species listed in Article 2.1.1.2 , those populations must be included in the *targeted surveillance*.

These provisions also apply if the *zone* or *compartment* to be *declared* free lies in an EHN-infected country.

Article 2.1.1.7.

Maintenance of free status

A country or *zone* or *compartment* that is *declared* free from EHN following the provisions of point 1) of Articles 2.1.1.5 or 2.1.1.6, respectively, may maintain its status as EHN free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is *declared* free from EHN following the provisions of point 2) of Articles 2.1.1.5 or 2.1.1.6, respectively, may discontinue *targeted surveillance* and maintain its status as EHN free provided that conditions that are conducive to clinical expression of EHN, as described in Chapter 2.1.1 of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for *declared* free *zones* or *compartment* in infected countries and in all cases where conditions are not conducive to clinical expression of EHN, *targeted surveillance* will need to be continued, but at a level commensurate with the degree of risk assessed by the *Competent Authority*.

Article 2.1.1.8.

Suspension and restoration of free status

If a *Competent Authority* has reason to believe that any of the conditions for maintaining its status as an EHN free country or *zone* or *compartment*] has been breached, the *Competent Authority* should immediately suspend the free status, implement any necessary containment measures and conduct an investigation.

If the investigation confirms that the suspected breach has not taken place, free status may be restored.

If the investigation confirms that the suspected breach has taken place, suspension of free status is continued. The *Competent Authority* should carry out an epizootiological investigation to determine the likelihood of EHN *infection* having occurred. If this investigation concludes that *infection* has not occurred, free status may be restored.

If the investigation confirms a significant likelihood that *infection* has occurred, the *Competent Authority* must declare that the free status is lost. In order to restore free status, the conditions in Articles 2.1.1.5 or 2.1.1.6 must be complied with again in full. Steps leading to re-establishment of free status may require depopulation, *fallowing*, *disinfection* and other measures, as described in Section 1.6, as well as *zoning* as described in Section 1.4.

Article 2.1.1.9.

When importing live fish of the species listed in Article 2.1.1.2, or their *sexual products*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.1.1.5 or 2.1.1.6 (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from EHN.

The certificate shall be in accordance with Model Certificate No. 1 given in Part 6 of this *Aquatic Code*. This certificate may not be required for *commodities* that can be traded safely (see Article 2.1.1.2).

Article 2.1.1.10.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 2.1.1.9, or cannot certify that the consignment originates from a country, *zone* or *compartment* free from EHN, the *importing country* should assess the risk of introduction and establishment of EHN associated with the importation of live fish of the species listed in Article 2.1.1.2, or their *sexual products*, from the *exporting country*, or seek assurance from the *exporting country* that *basic biosecurity conditions* are met, prior to a decision on whether to authorise an importation. The *importing country* should also consider applying risk management measures. This assessment should be made available to the *exporting country*.

Article 2.1.1.11.

When importing live fish of species other than those listed in Article 2.1.1.2, or their *sexual products*, the *Competent Authority* of the *importing country* should assess the risk of introduction and establishment of EHN associated with the importation prior to a decision on whether to authorise the importation, taking into account, for example, whether there is evidence for or against the presence of EHN in the place of origin. The *importing country* should also consider applying risk management measures. This assessment should be made available to the *exporting country*.

Article 2.1.1.12.

When importing dead fish of the *species* listed in Article 2.1.1.2, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.1.1.5 or 2.1.1.6 (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from EHN.

The certificate shall be in accordance with Model Certificate No. 2 given in Part 6 of this *Aquatic Code*. This certificate may not be required for *commodities* that can be traded safely (see Article 2.1.1.2).

Article 2.1.1.13.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred in Article 2.1.1.12, or cannot certify that the consignment originates from a country, *zone* or *compartment* free from EHN, the *importing country* should assess the risk of introduction and establishment of EHN associated with the importation from the *exporting country* of dead unviscerated fish of the species listed in Article 2.1.1.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Article 2.1.1.14.

Risk management

If a commodity is not listed as one that can be traded safely (see Article 2.1.1.2), or if the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Articles 2.1.1.9 and 2.1.1.12, or cannot certify the place of origin of the consignment as being free from EHN or if the *exporting country* is infected with EHN, or if the *commodity* is of unknown risk, the *importing country* should assess the risk of introduction and establishment of EHN associated with the importation from the *exporting country* including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these risks, if the consignment is:

- 1) for direct human consumption, or
- 2) live fish for human consumption with storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of EHN, or
- 3) has been processed, e.g. cooked, such that EHN – if present – is inactivated.

Article 2.1.1.15.

The *Competent Authorities* of *exporting countries* should not authorise the exportation of live fish or dead unviscerated fish from populations known to be infected with EHN without the prior agreement of the *importing country*.

CHAPTER 3.1.5.

INFECTION WITH *MARTEILIA REFRINGENS*

Article 3.1.5.1.

The disease agent is *Marteilia refringens*.

Article 3.1.5.2.

Susceptible and vector species

1) Naturally For the purpose of this Aquatic Code, susceptible species in which clinical signs of for infection with *Marteilia refringens* are known to develop are: *Ostrea* species, in particular the European flat oyster (*Ostrea edulis*), Australian mud oyster (*Ostrea angasi*), Argentinean oyster (*Ostrea puelchana*) and Chilean flat oyster (*Ostrea chilensis*), the Pacific oyster, *Crassostrea gigas*, blue mussel, *Mytilus edulis* and Mediterranean mussel, *M. galloprovincialis*.

Marteilia refringens can cause [asymptomatic] subclinical infection in [the] these susceptible species [listed in Article 3.1.5.2].

2) Experimental infections have not been reported in other species. The following commodities can be traded safely without *Marteilia refringens* related restrictions and regardless of the *Marteilia refringens* status of the exporting country, zone or compartment:

a) Gametes, eggs and larvae;

b) Processed non-viable molluscs (cooked, canned, smoked or frozen);

c) Fresh non-viable molluscs of the species listed above, half-shell or off-shell fresh molluscs.

3) The following other commodities may pose a risk, but can be traded safely subject to the conditions prescribed in Articles 3.1.5.9, or 3.1.5.12, as applicable, relating to the *Marteilia refringens* status of the molluscs in the exporting country, zone or compartment:

a) Live molluscs of the species listed above destined for direct human consumption without any re-immersion or immersion in holding facilities that avoid the potential introduction of *Marteilia refringens*.

b) Live molluscs of the species listed above not destined for direct human consumption. The Pacific oyster, *Crassostrea gigas*, is not regarded to be a vector of *Marteilia refringens*.

4) For mollusc commodities of unknown risk refer to Articles 3.1.5.10, 3.1.5.11 and 3.1.5.13 and 3.1.5.14

[Article 3.1.5.3.]

Marteilia refringens can cause asymptomatic infection in the susceptible species listed in Article 3.1.5.2.

Article 3.1.5.4.

Infections with *Marteilia* spp. of unclear taxonomic affiliation have been described in the following species: common edible cockle (*Cerastoderma [Cardium] edule*), blue mussel (*Mytilus edulis*), Mediterranean mussel (*Mytilus galloprovincialis*), giant clam (*Tridacna maxima*) and calico scallop (*Argopecten gibbus*.)

Article 3.1.5.[5]3.

Suspect cases of natural infection with *Marteilia refringens* in species other than those listed in Article[s] 3.1.5.2 [and 3.1.5.3] should be referred immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article 3.1.5.[6]4.

Methods for surveillance, diagnosis and confirmatory identification of *Marteilia refringens* are provided in the *Aquatic Manual*.

Article 3.1.5.[7]5.

***Marteilia refringens* free country**

A country may declare itself be [considered] ~~officially declared free~~ from *Marteilia refringens* if it meets the conditions in [Articles 3.1.5.8 or 3.1.5.9] point 1) or 2) or 3) below.

If a country shares water bodies of coastal areas with one or more other countries, it can only declare itself be declared a *Marteilia refringens* free country if all the shared coastal areas are *declared Marteilia refringens* free zones (see [Articles 3.1.5.10 to 3.1.5.12] Article 3.1.5.6).

[Article 3.1.5.8.]

1) A country where none of the species listed in Article 3.1.5.2 is present [or where there has never been any observed occurrence of] and where no abnormal mortalities have been caused by infection with *Marteilia refringens* [despite conditions that are conducive to its clinical expression] in other species for at least the past 25 years, as described in Chapter 3.1.3 of the *Aquatic Manual*, may declare itself be ~~officially declared~~ [considered] free from [infection with] *Marteilia refringens* when [prescribed biosecurity] basic biosecurity disease security conditions have been in place continuously in the country for at least the previous [2] 10 years and infection is not known to be established in wild populations; [as follows:

- 1) infection with *Marteilia refringens* is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) an *early detection system* is in place within the country enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant infections, and training of veterinarians or mollusc health specialists in detecting and reporting unusual infection occurrence; and
- 3) infection is not known to be established in wild populations; and
- 4) conditions applied to imports to prevent the introduction of *Marteilia refringens* (e.g. live molluscs introduced for aquaculture purposes or for human consumption) into the country are in place (see Section 1.4).]

OR

2) A country where the species listed in Article 3.1.5.2 are present, but there has never been any observed occurrence of infection with *Marteilia refringens* for at least the past 25 years despite conditions that are conducive to its clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the *Aquatic Manual*, may declare itself be ~~officially declared~~ [considered] free from *Marteilia refringens* when basic biosecurity disease security conditions have been in place continuously in the country for at least the previous 10 years and infection is not known to be established in wild populations;

[Article 3.1.5.9.]

OR

- 3) A country where the last known occurrence was within the previous 25 years or where the infection status prior to targeted surveillance was [previously] unknown, for example because of the absence of conditions conducive to clinical expression of the infection, as described in Chapter 3.1.3 of the Aquatic Manual, may declare itself free officially declared [considered free] from *Marteilia refringens* when:
- it meets [the prescribed biosecurity] basic biosecurity disease security conditions [detailed in Article 3.1.5.8]; and
 - targeted surveillance as described in Chapters 1.1.4 and 3.1.3 in the *Aquatic Manual* has been in place for at least the past 2 years for species listed in Article 3.1.5.2 in *aquaculture establishments* or wild populations without detection of [the disease agent listed in Article 3.1.5.1] *Marteilia refringens*.

Article 3.1.5.[10]6.

***Marteilia refringens* free zone or free compartment**

A zone or compartment free from of infection with *Marteilia refringens* may be established within the *territory* of one or more countries of infected or unknown status for *Marteilia refringens* and officially declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in [Articles 3.1.5.11 or 3.1.5.12] point 1) or 2) or 3) below.

Marteilia refringens free zones must comprise: one or more entire water body of coastal area(s) defined on the basis of the distribution of the susceptible species listed in Article 3.1.5.2, geographical and hydrographical criteria. Such zones must be clearly delineated on a map of the territory of the country(ies) concerned by the Competent Authority.

If a zone or compartment extends over more than one country, it can only be declared a *Marteilia refringens* free zone or compartment if the conditions outlined below apply to all [shared] areas of the zone or compartment.

[Article 3.1.5.11.]

- In a country of unknown status for *Marteilia refringens*, a zone or compartment where none of the species listed in Article 3.1.5.2 is present [or where there has never been any observed occurrence of] and where no abnormal mortalities have been caused by infection with *Marteilia refringens* in other species [despite conditions that are conducive to its clinical expression] for at least the past 25 years, as described in Chapter 3.1.3 of the Aquatic Manual, may be officially declared [considered] free from [infection with] *Marteilia refringens* when [prescribed biosecurity] basic biosecurity disease security conditions have been in place continuously in the zone or compartment for at least the previous [2] 10 years and infection is not known to be established in wild populations; [as follows:
 - infection with *Marteilia refringens* is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
 - an early detection system is in place within the zone enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant infections, and veterinarians or molluscs health specialists are trained in detecting and reporting unusual disease occurrence; and
 - infection is not known to be established in wild populations; and
 - official control measures to prevent the introduction of *Marteilia refringens* (e.g. live molluscs introduced for aquaculture purposes or for human consumption) into the zone are in place]

OR

- In a country of unknown status for *Marteilia refringens*, a zone or compartment where the species listed in Article 3.1.5.2 are present, but there has not been any observed occurrence of infection with *Marteilia refringens* for at least the past 25 years despite conditions that are conducive to its clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the Aquatic

Manual, may be ~~officially declared~~ [considered] free from *Marteilia refringens* when basic ~~biosecurity disease security~~ conditions have been in place continuously in the zone or compartment for at least the previous 10 years and infection is not known to be established in wild populations;

[Article 3.1.5.12.]

OR

3) A zone or compartment where the last known occurrence was within the previous 25 years or where the infection status prior to targeted surveillance was [previously] unknown, for example because of the absence of conditions conducive to clinical expression, including gross signs and abnormal mortality, of the infection as described in Chapter 3.1.3 of the *Aquatic Manual*, may be ~~officially declare itself~~ [considered] free from *Marteilia refringens* when:

- a) it meets [the prescribed biosecurity] ~~basic biosecurity disease security~~ conditions [detailed in Article 3.1.5.11]; and
- b) targeted surveillance as described in Chapters 1.1.4 and 3.1.3 in the *Aquatic Manual* has been in place for at least the past 2 years for the species listed in Article 3.1.5.2 in aquaculture establishments or wild populations without detection of [the disease agent listed in Article 3.1.5.1] *Marteilia refringens*.

These provisions also apply if the zone or compartment to be ~~officially~~ declared free lies in an *Marteilia refringens*-infected country.

[Article 3.1.5.13.]

***Marteilia refringens* free aquaculture establishment**

An aquaculture establishment free of infection with *Marteilia refringens* may be located within an *Marteilia refringens* infected country or zone or within a country or zone of unknown status with respect to *Marteilia refringens* if it meets the conditions referred to in Articles 3.1.5.14 or 3.1.5.15.

Such aquaculture establishments free of infection with *Marteilia refringens* must be supplied by a contained water source (e.g. a well, borehole, closed recirculation system, etc.) in which the culture system water cannot be contaminated by the disease agent, and be inaccessible to susceptible species or potential carriers from the natural environment.

Article 3.1.5.14.

An aquaculture establishment where none of the susceptible species listed in Article 3.1.5.2 is present or where there has never been any observed occurrence of infection with *Marteilia refringens* despite conditions that are conducive to its clinical expression may be considered free from infection with *Marteilia refringens* when prescribed biosecurity conditions have been in place continuously in the aquaculture establishment for at least the previous 2 years as follows:

- 1) infection with *Marteilia refringens* is compulsorily notifiable to the Competent Authority, including notification of suspicion; and
- 2) the aquaculture establishment complies with an early detection system enabling the Competent Authority to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant infections, and the staff are trained in detecting and reporting unusual disease occurrence; and
- 3) infection is not known to be established in wild populations; and
- 4) official control measures to prevent the introduction of *Marteilia refringens* into the aquaculture establishment are in place.

Article 3.1.5.15.

An aquaculture establishment where the last known occurrence of infection with *Marteilia refringens* was within the previous 25 years or the infection status was previously unknown, for example because of the absence of conditions conducive to clinical expression, may be considered free from infection with *Marteilia refringens* when:

- 1) it meets the prescribed biosecurity conditions detailed in Article 3.1.5.14; and

- 2) *targeted surveillance* as described in chapters 1.4 and 3.1.5 in the *Aquatic Manual* has been in place for at least the past 2 years without detection of the disease agent listed in Article 3.1.5.1.]

Article 3.1.5.[16]7.

Maintenance of free status

A country or zone or compartment [or *aquaculture establishment*] that is [considered] officially declared free from [infection with] *Marteilia refringens* following the provisions of [Articles 3.1.5.8, 3.1.5.11 and 3.1.5.14] point 1) or 2) of Articles 3.1.5.5 or 3.1.5.6, respectively, may maintain its status [as free from infection with *Marteilia refringens*] provided that [the prescribed biosecurity] basic biosecurity disease security conditions are continuously maintained.

A country or zone or compartment [or *aquaculture establishment*] that is [considered] officially declared free from [infection with] *Marteilia refringens* following the provisions of [Articles 3.1.5.9, 3.1.5.12 and 3.1.5.15] point 3) of Articles 3.1.5.5 or 3.1.5.6, respectively, may discontinue targeted surveillance and maintain its status as free from [infection with] *Marteilia refringens* provided that [*targeted surveillance* is continued at a level commensurate with the degree of risk assessed by the *Competent Authority*] conditions that are conducive to clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the *Aquatic Manual*, exist and country/zone basic biosecurity disease security conditions are continuously maintained.

However, for officially declared free zones or compartments in infected countries and in all cases where conditions are not conducive to clinical expression, including gross signs and abnormal mortality, targeted surveillance will need to be continued, but at a level commensurate with the degree of risk assessed by the *Competent Authority*.

Article 3.1.5.[17]8.

Suspension and restoration of free status

If a *Competent Authority* has reason to believe that any of the conditions for [recognition of country, zone or *aquaculture establishment* freedom] maintaining its status as a *Marteilia refringens* free country or zone or compartment has been breached, the *Competent Authority* should immediately suspend the free status, implement any necessary containment measures and conduct an investigation.

If the investigation confirms that the suspected breach has not taken place, free status may be restored.

If the investigation confirms that the suspected breach has taken place, suspension of free status is continued. The *Competent Authority* should carry out an epizootiological investigation to determine the likelihood of *Marteilia refringens* infection having occurred entry and establishment [and re-establish the conditions in Articles 3.1.5.7. to 3.1.5.9, 3.1.5.10. to 3.1.5.12, or 3.1.5.13. to 3.1.5.15 if *Marteilia refringens* free status is to be restored]. If this investigation concludes that infection has disease entry and establishment have not occurred, free status may be restored.

If the investigation confirms a significant likelihood that infection has disease entry and establishment have occurred, the *Competent Authority* must declare that the free status is lost. In order to restore *Marteilia refringens* free status, the conditions in Articles 3.1.5.5 or 3.1.5.6 must be complied with again in full. Steps leading to re-establishment of free status may require depopulation, fallowing, disinfection and other measures, as described in Section 1.6, as well as zoning as described in Section 1.4.

Article 3.1.5.[18]9.

When importing live molluscs of [any age group] the species listed in Article 3.1.5.2 for re-immersion, 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* or a *certifying official* approved by the *importing country*.

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This *certificate* must certify, on the basis of a surveillance scheme conducted according to the procedures described [above] in Articles 3.1.5.5 or 3.1.5.6 (as applicable), whether or not the place of production of the consignment is a country, ~~or zone~~ or compartment [or aquaculture establishment] officially declared free from [infection with] *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Aquatic Code*. This certificate may not be required for commodities that can be traded safely (see Article 3.1.5.2)

Article 3.1.5.[19]10.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.9, or cannot certify that the consignment originates from a country, zone or compartment place of production as being free from [infection with] *Marteilia refringens*, the *importing country* should assess the risks of introduction and establishment of *Marteilia refringens* associated with the importation of live molluscs of the species listed in Article 3.1.5.2 from the *exporting country*, or seek assurance from the *exporting country* that basic biosecurity disease security conditions are met, prior to a decision on whether to authorise an importation. The importing country should also consider applying risk management measures. This assessment should be made available to the exporting country.

Article 3.1.5.11.

When importing live molluscs of species other than those listed in Article 3.1.5.2, the Competent Authority of the importing country should assess the risk of introduction and establishment of Marteilia refringens associated with the importation prior to a decision on whether to authorise the importation, taking into account, for example, whether there is evidence for or against the presence of Marteilia refringens in the place of origin. The importing country should also consider applying risk management measures. This assessment should be made available to the exporting country.

The international aquatic animal health certificate may not be required for mollusc species that have been demonstrated not to be vectors of Marteilia refringens and listed in Article 3.1.5.2, even if the molluscs originate from an infected country or zone.

Article 3.1. 5.[20]12.

When importing live molluscs of [of commercial size] the species listed in Article 3.1.5.2 destined for human consumption, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of a surveillance scheme conducted according to the procedures described [above and detailed in the *Aquatic Manual*] in Articles 3.1.5.5 or 3.1.5.6 (as applicable), whether or not the place of production of the consignment is a country, ~~or zone~~ or compartment [or aquaculture establishment] officially declared free from *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Aquatic Code*. This certificate may not be required for commodities that can be traded safely (see Article 3.1.5.2) if the imported molluscs are destined for:

- 1) direct human consumption without any re-immersion, or
- 2) storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of Marteilia refringens.

Article 3.1. 5.[21]13.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.12, or cannot certify that the consignment originates from a country, zone or compartment place of production as being free from [infection with] *Marteilia refringens*, the *importing country* should assess the risks of introduction and establishment of *Marteilia refringens* associated with the importation [of molluscs of commercial size destined for human consumption] from the *exporting country* of molluscs of the species listed in Article 3.1.5.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these risks, if the consignment is destined for:

- 1) direct human consumption without any re-immersion, or
- 2) storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of *Marteilia refringens*.

Article 3.1.5.14.

Risk management

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.12, or cannot certify the place of production of the consignment as being free from *Marteilia refringens* or if *exporting country* is infected with *Marteilia refringens*, the *importing country* should assess the risk of introduction and establishment of *Marteilia refringens* associated with the importation from the *exporting country* of whole, or parts of, molluscs of the species referred to in Article 3.1.5.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these risks, if the consignment is:

- 1) for direct human consumption without any re-immersion, or
- 2) for storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of *Marteilia refringens*, or
- 3) has been processed, e.g. cooked, such that *Marteilia refringens* –if present– is inactivated.

Article 3.1. 5.14.

When importing live molluscs of species other than those listed in Article 3.1.5.2, the *importing country* should assess the risk of introduction and establishment of *Marteilia refringens* associated with the importation prior to a decision on whether to authorise the importation. This assessment should be made available to the *exporting country*.

Article 3.1. 5.[22]15

The *Competent Authorities* of *exporting countries* should not authorise the exportation of live molluscs from populations known to be infected with *Marteilia refringens* without the [full] prior agreement of the *importing country*.

[] deleted

CHAPTER 3.1.5.

INFECTION WITH *MARTEILIA REFRINGENS*

Article 3.1.5.1.

The disease agent is *Marteilia refringens*.

Article 3.1.5.2.

- 1) For the purpose of this *Aquatic Code*, susceptible species for infection with *Marteilia refringens* are: *Ostrea* species, in particular the European flat oyster (*Ostrea edulis*), Australian mud oyster (*Ostrea angasi*), Argentinean oyster (*Ostrea puelchana*) and Chilean flat oyster (*Ostrea chilensis*), the Pacific oyster, *Crassostrea gigas*, blue mussel, *Mytilus edulis* and Mediterranean mussel, *M. galloprovincialis*.

Marteilia refringens can cause subclinical infection in these susceptible species.

- 2) The following commodities can be traded safely without *Marteilia refringens* related restrictions and regardless of the *Marteilia refringens* status of the exporting country, zone or compartment:
 - a) Gametes, eggs and larvae;
 - b) Processed non-viable molluscs (cooked, canned, smoked or frozen);
 - c) Fresh non-viable molluscs of the species listed above, half-shell or off-shell fresh molluscs.
- 3) The following other commodities may pose a risk, but can be traded safely subject to the conditions prescribed in Articles 3.1.5.9, or 3.1.5.12, as applicable, relating to the *Marteilia refringens* status of the molluscs in the exporting country, zone or compartment:
 - a) Live molluscs of the species listed above destined for direct human consumption without any re-immersion or immersion in holding facilities that avoid the potential introduction of *Marteilia refringens*;
 - b) Live molluscs of the species listed above not destined for direct human consumption.
- 4) For mollusc commodities of unknown risk refer to Articles 3.1.5.10, 3.1.5.11 and 3.1.5.13 and 3.1.5.14

Article 3.1.5.3.

Suspect cases of natural infection with *Marteilia refringens* in species other than those listed in Article 3.1.5.2 should be referred immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article 3.1.5.4.

Methods for surveillance, diagnosis and confirmatory identification of *Marteilia refringens* are provided in the *Aquatic Manual*.

Article 3.1.5.5.

***Marteilia refringens* free country**

A country may *declare* itself free from *Marteilia refringens* if it meets the conditions in point 1) or 2) or 3) below.

If a country shares water bodies of coastal areas with one or more other countries, it can only *declare* itself a *Marteilia refringens* free country if all the shared coastal areas are *declared* *Marteilia refringens* free *zones* (see Article 3.1.5.6).

- 1) A country where none of the species listed in Article 3.1.5.2 is present and where no abnormal mortalities have been caused by infection with *Marteilia refringens* in other species for at least the past 25 years, as described in Chapter 3.1.3 of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the country for at least the previous 10 years and infection is not known to be established in wild populations;

OR

- 2) A country where the species listed in Article 3.1.5.2 are present, but there has never been any observed occurrence of infection with *Marteilia refringens* for at least the past 25 years despite conditions that are conducive to its clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the country for at least the previous 10 years and infection is not known to be established in wild populations;

OR

- 3) A country where the last known occurrence was within the previous 25 years or where the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression of the infection, as described in Chapter 3.1.3 of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when:
 - a) it meets *basic biosecurity conditions*; and
 - b) *targeted surveillance* as described in Chapters 1.1.4 and 3.1.3 in the *Aquatic Manual* has been in place for at least the past 2 years for species listed in Article 3.1.5.2 in *aquaculture establishments* or wild populations without detection of *Marteilia refringens*.

Article 3.1.5.6.

***Marteilia refringens* free zone or free compartment**

A *zone* or *compartment* free from *Marteilia refringens* may be established within the *territory* of one or more countries of infected or unknown status for *Marteilia refringens* and *declared* free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in point 1) or 2) or 3) below.

If a *zone* or *compartment* extends over more than one country, it can only be *declared* a *Marteilia refringens* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

- 1) In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where none of the species listed in Article 3.1.5.2 is present and where no abnormal mortalities have been caused by infection with *Marteilia refringens* in other species for at least the past 25 years, as described in Chapter 3.1.3 of the *Aquatic Manual*, may be *declared* free from *Marteilia refringens* when *basic biosecurity*

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conditions have been in place continuously in the *zone* or *compartment* for at least the previous 10 years and infection is not known to be established in wild populations;

OR

- 2) In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where the species listed in Article 3.1.5.2 are present, but there has not been any observed occurrence of infection with *Marteilia refringens* for at least the past 25 years despite conditions that are conducive to its clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the *Aquatic Manual*, may be *declared* free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the previous 10 years and infection is not known to be established in wild populations;

OR

- 3) A *zone* or *compartment* where the last known occurrence was within the previous 25 years or where the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, including gross signs and abnormal mortality, of the infection as described in Chapter 3.1.3 of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when:
 - a) it meets *basic biosecurity conditions*; and
 - b) *targeted surveillance* as described in Chapters 1.1.4 and 3.1.3 in the *Aquatic Manual* has been in place for at least the past 2 years for the species listed in Article 3.1.5.2 in *aquaculture establishments* or wild populations without detection of *Marteilia refringens*.

These provisions also apply if the *zone* or *compartment* to be *declared* free lies in an *Marteilia refringens*-infected country.

Article 3.1.5.7.

Maintenance of free status

A country or *zone* or *compartment* that is *declared* free from *Marteilia refringens* following the provisions of point 1) or 2) of Articles 3.1.5.5 or 3.1.5.6, respectively, may maintain its status provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is *declared* free from *Marteilia refringens* following the provisions of point 3) of Articles 3.1.5.5 or 3.1.5.6, respectively, may discontinue *targeted surveillance* and maintain its status as free from *Marteilia refringens* provided that conditions that are conducive to clinical expression, including gross signs and abnormal mortality, as described in Chapter 3.1.3 of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for *declared* free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression, including gross signs and abnormal mortality, *targeted surveillance* will need to be continued, but at a level commensurate with the degree of risk assessed by the *Competent Authority*.

Article 3.1.5.8.

Suspension and restoration of free status

If a *Competent Authority* has reason to believe that any of the conditions for maintaining its status as a *Marteilia refringens* free country or *zone* or *compartment* has been breached, the *Competent Authority* should

immediately suspend the free status, implement any necessary containment measures and conduct an investigation.

If the investigation confirms that the suspected breach has not taken place, free status may be restored.

If the investigation confirms that the suspected breach has taken place, suspension of free status is continued. The *Competent Authority* should carry out an epizootiological investigation to determine the likelihood of *Marteilia refringens* infection having occurred. If this investigation concludes that infection has not occurred, free status may be restored.

If the investigation confirms a significant likelihood that infection has occurred, the *Competent Authority* must declare that the free status is lost. In order to restore *Marteilia refringens* free status, the conditions in Articles 3.1.5.5 or 3.1.5.6 must be complied with again in full. Steps leading to re-establishment of free status may require depopulation, fallowing, disinfection and other measures, as described in Section 1.6, as well as zoning as described in Section 1.4.

Article 3.1.5.9.

When importing live molluscs of the species listed in Article 3.1.5.2 for re-immersion, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of a surveillance scheme conducted according to the procedures described in Articles 3.1.5.5 or 3.1.5.6 (as applicable), whether or not the place of production of the consignment is a country, zone or compartment declared free from *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Aquatic Code*. This certificate may not be required for commodities that can be traded safely (see Article 3.1.5.2)

Article 3.1.5.10.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.9, or cannot certify that the consignment originates from a country, zone or compartment free from *Marteilia refringens*, the *importing country* should assess the risks of introduction and establishment of *Marteilia refringens* associated with the importation of live molluscs of the species listed in Article 3.1.5.2 from the *exporting country*, or seek assurance from the *exporting country* that *basic biosecurity conditions* are met, prior to a decision on whether to authorise an importation. The *importing country* should also consider applying risk management measures. This assessment should be made available to the *exporting country*.

Article 3.1.5.11.

When importing live molluscs of species other than those listed in Article 3.1.5.2, the *Competent Authority* of the *importing country* should assess the risk of introduction and establishment of *Marteilia refringens* associated with the importation prior to a decision on whether to authorise the importation, taking into account, for example, whether there is evidence for or against the presence of *Marteilia refringens* in the place of origin. The *importing country* should also consider applying risk management measures. This assessment should be made available to the *exporting country*.

Article 3.1.5.12.

When importing live molluscs of the species listed in Article 3.1.5.2 destined for human consumption, 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* or a *certifying official* approved by the *importing country*.

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This *certificate* must certify, on the basis of a surveillance scheme conducted according to the procedures described in Articles 3.1.5.5 or 3.1.5.6 (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. 3 given in Part 6 of this *Aquatic Code*. This certificate may not be required for *commodities* that can be traded safely (see Article 3.1.5.2).

Article 3.1. 5.13.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.12, or cannot certify that the consignment originates from a country, *zone* or *compartment* free from *Marteilia refringens*, the *importing country* should assess the risks of introduction and establishment of *Marteilia refringens* associated with the importation from the *exporting country* of molluscs of the species listed in Article 3.1.5.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Article 3.1.5.14.

Risk management

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 3.1.5.12, or cannot certify the place of production of the consignment as being free from *Marteilia refringens* or if *exporting country* is infected with *Marteilia refringens*, the *importing country* should assess the risk of introduction and establishment of *Marteilia refringens* associated with the importation from the *exporting country* of whole, or parts of, molluscs of the species referred to in Article 3.1.5.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these risks, if the consignment is:

- 1) for direct human consumption without any re-immersion, or
- 2) for storage, during a short period before consumption, in tanks or holding facilities that ensure isolation from the local environment and avoid the potential introduction of *Marteilia refringens*, or
- 3) has been processed, e.g. cooked, such that *Marteilia refringens* – if present – is inactivated.

Article 3.1. 5.15

The *Competent Authorities* of *exporting countries* should not authorise the exportation of live molluscs from populations known to be infected with *Marteilia refringens* without the prior agreement of the *importing country*.

CHAPTER 4.1.2.

WHITE SPOT DISEASE

Article 4.1.2.1.

For the purposes of this *Aquatic Code*, the disease agent of white spot disease (WSD) is white spot syndrome virus (WSSV) in the genus *Whispovirus*. Synonyms commonly used in the scientific literature and official documents include: white spot virus (WSV), white spot bacilliform virus (WSBV), penaeid rod-shaped DNA virus (PRDV), and other names as listed in Chapter 4.1.2 of the *Aquatic Manual*.

Article 4.1.2.2.

Susceptible species

1) For the purpose of this *Aquatic Code*, all decapod (Order Decapoda) crustaceans, whether from marine, brackish or freshwater sources, are potential hosts for WSD. WSD is potentially lethal to most commercially cultivated penaeid (Family Penaeidae) shrimps and prawns. Transfers of other decapod crustaceans from marine, brackish water or freshwater sources to white spot free zones should be subject to risk analysis when there is evidence from experimental challenge studies that one or more species in the importing country and exporting country is susceptible to white spot disease.

[The disease agent listed in Article 4.1.2.1] WSSV can cause [asymptomatic] *subclinical* infection in these [respective susceptible] species [listed in Article 4.1.2.2].

~~2) Experimental WSD infections have been reported in many decapod species in which natural infections have not been recorded.~~

2) The following commodities can be traded safely without WSD-related restrictions and regardless of the WSD status of the exporting country, zone or compartment:

a) Cooked, canned or dried crustaceans for direct human consumption;

b) Crustacean by-products, such as flame-dried or sun-dried shrimp meal intended for use in animal feeds;

c) Artemia cysts.

3) The following other commodities may pose a risk, but can be traded safely subject to the conditions prescribed in Articles 4.1.2.9 or 4.1.2.12, as applicable, relating to the WSD status of the crustaceans in the exporting country, zone or compartment:

a) Peeled deveined and breaded crustaceans;

b) Frozen whole crustaceans, frozen tails/claws, whether block frozen or individually quick frozen;

c) Live whole crustaceans.

4) For crustacean commodities of unknown risk, refer to Articles 4.1.2.10, 4.1.2.11, 4.1.2.13 and 4.1.2.14.

[Article 4.1.2.3.]

The disease agent listed in Article 4.1.2.1 can cause asymptomatic infection in their respective susceptible species listed in Article 4.1.2.2.

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Article 4.1.2.4.

Experimental WSD infections have been reported in many decapod families where natural infections have not been reported.]

Article 4.1.2.[5]3

Suspect cases of natural infection with [the agent listed in Article 4.1.2.1] WSSV in species other than those [listed] referred to in Article[s] 4.1.2.2 [and Article 4.1.2.3] should be [referred] submitted immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article 4.1.2.[6]4.

Methods for surveillance, diagnosis and confirmatory identification of [of the disease agent] WSD are provided in the *Aquatic Manual*.

Article 4.1.2.[7]5.

WSD free country

A country may declare itself ~~be~~ [considered] officially declared free from WSD if it meets the conditions in [Articles 4.1.2.8, or 4.1.2.9] point 1) or 2) below.

If a country shares a water resource (coastal zone, gulf, inland farming area, etc.) with one or more other countries, it can only declare itself ~~be declared~~ a WSD free country if all the areas covered by the shared water resource are declared free zones (see Article[s] 4.1.2.10 to 4.1.2.12] 4.1.2.6).

[Article 4.1.2.8.]

1) A country where none of the species [listed] referred to in Article[s] 4.1.2.2 [and 4.1.2.3] is present or where these species are present but there has never been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 4.1.2 of the Aquatic Manual, may declare itself ~~be~~ officially declared [considered] free from WSD when [prescribed biosecurity] basic biosecurity disease security conditions have been in place continuously in the country for at least the previous 10years and infection is not known to be established in wild populations. [as follows:

- 1) WSD is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) an *early detection system* is in place within the country enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and training of veterinarians or crustacean health specialists in detecting and reporting unusual disease occurrence; and
- 3) infection is not known to be established in wild populations; and
- 4) conditions applied to imports to prevent the introduction of WSD (e.g. with importation of live crustaceans for aquaculture purposes or *commodity* products intended for reprocessing prior to *marketing*, etc.) into the country are in place (see Section 1.4)]

[Article 4.1.2.9.]

OR

2) A country where the last known clinical occurrence was within the previous 25 years or the infection status prior to targeted surveillance was [previously] unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 4.1.2 of the Aquatic Manual, may declare itself ~~be~~ officially declared [considered] free from WSD when:

- a) it meets [the prescribed biosecurity] basic biosecurity disease security conditions [detailed in Article 4.1.2.8]; and
- b) *targeted surveillance* as described in Chapters 1.1.4 and 4.1.2 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the [susceptible] species [listed] referred to in Article[s] 4.1.2.2 [and 4.1.2.3] without detection of [the disease agent listed in Article 4.1.2.1] WSSV. If there are areas of the country in which there are no such *aquaculture establishments* but in which there are wild populations of any of the [susceptible] species [listed] referred to in Article[s] 4.1.2.2 [and 4.1.2.3], those populations must be included in the *targeted surveillance*.

Article 4.1.2.[10]6.

WSD free zone or free compartment

A *zone or compartment* free from WSD may be established within the *territory* of one or more countries of infected or unknown status for WSD and officially declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone or compartment* meets the conditions referred to in [Articles 4.1.2.11. or 4.1.2.12] point 1) or 2) below.

~~Such WSD free zones must comprise: one or more distinct water resource (coastal zone, gulf, inland farming area, etc.). Such zones must be clearly delineated on a map of the territory of the country(ies) concerned by the Competent Authority.~~

If a *zone or compartment* extends over more than one country, it can only be *declared* a WSD free *zone or compartment* if the conditions outlined below apply to all [shared] areas of the *zone or compartment*.

[Article 4.1.2.11.]

1) In a country of unknown status for WSD, a *zone or compartment* where none of the species [listed] referred to in Article[s] 4.1.2.2 [and 4.1.2.3] is present or where these species are present but there has not been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 4.1.2 of the Aquatic Manual, may officially declared itself [considered] free from WSD when [prescribed biosecurity] basic biosecurity disease security conditions have been in place continuously in the *zone or compartment* for at least the previous 2 years [as follows:

- 1) WSD is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) an *early detection system* is in place within the *zone* enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and veterinarians or crustacean health specialists are trained in detecting and reporting unusual disease occurrence; and] and infection is not known to be established in wild populations, and official control measures to prevent the introduction of WSD (e.g. with importation of live crustaceans for aquaculture purposes or *commodity* products intended for reprocessing prior to *marketing*, etc.) into the *zone or compartment* are in place.

[Article 4.1.2.12.]

OR

2) A *zone or compartment* where the last known clinical occurrence was within the previous 25 years or the infection status prior to targeted surveillance was [previously] unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 4.1.2 of the Aquatic Manual, may declare itself be officially declared [considered] free from WSD when:

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- a) it meets [the prescribed biosecurity] basic biosecurity disease security conditions [detailed in Article 4.1.2.11]; and
- b) *targeted surveillance* as described in Chapters 1.4 and 4.1.2 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the [susceptible] species [listed] referred to in Article[s] 4.1.2.2 [and 4.1.2.3] without detection of [the disease agent listed in Article 4.1.2.1] WSSV. If there are areas of the *zone* or compartment in which there are no such *aquaculture establishments* but in which there are wild populations of any of the [susceptible] species [listed] referred to in Article[s] 4.1.2.2 [and 4.1.2.3], those populations must be included in the *targeted surveillance*.

These provisions also apply if the *zone* or compartment to be officially declared free lies in a WSD-infected country.

[Article 4.1.2.13.]

WSD free aquaculture establishment

A WSD free *aquaculture establishment* may be located within a WSD infected country or zone or within a country or zone of unknown status with respect to WSD if it meets the conditions referred to in Articles 4.1.2.14 or 4.1.2.15. Such WSD free *aquaculture establishments* must be supplied by a contained water source (e.g. a well, borehole, closed recirculation system, etc.) in which the culture system water cannot be contaminated by the disease agent and is inaccessible to susceptible species or potential carriers from the natural environment.

Article 4.1.2.14.

An *aquaculture establishment* where none of the species listed in Articles 4.1.2.2 and 4.1.2.3 is present or where there has never been any observed occurrence of the disease despite conditions that are conducive to its clinical expression may be considered free from WSD when *prescribed biosecurity conditions* have been in place continuously in the *aquaculture establishment* for at least the previous 2 years as follows:

- 1) WSD is compulsorily notifiable to the *Competent Authority*, including notification of suspicion; and
- 2) the *aquaculture establishment* complies with an *early detection system* enabling the *Competent Authority* to undertake effective disease investigation and reporting, including access to laboratories capable of diagnosing and differentiating relevant diseases, and the staff are trained in detecting and reporting unusual disease occurrence; and
- 3) official control measures to prevent the introduction of WSD into the *aquaculture establishment* are in place.

Article 4.1.2.15.

An *aquaculture establishment* where the last known occurrence of WSD was within the previous 25 years or the infection status was previously unknown, for example because of the absence of conditions conducive to clinical expression, may be considered free from WSD when:

- 1) it meets the *prescribed biosecurity conditions* detailed in Article 4.1.2.14; and
- 2) *targeted surveillance* as described in chapters 1.4 and 4.1.2 in the *Aquatic Manual* has been in place for at least the past 2 years without detection of the disease agent listed in Article 4.1.2.1.]

Article 4.1.2.[16].

Maintenance of free status

A country or zone or compartment [or aquaculture establishment] that is [considered] officially declared free from WSD following the provisions of [Articles 4.1.2.8, 4.1.2.11 and 4.1.2.14] point 1) of Articles 4.1.2.5 or 4.1.2.6, respectively, may maintain its status as WSD free provided that [the prescribed biosecurity] basic biosecurity disease security conditions are continuously maintained.

A country or zone or compartment [or aquaculture establishment] that is [considered] officially declared free from WSD following the provisions of [Articles 4.1.2.9, 4.1.2.12 and 4.1.2.15] point 2) of Articles 4.1.2.5 or 4.1.2.6,

respectively, may discontinue *targeted surveillance* and maintain its status as WSD free provided that conditions that are conducive to clinical expression of WSD, as described in Chapter 4.1.2 of the *Aquatic Manual*, exist and [the prescribed biosecurity] basic biosecurity disease security conditions are continuously maintained.

However, for officially declared free zones or compartment in infected countries and in all cases where conditions are not conducive to clinical expression of WSD, *targeted surveillance* will need to be continued, but at a level commensurate with the degree of risk assessed by the *Competent Authority*.

Article 4.1.2.[17]8.

Suspension and restoration of free status

If a *Competent Authority* has reason to believe that any of the conditions for [recognition of country, zone or aquaculture establishment freedom] maintaining its status as a WSD free country or zone or compartment has been breached, it should immediately suspend the free status, implement any necessary containment measures and conduct an investigation.

If the investigation confirms that the suspected breach has not taken place, free status may be restored.

If the investigation confirms that the suspected breach has taken place, suspension of free status is continued. The *Competent Authority* should carry out an epizootiological investigation to determine the likelihood of WSD infection having occurred disease entry and establishment [and re-establish the conditions in Articles 4.1.2.7. to 4.1.2.9, 4.1.2.10. to 4.1.2.12, or 4.1.2.13. to 4.1.2.15 if free status is to be restored. Steps leading to re-establishment of free status may require depopulation, fallowing, disinfection and other measures as described in Section 1.6]. If this investigation concludes that infection has disease entry and establishment have not occurred, free status may be restored.

If the investigation confirms a significant likelihood that infection has disease entry and establishment have occurred, the Competent Authority must declare that the free status is lost. In order to restore free status, the conditions in Article 4.1.2.5 or 4.1.2.6 must be complied with again in full. Steps leading to re-establishment of free status may require depopulation, fallowing, disinfection and other measures as described in Section 1.6, as well as zoning as described in Section 1.4.

Article 4.1.2.[18]9.

When importing live crustaceans of [any life stage] the [susceptible] species referred to in Article 4.1.2.1, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of [a surveillance scheme conducted according to the procedures described above and detailed in the *Aquatic Manual*] the procedures described in Articles 4.1.2.5 or 4.1.2.6 (as applicable), whether or not the place of production of the consignment is a country, or zone or compartment [or aquaculture establishment] officially declared free from WSD.

The certificate shall be in accordance with Model Certificate No. 4 given in Part 6 of this *Aquatic Code*. The certificate may not be required for *commodities* that can be traded safely (see Article 4.1.2.2).

Article 4.1.2.[19]10.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 4.1.2.9, or cannot certify that the consignment originates from a country, zone or compartment the place of production of the consignment as being free from WSD, the *importing country* should assess the risk[s] of introduction and establishment of WSSV associated with the importation of live crustaceans of [any life stage] the species referred in Article 4.1.2.2, from the exporting country or seek assurance from the exporting

country that basic biosecurity disease security conditions are met prior to a decision on whether to authorise an importation. The importing country should also consider applying risk management measures. This assessment should be made available to the exporting country.

Article 4.1.2.11.

When importing live crustaceans of species other than those referred to in Article 4.1.2.2, the Competent Authority of the importing country should assess the risk of introduction and establishment of WSD associated with the importation prior to a decision on whether to authorise the importation, taking into account, for example, whether there is evidence for or against the presence of WSSV in the place of origin. The importing country should also consider applying risk management measures. This assessment should be made available to the exporting country.

Article 4.1.2.[20]12.

When importing dead crustaceans of the species referred to in Article 4.1.2.2, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of [a surveillance scheme conducted according to the procedures described above and detailed in the Aquatic Manual] the procedures described in Articles 4.1.2.5 or 4.1.2.6 (as applicable), whether or not the place of production is a *country*, ~~or zone~~ or compartment [or aquaculture establishment] officially declared free from WSD.

The certificate shall be in accordance with Model Certificate No. 5 given in Part 6 of this *Aquatic Code*. This certificate may not be required for commodities that can be traded safely (see Article 4.1.2.2).

Article 4.1.2.[21]13.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 4.1.2.12, or cannot certify that the consignment originates from a country, zone or compartment the place of production of the consignment as being free from WSD, the *importing country* should assess the risk[s] of introduction and establishment of WSSV associated with the importation from the exporting country of whole, or parts of, dead crustaceans of the species referred to in Article 4.1.2.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the exporting country.

Rather than refusing such imports, the importing country may opt to manage these risks, if the consignment is:

- 1) — destined directly for human consumption without further processing, or
- 2) — destined for processing in establishments with safe disposal of processing waste in a manner that ensures isolation from the local environment to avoid the potential introduction of [WSD] WSSV, or
- 3) — has been treated, e.g. cooked, such that [white spot virus] WSSV is inactivated.

Article 4.1.2.14.

Risk management

If the Competent Authority of the exporting country does not provide the certificate referred to in Article 4.1.2.12, or cannot certify the place of production of the consignment as being free from WSD or if exporting country is infected with WSSV, the importing country should assess the risk of introduction and

establishment of WSSV associated with the importation from the *exporting country* of whole, or parts of, crustaceans of the species referred to in Article 4.1.2.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these risks, if the consignment is:

- 1) *destined directly for human consumption without further processing, or*
- 2) *destined for processing in establishments with safe disposal of processing waste in a manner that ensures isolation from the local environment to avoid the potential introduction of WSSV, or*
- 3) *has been treated, e.g. cooked, such that WSSV –if present- is inactivated.*

Article 4.1.2.[22]15.

The *Competent Authorities* of *exporting countries* should not authorise the exportation of live or dead crustaceans [of any life stage] from populations known to be infected with [WSD] WSSV without the [full] prior agreement of the *importing country*.

[] deleted

CHAPTER 4.1.2.

WHITE SPOT DISEASE

Article 4.1.2.1.

For the purposes of this *Aquatic Code*, the disease agent of white spot disease (WSD) is white spot syndrome virus (WSSV) in the genus *Whispovirus*. Synonyms commonly used in the scientific literature and official documents include: white spot virus (WSV), white spot bacilliform virus (WSBV), penaeid rod-shaped DNA virus (PRDV), and other names as listed in Chapter 4.1.2 of the *Aquatic Manual*.

Article 4.1.2.2.

- 1) For the purpose of this *Aquatic Code*, all decapod (Order Decapoda) crustaceans, whether from marine, brackish or freshwater sources, are potential hosts for WSD. WSD is potentially lethal to most commercially cultivated penaeid (Family Penaeidae) shrimps and prawns. Transfers of other decapod crustaceans from marine, brackish water or freshwater sources to white spot free *zones* should be subject to risk analysis when there is evidence from experimental challenge studies that one or more species in the *importing country* and *exporting country* is susceptible to white spot disease.

WSSV can cause *subclinical* infection in these species.

- 2) The following *commodities* can be traded safely without WSD-related restrictions and regardless of the WSD status of the *exporting country*, *zone* or *compartment*:
 - a) Cooked, canned or dried crustaceans for direct human consumption;
 - b) Crustacean by-products, such as flame-dried or sun-dried shrimp meal intended for use in animal feeds;
 - c) *Artemia* cysts.
- 3) The following other *commodities* may pose a risk, but can be traded safely subject to the conditions prescribed in Articles 4.1.2.9 or 4.1.2.12, as applicable, relating to the WSD status of the crustaceans in the *exporting country*, *zone* or *compartment*:
 - a) Peeled deveined and breaded crustaceans;
 - b) Frozen whole crustaceans, frozen tails/claws, whether block frozen or individually quick frozen;
 - c) Live whole crustaceans.
- 4) For crustacean *commodities* of unknown risk, refer to Articles 4.1.2.10, 4.1.2.11, 4.1.2.13 and 4.1.2.14.

Article 4.1.2.3

Suspect cases of natural infection with WSSV in species other than those referred to in Article 4.1.2.2 should be submitted immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article 4.1.2.4.

Methods for surveillance, diagnosis and confirmatory identification of WSD are provided in the *Aquatic Manual*.

Article 4.1.2.5.

WSD free country

A country may *declare* itself free from WSD if it meets the conditions in point 1) or 2) below.

If a country shares a water resource (coastal zone, gulf, inland farming area, etc.) with one or more other countries, it can only *declare* itself a WSD free country if all the areas covered by the shared water resource are *declared* free *zones* (see Article 4.1.2.6).

- 1) A country where none of the species referred to in Article 4.1.2.2 is present or where these species are present but there has never been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 4.1.2 of the *Aquatic Manual*, may *declare* itself free from WSD when *basic biosecurity conditions* have been in place continuously in the country for at least the previous 10 years and infection is not known to be established in wild populations.

OR

- 2) A country where the last known clinical occurrence was within the previous 25 years or the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 4.1.2 of the *Aquatic Manual*, may *declare* itself free from WSD when:
 - a) it meets *basic biosecurity conditions*; and
 - b) *targeted surveillance* as described in Chapters 1.1.4 and 4.1.2 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the species referred to in Article 4.1.2.2 without detection of WSSV. If there are areas of the country in which there are no such *aquaculture establishments* but in which there are wild populations of any of the species referred to in Article 4.1.2.2, those populations must be included in the *targeted surveillance*.

Article 4.1.2.6.

WSD free zone or free compartment

A *zone* or *compartment* free from WSD may be established within the *territory* of one or more countries of infected or unknown status for WSD and *declared* free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in point 1) or 2) below.

If a *zone* or *compartment* extends over more than one country, it can only be *declared* a WSD free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

- 1) In a country of unknown status for WSD, a *zone* or *compartment* where none of the species referred to in Article 4.1.2.2 is present or where these species are present but there has not been any observed occurrence of the disease for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 4.1.2 of the *Aquatic Manual*, may *declared* itself free from WSD when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the previous 2 years and infection is not known to be established in wild populations, and official control measures to prevent the introduction of WSD (e.g. with importation of live crustaceans for aquaculture purposes or *commodity* products intended for reprocessing prior to *marketing*, etc.) into the *zone* or *compartment* are in place.

OR

- 2) A *zone* or *compartment* where the last known clinical occurrence was within the previous 25 years or the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter 4.1.2 of the *Aquatic Manual*, may declare itself free from WSD when:
- a) it meets *basic biosecurity conditions* ; and
 - b) *targeted surveillance* as described in Chapters 1.1.4 and 4.1.2 of the *Aquatic Manual* has been in place for at least the past 2 years in *aquaculture establishments* holding any of the species referred to in Article 4.1.2.2 without detection of WSSV. If there are areas of the *zone* or *compartment* in which there are no such *aquaculture establishments* but in which there are wild populations of any of the species referred to in Article 4.1.2.2 , those populations must be included in the *targeted surveillance*.

These provisions also apply if the *zone* or *compartment* to be declared free lies in a WSD-infected country.

Article 4.1.2.7.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from WSD following the provisions of point 1) of Articles 4.1.2.5 or 4.1.2.6, respectively, may maintain its status as WSD free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from WSD following the provisions of point 2) of Articles 4.1.2.5 or 4.1.2.6, respectively, may discontinue *targeted surveillance* and maintain its status as WSD free provided that conditions that are conducive to clinical expression of WSD, as described in Chapter 4.1.2 of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartment* in infected countries and in all cases where conditions are not conducive to clinical expression of WSD, *targeted surveillance* will need to be continued, but at a level commensurate with the degree of risk assessed by the *Competent Authority*.

Article 4.1.2.8.

Suspension and restoration of free status

If a *Competent Authority* has reason to believe that any of the conditions for maintaining its status as a WSD free country or *zone* or *compartment* has been breached, it should immediately suspend the free status, implement any necessary containment measures and conduct an investigation.

If the investigation confirms that the suspected breach has not taken place, free status may be restored.

If the investigation confirms that the suspected breach has taken place, suspension of free status is continued. The *Competent Authority* should carry out an epizootiological investigation to determine the likelihood of WSD *infection* having occurred. If this investigation concludes that *infection* has not occurred, free status may be restored.

If the investigation confirms a significant likelihood that *infection* has occurred, the *Competent Authority* must declare that the free status is lost. In order to restore free status, the conditions in Article 4.1.2.5 or 4.1.2.6 must be complied with again in full. Steps leading to re-establishment of free status may require

depopulation, *fallowing*, *disinfection* and other measures as described in Section 1.6, as well as zoning as described in Section 1.4.

Article 4.1.2.9.

When importing live crustaceans of the species referred to in Article 4.1.2.1, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 4.1.2.5 or 4.1.2.6 (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from WSD.

The certificate shall be in accordance with Model Certificate No. 4 given in Part 6 of this *Aquatic Code*. The certificate may not be required for *commodities* that can be traded safely (see Article 4.1.2.2).

Article 4.1.2.10.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 4.1.2.9, or cannot certify that the consignment originates from a country, *zone* or *compartment* free from WSD, the *importing country* should assess the risk of introduction and establishment of WSSV associated with the importation of live crustaceans of the species referred in Article 4.1.2.2, from the *exporting country* or seek assurance from the *exporting country* that *basic biosecurity conditions* are met prior to a decision on whether to authorise an importation. The importing country should also consider applying risk management measures. This assessment should be made available to the *exporting country*.

Article 4.1.2.11.

When importing live crustaceans of species other than those referred to in Article 4.1.2.2, the *Competent Authority* of the *importing country* should assess the risk of introduction and establishment of WSD associated with the importation prior to a decision on whether to authorise the importation, taking into account, for example, whether there is evidence for or against the presence of WSSV in the place of origin. The importing country should also consider applying risk management measures. This assessment should be made available to the *exporting country*.

Article 4.1.2.12.

When importing dead crustaceans of the *species* referred to in Article 4.1.2.2, 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* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 4.1.2.5 or 4.1.2.6 (as applicable), whether or not the place of production is a country, *zone* or *compartment* declared free from WSD.

The certificate shall be in accordance with Model Certificate No. 5 given in Part 6 of this *Aquatic Code*. This certificate may not be required for *commodities* that can be traded safely (see Article 4.1.2.2).

Article 4.1.2.13.

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 4.1.2.12, or cannot certify that the consignment originates from a country, *zone* or *compartment* free from WSD, the *importing country* should assess the risk of introduction and establishment of WSSV associated with the importation from the *exporting country* of whole, or parts of, dead crustaceans of the species

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referred to in Article 4.1.2.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Article 4.1.2.14.

Risk management

If the *Competent Authority* of the *exporting country* does not provide the certificate referred to in Article 4.1.2.12, or cannot certify the place of production of the consignment as being free from WSD or if *exporting country* is infected with WSSV, the *importing country* should assess the risk of introduction and establishment of WSSV associated with the importation from the *exporting country* of whole, or parts of, crustaceans of the species referred to in Article 4.1.2.2, including consideration of applying risk management measures, prior to a decision on whether to authorise an importation. This assessment should be made available to the *exporting country*.

Rather than refusing such imports, the *importing country* may opt to manage these risks, if the consignment is:

- 1) destined directly for human consumption without further processing, or
- 2) destined for processing in establishments with safe disposal of processing waste in a manner that ensures isolation from the local environment to avoid the potential introduction of WSSV, or
- 3) has been treated, e.g. cooked, such that WSSV – if present – is inactivated.

Article 4.1.2.15.

The *Competent Authorities* of *exporting countries* should not authorise the exportation of live or dead crustaceans from populations known to be infected with WSSV without the prior agreement of the *importing country*.

Model Certificate No. 1.

**INTERNATIONAL AQUATIC ANIMAL
HEALTH CERTIFICATE FOR
LIVE FISH AND GAMETES**

LIVE FISH AND GAMETES

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

- Cultured stocks Wild stocks Fish Sperm Unfertilised eggs
 Fertilised eggs Larvae

1) Species

Latin Scientific name:.....

Common name:.....

2) Age (years): Unknown 0+ 1+ 2+ >2+

3) Total weight (kg):.....

OR

Number (£1000):.....

II. Place of harvest production

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

III. Origin of consignment (if different from II)

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

IV. Destination

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

4) Nature and identification of means of transport:.....

.....

V. Declaration

I, the undersigned, certify that the live fish and/or fish larvae, fish gametes, ova and fertilised eggs in the present consignment have as their place of production a: Country, Zone, Aquaculture establishment that has been subjected to an official fish health surveillance scheme according to the procedures described in the OIE *Manual of Diagnostic Tests for Aquatic Animals* and that the Country, Zone or Aquaculture establishment identified in Section II is officially recognised as being free from the pathogens causing the diseases listed in the *Aquatic Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Epizootic haematopoietic necrosis						
Infectious haematopoietic necrosis						
<i>Oncorhynchus masou</i> virus disease						
Spring viraemia of carp						
Viral haemorrhagic septicaemia						
And any of the following if required by the importing country						
Channel catfish virus disease						
Viral encephalopathy and retinopathy						
Infectious pancreatic necrosis						
Infectious salmon anaemia						
Epizootic ulcerative syndrome						
Bacterial kidney disease (<i>Renibacterium salmoninarum</i>)						
Enteric septicaemia of catfish (<i>Edwardsiella ictaluri</i>)						
Piscirickettsiosis (<i>Piscirickettsia salmonis</i>)						
Gyrodactylosis (<i>Gyrodactylus salaris</i>)						
Red sea bream iridoviral disease						
White sturgeon iridoviral disease						

Exporting country:.....

Competent Authority:.....

Stamp:

Date:.....

Issued at:.....

Name and address of Certifying Official:

.....

Signature:.....

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

Model Certificate No. 2.

INTERNATIONAL AQUATIC ANIMAL
HEALTH CERTIFICATE FOR
DEAD **UNEVISCERATED** FISH

DEAD **UNEVISCERATED** FISH

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

Eviscerated **Uneviscerated**

Cultured stocks Wild stocks

1) Species:

Latin Scientific name:.....

Common name:.....

2) Age (years): Unknown 0+ 1+ 2+ >2+

3) Total weight (kg):.....

OR

Number (£1000):.....

II. Place of production

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

III. Destination

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

4) Nature and identification of means of transport:.....

.....

IV. Declaration

I, the undersigned, certify that the dead fish and/or fish products in the present consignment have as their place of production a: Country, Zone, Aquaculture establishment that has been subjected to an official fish health surveillance scheme according to the procedures described in the OIE *Manual of Diagnostic Tests for Aquatic Animals* and that the Country, Zone or Aquaculture establishment identified in Section II is officially recognised as being free from the pathogens causing the diseases listed in the *Aquatic Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Epizootic haematopoietic necrosis						
Infectious haematopoietic necrosis						
<i>Oncorhynchus mason</i> virus disease						
Spring viraemia of carp						
Viral haemorrhagic septicaemia						
And any of the following if required by the importing country						
Channel catfish virus disease						
Viral encephalopathy and retinopathy						
Infectious pancreatic necrosis						
Infectious salmon anaemia						
Epizootic ulcerative syndrome						
Bacterial kidney disease (<i>Renibacterium salmoninarum</i>)						
Enteric septicaemia of catfish (<i>Edwardsiella ictaluri</i>)						
Piscirickettsiosis (<i>Piscirickettsia salmonis</i>)						
Gyrodactylosis (<i>Gyrodactylus salaris</i>)						
Red sea bream iridoviral disease						
White sturgeon iridoviral disease						

Exporting country:.....

Competent Authority:.....

Stamp:

Date:.....

Issued at:.....

Name and address of Certifying Official:

.....

.....

.....

Signature:.....

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment

Model Certificate No. 3.

**INTERNATIONAL AQUATIC ANIMAL
HEALTH CERTIFICATE FOR
LIVE MOLLUSCS AND GAMETES**

LIVE MOLLUSCS AND GAMETES

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

Cultured stocks Wild stocks

1) Species:

Latin Scientific name:.....

Common name:.....

2) Age: Gametes Unknown >24 months 12! 24 months
 0! 11 months larvae

3) Total weight (kg):.....
 OR

Number (£1000):.....

II. Place of harvest production

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:
 Name:.....
 Location:.....

III. Origin of consignment (if different from II)

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:
 Name:.....
 Location:.....

IV. Destination

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:
 Name:.....
 Location:.....

4) Nature and identification of means of transport:.....

V. Declaration

I, the undersigned, certify that the live molluscs and/or gametes in the present consignment have as their place of **harvest production** a: Country, Zone, Aquaculture establishment that is subjected to an official mollusc health surveillance scheme according to the procedures described in the *OIE Manual of Diagnostic Tests for Aquatic Animals*, and that the Country, Zone or Aquaculture establishment identified in Sections II and III above is/are officially recognised as being free from the pathogens causing the diseases listed in the *Aquatic Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Infection with <i>Bonamia exitiosus</i>						
Infection with <i>Bonamia ostreae</i>						
Infection with <i>Haplosporidium nelsoni</i>						
Infection with <i>Marteilia refringens</i>						
Infection with <i>Marteilia sydneyi</i>						
Infection with <i>Mikrocytos mackini</i>						
Infection with <i>Mikrocytos roughleyi</i>						
Infection with <i>Perkinsus marinus</i>						
Infection with <i>Perkinsus olseni/atlanticus</i>						
And any of the following if required by the importing country						
Infection with <i>Candidatus Xenohalictis californiensis</i>						
Infection with <i>Haplosporidium costale</i>						

Exporting country:.....

Competent Authority:.....

Stamp:

Date:.....

Issued at:.....

Name and address of Certifying Official:

.....

.....

.....

Signature:.....

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

Model Certificate No. 4.

**INTERNATIONAL AQUATIC ANIMAL
HEALTH CERTIFICATE FOR
LIVE CRUSTACEANS**

LIVE CRUSTACEANS

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

Cultured stocks Wild stocks

1) Species:

Latin Scientific name:.....

Common name:.....

2) Age: Fertilised eggs or nauplii Postlarvae Juveniles Broodstock

3) Total weight (kg):.....

OR

Number (£1000):.....

II. Place of harvest production

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

III. Origin of consignment (if different from II)

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

IV. Destination

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

4) Nature and identification of means of transport:.....

.....

V. Declaration

I, the undersigned, certify that the live crustaceans in the present consignment have as their place of harvest production a: Country, Zone, Aquaculture establishment that is subjected to an official crustacean health surveillance scheme according to the procedures described in the OIE *Manual of Diagnostic Tests for Aquatic Animals*, and that the Country, Zone, or Aquaculture establishment identified in Sections II and III above is/are officially recognised as being free from the pathogens causing the diseases listed in the *Aquatic Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Taura syndrome						
White spot disease						
Yellowhead disease						
And any of the following if required by the importing country						
Tetrahedral baculovirus (<i>Baculovirus penaei</i>)						
Spherical baculovirus (<i>Penaeus monodon</i> - type baculovirus)						
Infectious hypodermal and haematopoietic necrosis						
Crayfish plague (<i>Aphanomyces astaci</i>)						
Spawner-isolated mortality virus disease						

Exporting country:.....

Competent Authority:.....

Stamp:

Date:.....

Issued at:.....

Name and address of Certifying Official:

.....

Signature:.....

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

Model Certificate No. 5.

**INTERNATIONAL AQUATIC ANIMAL
HEALTH CERTIFICATE FOR
DEAD CRUSTACEANS**

DEAD CRUSTACEANS

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

- Cultured stocks Wild stocks

1) Species:

Latin Scientific name:.....

Common name:.....

2) Quantity (total weight, kg):.....

OR

Number (£1000):.....

- 3) Head on animals Head off animals Peeled animals
 Block frozen Individually quick frozen Other processing method

II. Place of harvest production

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

III. Origin of consignment (if different from II)

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

IV. Destination

1) Country:.....

2) Zone:.....

3) Company:.....

4) Nature and identification of means of transport:.....

V. Declaration

I, the undersigned, certify that the dead crustaceans in the present consignment have as their place of harvest production a: Country, Zone, Aquaculture establishment that is subjected to an official crustacean health surveillance scheme according to the procedures described in the OIE *Manual of Diagnostic Tests for Aquatic Animals*, and that the Country, Zone, or Aquaculture establishment identified in Sections II and III above is/are officially recognised as being free from the pathogens causing the diseases listed in the *Aquatic Code*, as identified in the table below, and that the crustaceans have not been subjected to emergency harvest due to the suspicion or the confirmation of the presence of the diseases identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Taura syndrome						
White spot disease						
Yellowhead disease						
And any of the following if required by the importing country						
Tetrahedral baculovirus (<i>Baculovirus penaei</i>)						
Spherical baculovirus (<i>Penaeus monodon</i> - type baculovirus)						
Infectious hypodermal and haematopoietic necrosis						
Crayfish plague (<i>Aphanomyces astaci</i>)						
Spawner-isolated mortality virus disease						

Exporting country:.....

Competent Authority:.....

Stamp:

Date:.....

Issued at:.....

Name and address of Certifying Official:

.....

.....

.....

Signature:.....

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

APPENDIX 5.2.1.

GENERAL RECOMMENDATIONS ON DISINFECTION

Article 5.2.2.1.

Specific *disinfection* methods are provided in Chapter 1.1.5 of the *Aquatic Manual*.

Article 5.2.2.

Disinfection is employed as a common disease management tool in aquaculture. It may be used for disease prevention, control or eradication and to prevent the spread of infectious agents in and from an aquaculture establishment. *Disinfection* may consequently be used as a routine practice in biosecurity programmes designed to exclude specific diseases, as well as a routine sanitary measure employed to reduce disease incidence within *aquaculture establishments*.

Disinfection of installations and equipments should be carried out in places where and according to procedures and methods for which the risk of contamination to other waters and other aquatic animal populations is avoided. For example, organic material generated/removed during the cleaning process, such as pond sludge, etc., should be disposed in an appropriate manner that prevents spread of disease by such material and is environmentally safe. There is a great variety of products and processes to wash and disinfect installations or equipments that can be used in an *aquaculture establishment* including vehicles and boats. The correct choice of such products will depend on their efficacy, potential effect on aquatic animals and environmental impact, and costs induced by their use. *Disinfection* procedures should be part of a *disinfection* programme which establish the best and appropriate available methods to prevent the entry or decrease the load of targeted pathogens in an *aquaculture establishment*.

Following *disinfection* or stamping-out, the *aquaculture establishment* should be restocked from a disease-free source.

Article 5.2.4.3.

Disinfectants are chemical substances acting on micro-organisms and their vital cellular processes, either by controlling their multiplication or by killing the agent. There are two main groups:

1. Oxidative disinfectants (chlorides, iodides, iodophores) of high germicide power and action scope. They have a corrosive and irritant effect on surfaces and mucosa. The iodine present in iodophores is associated to other elements which improve their actions by giving them the humectant properties of detergents.
2. Disinfectants of selective actions (quaternary ammonia, phenols, formaldehyde and alcohol) acting on the cell membrane of the micro-organisms. Their germicide action depends on the dose. The higher the resistance of the micro-organisms to be controlled, the higher the disinfectant concentrations required.

Temperature is a determinant factor in the action of disinfectants. At high temperature, the disinfectant action is faster as long as the decomposition limit of the product is not reached. Similarly, pH also affects the action of disinfectants. For example, quaternary ammonia is more efficient at alkaline pH while iodine and iodophores are more efficient at neutral or acid pH.

Special attention ought to be paid to organic matters and greasy substances. It is recommended to clean thoroughly the surfaces to be disinfected before applying disinfectants since their actions can drastically decrease due to the presence of these elements.

The use of disinfectants entails the implementation of measures to protect personnel and cultured aquatic animals and to mitigate environmental effects. It is first necessary to protect the skin and eyes from contact with dangerous substances by using impermeable clothing, rubber boots, glasses and a hat. The respiratory tract must be protected by wearing a mask and the operator must not touch any food nor smoke without having thoroughly washed his/her hands. Finally, the disinfectants must be stored in a way that presents no direct or indirect danger to animal or human life and the environment.

Approved procedures for the use of disinfectants in aquaculture should be established. An approval scheme should consider *disinfection* effect against target pathogens, toxicological and ecotoxicological properties of the disinfectants.

Article 5.2.4.4.

The choice of *disinfection* procedures depends on the size, type and nature of the materials and facilities to be disinfected. The surfaces to be disinfected consist of fabric or woven material (clothes, nets), hard surfaces (plastic, cement) or permeable materials (earth, gravel). *Disinfection* is more difficult for permeable surfaces and requires more time. The skin of personnel must be disinfected with non-corrosive products.

Disinfection procedures must be established and used according to the objectives of *disinfection* and identified risks. Diseased aquatic animals, mortality fluids and tissues (viscera, blood, mucus, faeces, affluent waters) and the association of them to equipments and workers are risk factors in the transmission of pathogens, that could eventually infect healthy aquatic animal populations.

Basic *disinfection* protocols include the removal of all aquatic animals, dead and alive from the facility, a cleaning program which is designed to eliminate all the remaining organic matter adhered to the surfaces, the use of disinfectants on equipments and installations and a final step of neutralisation of chemical products.

When removing animals from the facilities prior to *disinfection*, the direct disposal of diseased populations of aquatic animals of any life stage or age into receiving waters is a dangerous practice which facilitates the spread of disease from farmed to wild populations or to neighbouring farms that use the same water supply. Such disposal should not be permitted. When the decision is made to discard a population due to the presence of disease, the stock in the tank or pond should be harvested and/or humanely killed in the tank or pond. The water in the tank or pond should be disinfected (see specific sections in Chapter 1.1.5 of the *Aquatic Manual*) prior to discharge. The emptied tank or pond should be disinfected prior to restocking.

***Aquatic Manual* disease chapter template**

1. Case definition

(Please start this chapter with a simple definition of the disease)

“For the purpose of this chapter, DISEASE NAME is considered to be INFECTION WITH PATHOGEN NAME.”

2. Information for the design of surveillance programmes

(Information on some of the following items is required for the design of surveillance programmes as described in Chapter 1.1.4 of the *Aquatic Manual*. Information on other items is needed to provide details on possible risk management and disease control measures as described in the *Aquatic Code*.

There is no need to split the sections a) to d) into subsections to address each item. Also, it is acknowledged that it will not be possible to provide – and reference – scientific data on each of these items for each disease; some aspects will be well covered, while there will be a dearth of information on others. Authors may wish to draw attention to areas where there is a significant lack of information).

a) Agent factors

- Aetiological agent, agent strains
- Survival outside the host
- Stability of the agent
- Life cycle

b) Host factors

- Susceptible host species
- Susceptible stages of the host
- Species or sub-population predilection (probability of detection)
- Target organs and infected tissue
- Persistent infection with lifelong carriers
- Vectors

c) Disease pattern

- Transmission mechanisms
- Prevalence
- Geographical distribution
- Mortality and morbidity
- Economic and/or production impact of the disease

d) Control and prevention

- Vaccination
- Chemotherapy
- Immunostimulation
- Resistance breeding
- Restocking with resistant species
- Blocking agents
- General husbandry practices

3. Diagnostic methods

(Please provide a description of diagnostic methods.)

The diagnostic methods should include the entire gambit of a disease investigation in a population or an individual animal, i.e. provide descriptions of the clinical, histological etc picture, and not simply the agent detection methods. In previous editions of the *Aquatic Manual*, this information was often captured in the introduction.

It is acknowledged that not all methods listed will be applicable to all diseases. Only the ones that are appropriate should be listed and described)

a) Field diagnostic methods

(This includes observation of the animal and its environment, and gross clinical examinations)

- Clinical signs

b) Clinical methods

(This includes methods that focus on the effects of the pathological agent on the host, rather than on agent detection)

- Gross pathology
- Clinical chemistry
- Microscopic pathology
 - Wet mounts
 - Smears
 - Fixed sections
- Electron microscopy/cytopathology

c) Agent detection and identification methods

(This includes methods that detect, possibly isolate and amplify, and identify the agent. For each method, information on the items in the text box on the right hand side should be provided. This information is required to allow the reader to follow the technique, but also to provide the necessary data – e.g. specificity and sensitivity – that are required for the development of a sampling and surveillance programme.)

- Direct detection methods
 - a. Microscopic methods
 - Wet mounts
 - Smears
 - Fixed sections
 - b. Agent isolation and identification
 - Cell culture/artificial media
 - Antibody-based antigen detection methods (IFAT, ELISA, ...)
 - Molecular techniques (PCR, ISH, sequencing...)
 - Agent purification
- Indirect detection methods
 - Serological methods

- | |
|---|
| <ul style="list-style-type: none"> ⇒ Samples to be taken ⇒ Technical procedure <ul style="list-style-type: none"> ▪ Positive/negative controls ⇒ Levels of validation <ul style="list-style-type: none"> ▪ Specificity and sensitivity ▪ Reference 'Gold' standard ⇒ Interpretation of results ⇒ Availability of test (from Reference Laboratories, commercial sources or easily synthesised) |
|---|

4. Rating of tests against purpose of use

(This information is needed to determine which test is appropriate for various purposes. For example, a particular method may be highly suitable to diagnose clinical cases of disease in individual animals of a certain age group, but the same method may be rather unsuitable for assessing the infection status of large numbers of clinically health animals. It is an assessment of the test's 'fitness for purpose'.)

	Purpose 1	Purpose 2		
Method 1				
Method 2				

5. Corroborative diagnostic criteria

(Please define, based on the information provided in 1.-4., what constitutes a suspect case of disease, and a confirmed case of disease. This information is required, for example for the purpose of disease investigations, especially in cases where 'free' status is threatened. It would also be required when surveillance of healthy populations yields controversial results, for example, positive PCR signals in the absence of any other evidence of infection.

The definitions of 'suspect' and 'confirmed' will most likely be a combination of positive results from a range of different methods as described under 3.

For example, a certain level of mortality at the right time of the year (see under 2b), in susceptible animals (see under 2a.), together with matching clinical signs (see under 3a), liver lesions and histopathology (see under 3b) could be sufficient for suspicion of DISEASE X. Several combinations may be possible. A confirmed case could be defined where in addition to the above, the agent has been detected. However, detection of viable agents without any disease signs could also constitute a confirmed case. The definitions may differ between different species and may depend on whether case is outside the known geographical/host range.)

a) Definition of suspect case

b) Definition of confirmed case

6. Prescribed diagnostic/detection methods to declare freedom

(Please prescribe the methods, based on the information provided in 1.-3., and assessed in 4., for *targeted surveillance* to declare freedom from infection as outlined in the *Aquatic Code*)

REFERENCES

(Please provide a list key references that confirm the information in the chapter and references that provide useful additional information. References should be to documents that are readily accessible.)

*
* *

PROTOCOL FOR THE PROPOSED NEW CONFIRMATORY TEST FOR SPRING VIRAEMIA OF CARP

1.2.2 Confirmatory identification methods

Polymerase chain reaction

The genome of spring viraemia of carp virus (SVCV) consists of a single strand of RNA of approximately 11 kb, with negative polarity. Amplification of a 714 bp fragment of SVCV cDNA is performed using primers derived from sequences of the region coding for the glycoprotein gene: 5'-TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC-3' (SVCVF1) and 5'-AGA-TGG-TAT-GGA-CCC-CAA-TAC-ATH*-ACN*-CAY*-3' SVC R2), using a modification of according to the method of Stone *et al.* (2003).

Total RNA¹¹ is extracted from 100 µl of viral supernatant from infected EPC cells using the Trizol Reagent™ and dissolved in 40 µl molecular biology grade water according to the method of Strommen & Stone (1997) DNase- and RNase-free water (BHD).

For cDNA synthesis, a reverse transcription reaction is performed at 37°C for 1 hour in a 20 µl volume consisting of 1 x M-MLV RT reaction buffer (50 mM Tris, pH 8.3, 75 mM KCl, 10 mM DTT, 3 mM MgCl₂) containing 1 mM dNTP, 100 pmol SVCV R2 primer, 20 units M-MLV reverse transcriptase (Promega, Southampton UK) or equivalent reverse transcriptase and 1/10 of the total RNA extracted above. Polymerase chain reaction (PCR) is performed in a 50 µl reaction volume 1 x PCR buffer (50 mM KCl, 10 mM Tris/HCl, pH 9.0, and 0.1% Triton X-100) containing 2.5 mM MgCl₂, 200 µM dNTPs, 50 pmol each of the SVCV R4 and SVCV F1 primers, 1.25 units of RedHot DNA polymerase (AB Gene, Epsom, UK) or equivalent Taq DNA polymerase, and 2.5 µl reverse transcription reaction mix. The reaction mix is overlaid with mineral oil and subjected to 35 temperature cycles of: 1 minute at 95°C, 1 minute at 55°C and 1 minute at 72°C followed by a final extension step of 10 minutes at 72°C. Amplified DNA (714 bp) is analysed by agarose gel electrophoresis

If the cytopathic effects in culture are not extensive it is possible that a product will not be generated using a single round of amplification. To avoid such problems use the semi-nested assay using primers:

5'-TCT-TGG-AGC-CAA-ATA-GCT-CAR*-R*TC-3' (SVCVF1) and

5'-CTG-GGG-TTT-CCN*-CCT-CAA-AGY*-TGY*-3' (SVC R4) according to Stone *et al.* (2003). The second round of PCR is performed in a 50 µl reaction volume 1 x PCR buffer (50 mM KCl, 10 mM Tris/HCl, pH 9.0, and 0.1% Triton X-100) containing 2.5 mM MgCl₂, 200 µM dNTPs, 50 pmol each of the SVCV R2 R4 and SVCV F1 primers, 1.25 units of RedHot DNA polymerase (AB Gene, Epsom, UK) or equivalent Taq DNA polymerase, and 2.5 µl of the first round product. The reaction mix is overlaid with mineral oil and subjected to 35 temperature cycles of: 1 minute at 95°C, 1 minute at 55°C and 1 minute at 72°C followed by a final extension step of 10 minutes at 72°C. Amplified DNA (606 bp) is analysed by agarose gel electrophoresis

All amplified products are confirmed as SVCV in origin by cloning¹² and sequencing, and the SVCV subtype (Ia-Id) is identified using a BLAST search (<http://www.ebi.ac.uk/blastall/index.html>) or by

¹¹ A number of total RNA extraction kits are available commercially that will produce high quality RNA suitable for RT-PCR. Examples are Trizol Reagent™ (BRL, Life Technologies, Paisley, UK), SV Total RNA isolation system (Promega) and Nucleospin® RNA (AB gene).

¹² In some cases where the cytopathic effect is extensive and the virus replicates to a high titre, sufficient PCR amplicon will be available for direct sequencing. Where the amplified product is weak it is recommended that the product be inserted into an appropriate sequencing vector (e.g. pGEM-T, pCR® 4- TOPO®) prior to undertaking the sequencing. At least two independent amplification and sequencing events should be undertaken to eliminate potential sequence errors introduced by the Taq polymerase.

phylogenetic analysis using the SVCV sequences available in the fish pathogen.net database. Phylogenetic analysis is undertaken using a 550 bp region corresponding to nucleotides 405–954 of the glycoprotein gene.

*SVCV primer annealing sites were identified by the alignment of the published amino acid sequences for the glycoprotein of SVCV (Bjorklund *et al.* 1996; Genbank accession no. U18101), and the vesicular stomatitis virus (VSV) New Jersey (Gallione & Rose 1983; Genbank accession no. V01214), and Piry strains (Genbank accession no. D26175). Primers were then designed to anneal to the regions encoding the conserved amino acids using the published sequence for SVCV (Bjorklund *et al.* 1996) as a skeleton, and introducing degenerate bases at the 3' termini to allow for potential differences in codon usage. The appropriate IUB codes have been used where appropriate.

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Aquatic Animals Commission Work Plan for 2004
Update <i>Aquatic Animal Health Code</i>
<ul style="list-style-type: none"> • Revise the list of diseases in the <i>Aquatic Code</i> • Revise all disease chapters in the <i>Aquatic Code</i>, in line with requirements for surveillance for recognition of freedom from infection • Harmonise horizontal chapters with those in the <i>Terrestrial Code</i> • Draft new <i>Aquatic Code</i> Chapter on disposal of aquatic animal waste • Develop guiding principles for the listing of closely related disease agents • Harmonise the naming principles for diseases of fish, molluscs and crustaceans
Update <i>Manual of Diagnostic Tests for Aquatic Animals</i>
<ul style="list-style-type: none"> • Revise the specific <i>Aquatic Manual</i> Chapters on disinfection of fish and of mollusc <i>aquaculture establishments</i> • Revise <i>Aquatic Manual</i> Chapter 1.1.4 (Requirements for surveillance for international recognition of freedom from infection) in line with changes made to the <i>Aquatic Code</i> • Develop a new template for disease chapters for future editions of the <i>Aquatic Manual</i> to be used by authors, including specific requirements for monitoring and surveillance • Ask authors for preparation of updates of disease chapters for the fifth edition of the <i>Aquatic Manual</i>
Meetings
<ul style="list-style-type: none"> • Aquaculture Biosecurity: Approaches to the Prevention, Control, and Eradication of Aquatic Animal Disease (Special Session of World Aquaculture Society Triennial Conference, 'Aquaculture 2004'), Hawaii, 3–5 March 2004 • OIE Global Conference on Aquatic Animal Disease Emergencies (target date: end of 2005) • Meetings of OIE Regional Commissions
Other issues
<ul style="list-style-type: none"> • Evaluate Member Countries' comments on proposed changes to the <i>Aquatic Code</i> and <i>Aquatic Manual</i> and make appropriate changes in time for submission to the OIE International Committee for adoption • Enhance the Commission's web pages • Develop criteria for identification of appropriate OIE-sponsored publications in the field of aquatic animal health • Consider new candidates for OIE Reference Laboratories for listed diseases • Evaluate annual reports (2003) of OIE Reference Laboratories and Collaborating Centre for aquatic animal diseases • Ask diagnostic chapter authors to update disease cards for listed diseases

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