COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING PAPER

Draft written positions of the Community on the report of the meeting of the OIE [World Organisation for Animal Health] Aquatic Animals Health Standards Commission [Paris January 2005] to be submitted for consideration before the General Session in May 2005

ANNEX A

EUROPEAN UNION

Brussels
E2 YT D(2005) 520484

Subject: Meeting of the Aquatic Animals Standards Commission – January 2005

Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of the Bureau of the Aquatic Animals Standards Commission.

The European Community wish to thank the OIE for the efforts done by the Aquatic Animals Standards Commission to circulate the unofficial version of the report so shortly after the meeting, in order to leave OIE Members sufficient time for reflection and elaboration of well prepared comments.

Thank you for the continued excellent collaboration and trust you will find our comments constructive and useful.

Jaana Husu-Kallio

Deputy Director General

Enclosures: 2

Copy: All CVOs Member States, Bulgaria, Iceland, Norway, Romania and Switzerland

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Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
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January 2005

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

Paris, 13–19 January 2005

The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Commission) met at the OIE Headquarters from 13 to 19 January 2005. 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. He thanked the members of the Commission for their dedicated and continuing good work.

He informed the Commission that meetings of the Aquatic Animals Commission, Terrestrial Animal Health Standards Commission and the Scientific Commission for Animal Diseases this year have been organised to allow coordination and harmonisation of their work and this arrangement will continue. He suggested that for next year, the Aquatic Animals Commission consider, if possible, also meeting with the Biological Standards Commission.

He drew attention to the recent meeting of the Administrative Commission, which drafted a new OIE strategic plan for 2005-2010, taking into account comments from Member Countries, with an increased emphasis on the OIE's work on aquatic animals.

The Commission examined draft revised texts related to the *Aquatic Animals Health Code* (hereafter referred to as the *Aquatic Code*) circulated for Member Countries' comment by the Bureau of the Commission after its October 2004 meeting, and comments received on those texts. The outcome of the Commission's work is presented as appendices to this report. Amendments made to existing chapters and previously circulated drafts are shown as double underlined text, with deleted text in strikeout. A yellow background is used to distinguish amendments and deletions made at this meeting from those made at the meeting of the Bureau in October 2004.

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

Member Countries are strongly encouraged to send comments on Appendices III to XII to the OIE Headquarters by **1 May 2005** to allow their examination before the OIE General Session. Subject to Member Countries' comment, Appendices III, IV, V, VII, VIII, IX, X, XI and XII will be proposed for adoption at the next OIE General Session.

1. *Member Countries' comments on the report of the meeting of the Bureau of the Commission (October 2004)*

Community position

The Community appreciates the efforts done by the OIE AAC with respect to submitting the report in a reasonable time after the AAC meeting.

The Aquatic Animals Commission was appreciative of the Member Countries that had responded to the request for comments: Australia, Argentina, European Union (EU), Italy, Morocco, New Zealand, Norway, Romania, the Slovak Republic, and the United States of America (USA). Comments were also received from the OIE Reference Laboratory for viral encephalopathy and retinopathy.

The Commission appreciates the increased number of Member Countries providing comments (despite the short time provided) and has planned the 2005 Bureau meeting for August to provide more time for comment prior to the January 2006 meeting of the Commission. The Commission also decided, in conjunction with the Director General, that in the future its reports would be circulated to OIE Reference Laboratories for comment but noted that responses would need to be sent to the OIE through the relevant Delegate.

The EU recommended that the International Database for Aquatic Animal Diseases be updated. The Commission is aware of the discrepancy between the disease list on the database and that in the *Aquatic Code*, but has decided to await the adoption of the new disease list prior to making the necessary changes. It is not intended to delete the data already accumulated for diseases that will be de-listed.

Member Countries' comments on specific agenda items are addressed in the relevant sections below.

2. *Aquatic Animal Health Code*

Community position

The Community appreciates the efforts done by the OIE AAC with respect to amendments of the Code. Technical comments are included in the relevant Appendices.

The Community can agree to proposals in Appendixes VII, VIII, XI, XII.

With regard to the proposals in Appendixes III, IV, V, IX, X, the Community have further comments that it would like to see taken into account before it can give its support.

2.1. Definitions (Chapter 1.1.1.)

The EU proposed new definitions for *Aquatic Animals* and *Aquaculture Animals* because they felt that wild fish were not sufficiently covered by the *Aquatic Code*. The Commission draws Member Countries' attention to the current definition of *Aquatic Animals* that already includes wild animals.

Other definitions were modified in line with the Member Countries' comments, and new definitions were proposed, as shown in Appendix III.

2.2. Revision of Chapter 1.1.2. on disease listing and notification criteria

New Zealand suggested changes to criteria 4, 5 and 6. The Commission considered the comments and decided that the suggested changes were not warranted at this time.

The EU reiterated its comment on criterion 1 (i.e. to make reference to the high cost of control measures for a disease), the Commission considers that it adequately addressed this item with the explanation given in its January 2004 meeting report.

In response to a comment from Australia, the Commission made a change to the wording of criterion 6.

In addition, the Commission removed a condition in criterion 7, which is inappropriate for listing of new diseases, and made the wording for criteria for immediate notification consistent with those in Chapter 1.2.1. (Notification and epidemiological information).

Those changes are shown in Appendix IV.

2.3. Revision of the list of diseases (Chapter 1.1.3.)

Community position

The Community will draw the attention of the OIE AAC to the fact that the Community did submit justification for retaining Microcytos mackini on the list. However, we apologies for the fact that it was not submitted within the deadline. There also appears to be some contradiction in the report, as it is stated in this section that the disease should be removed from the list, while it is maintained in the disease list in Appendix V. The Community considers that M mackini should remain on the list at Appendix V and the justification in support of this position is annexed to this document

The Commission considered Member Countries' comments on its suggested changes to the list of diseases, and appreciated the effort to which some Member Countries had gone to, at very short notice, to provide justification of their views. The Commission accepted some of the comments and made appropriate changes.

The Commission accepted Australia's concerns that the report of the Bureau meeting was unclear and that it did not explicitly request Member Countries' comments or evaluations of the recommendations of the *ad hoc* teams and appeared to seek comments only on the resulting list of diseases proposed by the Commission.

The Commission did not agree with Australia that only peer-reviewed journals should be used as a source of information for its work but considers it most efficient to use many sources, including OIE Reference Laboratories, other international experts, and the outcomes of international conferences of experts, in developing and improving its standards. This approach is especially applicable in addressing emerging diseases. All OIE Commissions operate in this fashion.

Addressing New Zealand's comments, the Commission responded that, in line with their terms of reference, the *ad hoc* teams had initially assessed each currently listed disease but had then provided a detailed assessment only for those diseases identified as candidates for de-listing or addition.

For some of the crustacean diseases suggested for addition to the list, the Commission will apply the concept of 'listing as an emerging disease' if this concept is adopted by Member Countries (see Agenda item 4.1.3).

The Commission is concerned to ensure that all Member Countries understand the purpose of the OIE list of aquatic diseases. The Commission stresses that the primary purpose of listing a disease is for the OIE to collate and disseminate information on the occurrence and control of that disease world-wide. It is not the case that diseases proposed for de-listing are considered to be of no importance to some Member Countries; rather, diseases proposed for de-listing are considered not to meet the listing criteria agreed by Member Countries. Member Countries may still impose import restrictions addressing those diseases if this is justified on the basis of a science based import risk analysis and on their animal health situation.

The rationale for retention, removal or addition of diseases is given below for each of the diseases assessed; the proposed revised list is given in Appendix V. Those Member Countries not in agreement with those assessments are invited to provide their own assessment.

Fish diseases

Epizootic haematopoietic necrosis (EHN)

New Zealand commented that EHN did not seem to meet the listing criteria and provided scientific reasons to support their view. The Commission referred the New Zealand comments to the OIE Reference Laboratory for EHN, which disagreed with some of the New Zealand arguments. As a result, the Commission recommends the retention of EHN on the list.

Infectious haematopoietic necrosis (IHN)

Dissenting views were not received. The Commission recommends the retention of IHN on the list.

Oncorhynchus masou virus disease (OMVD)

Dissenting views were not received. The Commission recommends the removal of OMVD from the list.

Spring viraemia of carp (SVC)

Dissenting views were not received. The Commission recommends the retention of SVC on the list.

Viral haemorrhagic septicaemia (VHS)

The USA suggested the Commission consider de-listing certain strains of listed disease agents that have a world-wide distribution and cause little mortality, such as marine strains of VHS. The Commission had sought advice from the OIE Reference Laboratory for VHS, which recommended that it would be premature to do so because methods for reliable differentiation of such strains from the virulent strains of VHS had not been sufficiently developed at this stage. Until better techniques to distinguish between pathogenic and non-pathogenic strains are developed, the Commission takes the view that it would be impractical to make such a differentiation. However, the Commission agrees that it is important to keep this issue under review. The Commission recommends the retention of VHS as described in the *Manual of Diagnostic Tests for Aquatic Animals* (hereafter referred to as the *Aquatic Manual*).

Channel catfish virus disease (CCVD)

Dissenting views were not received. The Commission recommends the removal of CCVD from the list.

Viral encephalopathy and retinopathy (VER)

Australia and Norway pointed out some inconsistency in the reasoning for criteria being met or not. The Commission, whilst accepting these comments, concluded that they did not change the overall assessment that VER does not meet the required criteria for listing. The Commission recommends the removal of VER from the list.

Infectious pancreatic necrosis (IPN)

The EU reiterated its comment on the report of the October 2003 meeting of the Commission regarding its claim that IPN did comply with listing criteria 2 and 7, and provided scientific justification to support its view. The Commission will refer the EU assessment to the OIE Reference Laboratory for IPN and to the fish team of the *ad hoc* Group, for their opinion for consideration by the Bureau of the Commission in early May 2005, at which time a final recommendation will be prepared for presentation at the General Session.

Infectious salmon anaemia (ISA)

Dissenting views were not received. The Commission recommends the retention of ISA on the list.

Epizootic ulcerative syndrome (EUS)

Dissenting views were not received. The Commission recommends the retention of EUS on the list.

Bacterial kidney disease (*Renibacterium salmoninarum*)

The EU reiterated its comment on the report of the October 2003 meeting of the Commission regarding its claim that BKD did comply with listing criteria 1, 2 and 7, and provided scientific justification to support its view. The Commission will refer the EU assessment to the OIE Reference Laboratory for BKD and to the fish team of the *ad hoc* Group, for their opinion in time for consideration by the Bureau of the Commission in early May 2005, at which time a final recommendation will be prepared for presentation at the General Session.

Enteric septicaemia of catfish (*Edwardsiella ictaluri*) (ESC)

Dissenting views were not received. The Commission recommends the removal of ESC from the list.

Piscirickettsiosis (*Piscirickettsia salmonis*)

Dissenting views were not received. The Commission recommends the removal of *Piscirickettsiosis* from the list.

Gyrodactylosis (*Gyrodactylus salaris*)

Dissenting views were not received. The Commission recommends the retention of gyrodactylosis on the list.

Red sea bream iridoviral disease (RSIVD)

Dissenting views were not received. The Commission recommends the retention of RSIVD on the list.

White sturgeon iridoviral disease (WSIVD)

Dissenting views were not received. The Commission recommends the removal of WSIVD from the list.

Koi herpes virus (KHV)

The EU, supported by Norway, invited the Commission to evaluate the EU's assessment for listing koi herpes virus. The assessment was referred for evaluation to the fish team of the *ad hoc* Group, which agreed that many of the criteria for listing a disease by the OIE are met. However, further clarification on some aspects of the assessment is needed. The Commission therefore seeks Member Countries' comments on the EU assessment (see page 166 of EU comments: http://europa.eu.int/comm/food/international/organisations/ah_pcad_oie13_en.pdf) as well the comments from the fish team of the *ad hoc* Group (see Appendix VI). These will be considered by the Bureau of the Commission in early May 2005, at which time a final recommendation will be prepared for presentation at the General Session.

Mollusc diseases

Infection with *Bonamia ostreae*

Dissenting views were not received. The Commission recommends the retention of Infection with *Bonamia ostreae* on the list.

Infection with *Bonamia ~~exitiosus~~ exitiosa*

Dissenting views were not received. The Commission recommends the retention of Infection with *Bonamia exitiosa* on the list.

Infection with *Mikrocytos roughleyi*

Dissenting views were not received. The Commission recommends the removal of Infection with *Mikrocytos roughleyi* from the list.

Infection with *Haplosporidium nelsoni*

Dissenting views were not received. The Commission recommends the removal of Infection with *Haplosporidium nelsoni* from the list.

Infection with *Marteilia refringens*

Dissenting views were not received. The Commission recommends the retention of Infection with *Marteilia refringens* on the list.

Infection with *Marteilia sydneyi*

Dissenting views were not received. The Commission recommends the removal of Infection with *Marteilia sydneyi* from the list.

Infection with *Mikrocytos mackini*

The EU suggested that *Mikrocytos mackini* be retained; however, no justification was provided. The Commission recommends the removal of Infection with *Mikrocytos mackini* from the list.

Infection with *Perkinsus marinus*

Dissenting views were not received. The Commission recommends the retention of Infection with *Perkinsus marinus* on the list.

Perkinsus olseni~~*/atlanticus*~~

Italy and the EU, supported by Norway, provided an assessment concluding that Infection with *Perkinsus olseni* should be de-listed because criterion 7 is not met. The Commission disagreed. The Commission also noted Australia's concerns regarding criteria 1 and 4, but concluded that these concerns do not influence the outcome of the assessment. The Commission recommends the retention of Infection with *Perkinsus olseni* on the list.

In addition, the Commission considers it timely to delete "*atlanticus*" from the name of the agent so that the disease now reads: "Infection with *Perkinsus olseni*". Member Countries are reminded that the two species names were listed in parallel for an interim period to show that they are synonymous.

Infection with *Haplosporidium costale*

Dissenting views were not received. The Commission recommends the removal of Infection with *Haplosporidium costale* from the list.

Infection with ~~Candidatus~~ *Xenohaliotis californiensis*

Dissenting views were not received. The Commission recommends the retention of Infection with Candidatus *Xenohaliotis californiensis* on the list. In addition, the Commission considers it timely to delete "candidatus" from the name of the agent so that the disease now reads: "infection with *Xenohaliotis californiensis*" to comply with the usual taxonomy (genus and species).

Crustacean diseases

Taura syndrome (TS)

Dissenting views were not received. The Commission recommends the retention of TS on the list.

White spot disease (WSD)

Dissenting views were not received. The Commission recommends the retention of WSD on the list.

Yellowhead disease (YHD)

Dissenting views were not received. The Commission recommends the retention of YHD on the list.

Tetrahedral baculovirosis (*Baculovirus penaei*)

Dissenting views were not received. The Commission recommends the retention of Tetrahedral baculovirosis (*Baculovirus penaei*) on the list.

Spherical baculovirosis (*Penaeus monodon*-type baculovirus)

Dissenting views were not received. The Commission recommends the retention of Spherical baculovirosis (*Penaeus monodon*-type baculovirus) on the list.

Infectious hypodermal and haematopoietic necrosis (IHHN)

Dissenting views were not received. The Commission recommends the retention of IHHN on the list.

Crayfish plague (*Aphanomyces astaci*)

Dissenting views were not received. The Commission recommends the retention of Crayfish plague (*Aphanomyces astaci*) on the list.

Spawner-isolated mortality virus disease (SMVD)

Dissenting views were not received. The Commission recommends the removal of SMVD from the list.

Necrotising hepatopancreatitis (NHP)

Australia questioned the proposed listing of NHP in relation to criteria 4 and 8. The Commission disagreed because several robust diagnostic tests are available for confirmation of presumptive infections. The EU, supported by Norway, expressed concerns regarding criteria 1, 6 and 7. Regarding criterion 1, the Commission reiterates that control of NHP with medicated feeds is not always effective. Regarding criterion 6, the Commission noted that absence of evidence of transmission of disease (e.g. to Asian countries) is likely due to environmental conditions in those countries not being conducive to clinical expression, in contrast to disease outbreaks where conditions are conducive to clinical expression. Regarding criterion 7, the Commission considers that NHP has never been officially reported outside the Americas. The Commission recommends the addition of NHP to the list.

Infection with Mourilyan virus (MoV)

The Commission agrees with the EU (supported by Norway) and Australian comments that MoV may not fully meet criteria 4 or 5. Therefore, the Commission does not recommend the listing of MoV at this time.

The Commission may consider MoV as a candidate for listing as an emerging disease. (See Item 4.1.3.)

Infectious myonecrosis (IMN)

The EU (supported by Norway) expressed the opinion that IMN fails to meet criterion 7. The Commission concluded that given the very limited geographical distribution (confined to parts of one country) of IMN, this disease does meet criterion 7; many countries with susceptible species could declare freedom on the basis of historical freedom as outlined in Chapter 1.1.4. of the *Aquatic Manual*. The Commission agrees with Australia on the need for confirmatory test methods when diagnosis is made using histological methods, and notes that molecular tests are available for confirmatory testing. The Commission recommends the addition of IMN to the list.

White tail disease (WTD)

The Commission agrees with Australia that WTD may not fully meet criterion 4. Therefore, the Commission does not recommend the listing of WTD at this time.

The Commission may consider WTD for listing as an emerging disease. (See Item 4.1.3.)

Infection with hepatopancreatic parvovirus (HPV)

The Commission agrees with EU (supported by Norway) and Australian comments that HPV may not fully meet criteria 1 and 8. Therefore, the Commission does not recommend the listing of HPV at this time.

The Commission may consider HPV as a candidate for listing as an emerging disease. (See Item 4.1.3.)

2.4. Revision of Chapter 1.2.1. on notifications and epidemiological information

The Commission made a number of amendments to this chapter based on Member Countries' comments (see Appendix VII).

2.5. Harmonisation of the structure of disease chapters for future editions of the *Aquatic Code*

The Commission received Member Countries' comments on the draft chapters for epizootic haematopoietic necrosis, infection with *Marteilia refringens* and white spot disease.

The EU requested the OIE to consider a formal procedure for 'fast track' inclusion of new susceptible species for a listed disease. The Commission agreed where such evidence becomes available it needs to be scrutinised and subjected to a review process and that the regular consultation process with Member Countries is appropriate for this purpose. However, the Commission will propose that OIE Reference Laboratories be requested to notify the OIE Central Bureau when they become aware of a new susceptible species for a listed disease.

The EU also asked for justification for identifying mussels as susceptible species for *M. refringens*. The Commission provides the following justification:

Marteilia maurini was initially described by Comps *et al.* (1982) as a closely related species of *M. refringens*, but essentially parasitising mussels. Later, 18S sequence and ultrastructural comparative studies have cast some doubts on the existence of the two species of *Marteilia* (Berthe *et al*., 2000; Longshaw *et al*., 2001). Le Roux *et al.* (2001) assessed the existence of two clusters of *Marteilia* isolates that have been given equivalence to *M. refringens* and *M. maurini*, based on ITS sequences. However, Lopez-Flores *et al*. (2004) refuted these results. Moreover, both authors have detected *M. refringens*-type profiles in mussels. In consequence, mussels should be regarded as susceptible to infection with *Marteilia refringens*. The methods in the *Aquatic Manual* enable differentiation between the two *Marteilia* species.

- BERTHE F.C.J., LE ROUX F., PEYRETAILLADE E., PEYRET P., RODRIGUEZ D., GOUY M. & VIVARÈS C.P. (2000). The existence of the phylum Paramyxea Desportes and Perkins, 1990 is validated by the phylogenetic analysis of the *Marteilia refringens* small subunit ribosomal RNA. *J. Euk. Microbiol*., **47**, 288-293.

- COMPS M., PICHOT Y. & PAPAYIANNI P. (1982). Recherche sur *Marteilia maurini* n. sp. parasite de la moule *Mytilus galloprovincialis* Lmk. *Rev. Trav. Inst. Pêches Mar*., **45**, 211-214.

- LE ROUX F., LORENZO G., PEYRET P., AUDEMARD C., FIGUERAS A., VIVARÈS C., GOUY M. & BERTHE F.C.J. (2001). Molecular evidence for the existence of two species of *Marteilia* in Europe. *J. Euk. Microbiol*., **48**, 449-454.

- LONGSHAW M., FEIST S.W., MATTHEWS A. & FIGUERAS A. (2001). Ultrastructural characterisation of *Marteilia* species (Paramyxea) from *Ostrea edulis*, *Mytilus edulis* and *Mytilus galloprovincialis* in Europe. *Dis. Aquat. Org*., **44**, 137-142.

- LOPEZ-FLORES I., DE LA HERRAN R., GARRIDO-RAMOS M.A., NAVAS J.I., RUIZ-REJON C. & RUIZ-REJON M. (2004). The molecular diagnosis of *Marteilia refringens* and differentiation between *Marteilia* strains infecting oysters and mussels based on the rDNA IGS sequence. *Parasitology*, **129**, 411-419.

Australia questioned the justification for the listing of commodities under item 1 in Article X.X.X.3. The Commission agrees that scientific justification needs to be provided before listing a commodity. Therefore, the OIE will convene an *ad hoc* group to provide such justification.

The EU raised the need to establish buffer zones adjacent to non-declared free countries. The Commission, after consulting the *Terrestrial Code*, noted that the concept is usually applied to separate infected from non-infected countries or zones with the purpose of preventing spread of the disease from the infected country or zone. The Commission provided a new definition of "buffer zone" (see Appendix III) but would welcome EU clarifications on their request.

The Commission prepared revised versions of the three disease chapters (see Appendix VIII, IX and X).

2.6. Appendix on General Recommendations on Disinfection

The Commission received comments from Australia, Morocco, New Zealand and Norway. The appropriate changes were made. A version showing all the amendments and a clean version of the chapter are provided at Appendix XI.

3. *Manual of Diagnostic Tests for Aquatic Animals*

Community position

As stated under item 8, the Community would point out that the Work plan must include elaboration of disease specific surveillance articles or chapters.

3.1. Update on preparation of the fifth edition of the *Aquatic Manual*

The Commission reviewed the timetable for the production of the fifth edition of the *Aquatic Manual* taking into account the changes that may arise in the list of diseases. The list of authors and reviewers of all the chapters was updated. The first batch of draft chapters for currently listed diseases will be sent to Member Countries for comment in April 2005. Should there be new diseases added to the list in May 2005 (see item 2.3), corresponding draft chapters will be sent to Member Countries in November 2005. The Commission will take into account all comments at its January 2006 meeting in preparing the final drafts to be presented for adoption at the General Session in May 2006.

3.2. Review of the scope of the *Manual of Diagnostic Tests for Aquatic Animals*

Recognising that the OIE's remit includes prevention and control of animal diseases, the Commission has asked authors of chapters for the new edition of the *Aquatic Manual* to provide information on vaccination, chemotherapy, immunostimulation, etc. Depending on the scale of information provided, it may be appropriate to reconsider the title of the *Aquatic Manual*.

3.3. Revision of Chapter 1.1.4. entitled "Requirements for surveillance for international recognition of freedom from infection"

See agenda item 4.1.1.

3.4. Revision of Chapter on disinfection of fish aquaculture establishments

Dr Enriquez provided an update on the preparation of this chapter. A draft will be tabled at the next meeting of the Bureau in August 2005.

3.5. OIE procedure for validation of diagnostic tests

Dr Alejandro Schudel, Head of the OIE Scientific and Technical Department, informed the Commission about the implementation of Resolution No. XXIX, adopted by the International Committee in 2003, concerning the official OIE procedure for the validation of diagnostic tests. The system is now operative. The first validated tests for terrestrial animal diseases are expected to be presented to the International Committee in May 2005. The Commission welcomes this development and encourages interested parties to contact the OIE Central Bureau for information on how to apply to have their tests validated.

4. Joint meeting with the Terrestrial Animal Health Standards Commission

Community position

The Community is in the process of updating its aquatic animal health legislation, introducing the compartmentalisation principle. The Community would therefore be pleased to assist the OIE in the further development of compartmentalisation with regard to specific aquatic animal diseases.

The Commission was joined by Dr Alejandro Thiermann, President of the Code Commission, and Dr David Wilson, Head of the OIE International Trade Department, for this agenda item.

4.1. Continuing work on harmonisation of horizontal chapters in the *Aquatic* and *Terrestrial Codes*

The work on harmonisation will address initially the sections in Part 1 (General Provisions) of the *Aquatic Code*.

4.1.1. Requirements for surveillance for declaration of freedom from disease

The Commission prepared a draft of a proposed new chapter on aquatic animal health surveillance using, as a basis, the draft revision of Chapter 1.3.6. on surveillance and monitoring of animal health from the *Terrestrial Animal Health Code*. This draft (Appendix XII) provides general principles on surveillance for inclusion in the *Aquatic Code*. As proposed by the Aquatic Animals Commission, the OIE will convene an *ad hoc* group to review the contents of the current *Aquatic Manual* Chapter 1.1.4. entitled "Requirements for surveillance for international recognition of freedom from infection", taking into account previous comments from Canada, for the preparation of a detailed chapter on surveillance for the *Aquatic Manual.* In addition, the *ad hoc* group will also assist the Commission in reviewing the contents of the general information section of the *Aquatic Manual* (Chapters 1.1., 1.2. and 1.3.).

4.1.2. Compartmentalisation

The Commission received comments from Australia and the EU on the explanatory paper on compartmentalisation, requesting further clarification on, e.g. the need for "strong veterinary infrastructure" and zones and compartments in open marine areas. The Commission agreed with these comments and will make appropriate modifications to the explanatory paper. For example, the Commission will provide better examples for compartments in coastal areas and compartments extending over non-contiguous geographical areas.

4.1.3. Listing criteria for emerging diseases

When considering Member Countries' comments on the list of diseases (see Item 2.2. above), the Commission identified a lack of a fast-tracking procedure for listing emerging diseases that may not yet fully meet the current criteria for listing. The Commission noted the provisions in the *Terrestrial Code* (Chapter 2.1.1. on Criteria for listing diseases) for listing emerging terrestrial animal diseases and agreed a similar approach should be taken for such aquatic animal diseases. The Commission added an article to Chapter 1.1.2. on disease listing and notification criteria (see Appendix IV).

4.2. Report of the OIE *ad hoc* Group on Antimicrobial Resistance

Community position

The Community have forwarded the request to its Member States, and any observations will be sent to the OIE in a separate submission.

The report of the *ad hoc* Group on Antimicrobial Resistance, which operates under the auspices of the OIE Biological Standards Commission, contained a recommendation that the issue of antimicrobial resistance pertaining to aquaculture be referred to the Commission for deliberation. The Group requested the Commission to address this issue "as a matter of high priority". The Commission referred the *ad hoc* Group to a paper in the Proceedings of the OIE International Conference on Risk Analysis in Aquatic Animal Health, February 2000, entitled "Assessing the risks associated with the use of antimicrobial agents in aquaculture", for consideration at its next meeting, 26-28 January 2005. This paper states that "The use of antimicrobial agents in aquaculture represents a potential risk for the efficacy of the use of these agents in the therapy of human infectious diseases. This potential was first identified in 1971 but, despite twenty-eight years of research, little or no information relevant to estimating the size of the risk currently exists". The Commission invites Member Countries to comment on whether antimicrobial resistance in relation to human health is an issue in aquaculture.

4.3. Report of the OIE Working Group on Animal Welfare

The Commission noted the report of the Working Group on Animal Welfare and that the two *ad hoc* Groups on the welfare of aquatic animals (one on transport of aquatic animals and the other on aquatic animal slaughter) would be meeting in 2005. The reports of those *ad hoc* Groups will be submitted to the Commission for consideration after endorsement by the Working Group on Animal Welfare.

5. Joint meeting with the Animal Health Information Department

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

5.1. Update on implementation of new notification system

Dr Ben Jebara informed the Commission that the guidelines for completing the new form for immediate notification of relevant aquatic animal diseases have been sent to Member Countries. The new on-line six-monthly reporting system will become operative in July 2005. A letter from Dr Vallat (see agenda item 6.3.) will be sent to Delegates, suggesting that they appoint a specific official as the OIE contact person for aquatic animal diseases with responsibility for sending, under the authority of the Delegate, country reports on aquatic animal diseases to the OIE and to comment on the Commission's proposals for new Standards.

Dr Ben Jebara requested the Commission's assistance in evaluating a trial run of the new on-line reporting system. Later in the year, Dr Ben Jebara will liaise with the OIE Regional Representation for Asia and the Pacific and NACA[1] with a view to integrate the current Asia regional reporting system into the new OIE global electronic reporting system.

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

Community position

The Community appreciates the efforts done by the representations from OIE AAC in international forums.

6.1. Third Annual General Meeting of NACA's Asia Regional Advisory Group on Aquatic Animal Health, November 2004, Bangkok

The President reported that she had not been able to represent the Commission at this meeting, but with the prior agreement of the OIE, a colleague gave presentations on her behalf to update the meeting on developments in aquatic animal health since the OIE General Session in May 2004.

6.2. Conferences of OIE Regional Commissions

Prof. Donald Lightner reported that his presentation at the 17th Conference of the OIE Regional Commission for the Americas, which was held in Panama in November 2004, had been well received. Members of the Aquatic Animals Commission will give presentations during the upcoming Regional Commissions' Conferences in Khartoum (Africa) and Bahrain (Middle East). Dr Eli Katunguka-Rakishaya will give the presentation at the Khartoum Conference (February 2005) and Prof. Barry Hill will give the presentation at the Bahrain Conference (September 2005). Once these two presentations have been given, all five OIE Regional Commissions will have been informed of the importance of aquatic animal health in the veterinary field and the need for the greater involvement of the Veterinary Services in aquatic animal health. The Commission will propose to the Director General that an updated presentation be given at each subsequent Conference of the Regional Commissions, starting with the 24th Conference of the Regional Commission for Asia, the Far East and Oceania in November 2005.

6.3. Implementation of recommendations adopted by the OIE Regional Commission for Asia, the Far East and Oceania in 2003, and endorsed by the International Committee of the OIE in 2004

Recommendation No. 2 adopted by the OIE Regional Commission for Asia, the Far East and Oceania in 2003 and endorsed by the International Committee of the OIE in 2004, expressed concern that the level of reporting of aquatic animal diseases and provision of comments on draft texts for the *Aquatic Code* and *Manual* to the OIE was still poor, and therefore made some suggestions to improve this situation. For example, where primary responsibility for aquatic animal health rests with an authority other than the Veterinary Services, Member Countries could nominate a national aquatic focal point the other authority so that the OIE would circulate Commission reports to those focal points when circulating them to Delegates. The Director General will send a letter to Delegates, pointing out that the nomination of a national contact point for aquatic animal diseases has already proved useful in some Member Countries and requesting that the matter be given due consideration by those Member

[1] NACA: Network of Aquaculture Centres in Asia-Pacific

Countries where this is not yet in place.

6.4. Proposal to hold a Global Conference

The Commission further developed its plans to hold a Global Conference with the following focus: aquatic animal disease emergencies, involvement of veterinary services in aquatic animal health, co-operation between veterinary and fisheries authorities, and the enhancement of reporting mechanisms. Information will be available on the Commission's pages on the OIE web site in the near future. The Commission is awaiting responses from certain Member Countries on the feasibility of their hosting the Global Conference.

6.5. International meetings

6.5.1. Disease of Asian Aquaculture VI in Colombo, Sri Lanka, October 2005

The Commission has been formally invited by FAO to participate in an expert consultation with a view to preparing Technical Guidelines on Responsible Introductions and Movement of Live Aquatics as a supplement to the FAO Code of Conduct for Responsible Fisheries. This consultation will be held in conjunction with the 6th Symposium on Diseases in Asian Aquaculture (DAA VI). The Commission supports this initiative.

In addition, FAO supports a proposal made by NACA to provide an opportunity for veterinary/fishery authority dialogue at the DAA VI and has suggested the Commission's involvement. The Commission considers the veterinary/fishery authority dialogue to be highly relevant to its strategy to stimulate greater co-operation between fishery authorities and veterinary services on aquatic animal health issues and an excellent opportunity to progress the implementation of the Noumea recommendations (see Item 6.3.). An ideal mechanism to achieve this would be to hold a special half-day seminar during the DAA VI involving senior officials of the veterinary services and fishery authorities of Member Countries. The Commission seeks the approval of the Director General for OIE involvement.

6.5.2. ISVEE XI Symposium in Cairns (Australia) in August 2006

The President of the Commission reiterated that the President of the International Society for Veterinary Epidemiology and Economics (ISVEE) had requested the involvement of the Aquatic Animals Commission at the XI ISVEE Symposium, which will have a major focus on aquatic animal epidemiology. The Commission has previously welcomed the invitation to participate. In the meantime, at the X ISVEE Symposium, held in Viña del Mar (Chile), in November 2003, the International Society for Aquatic Animal Epidemiology (ISAAE) was formed to better address the increasing importance of veterinary epidemiology in the field of aquatic animal health. ISAAE will hold special sessions during ISVEE XI. The Commission seeks the approval of the Director General to participate in these meetings to hold a forum on surveillance to demonstrate disease freedom and obtain expert comment on the corresponding chapters for the *Aquatic Manual*.

6.6. OIE Regional Representation for the Americas

Dr Luis Barcos, OIE Regional Representative for the Americas, attended part of the meeting and tabled the Recommendation No. 4, adopted by the 17th Conference of the OIE Regional Commission for the Americas. This Recommendation proposes to amend the general rules of the OIE to allow a Regional Commission to establish committees and *ad hoc* groups to analyse, discuss and develop proposals in their specific expertise. These proposals would then be transmitted to the OIE Specialist Commissions. The Commission supports this initiative.

The Commission also noted the proposal from Canada to the OIE Regional Commission for the Americas to establish an OIE Inter-American Aquatic Animal Health *ad hoc* Group to *inter alia* examine ways to implement OIE standards for aquatic animal health in a manner that optimises harmonisation among the Member Countries of the Regional Commission. The Aquatic Animals Commission welcomes this proposal and will explore ways to be actively involved.

6.7. Including diseases of amphibians in the remit of the Commission

Australia commented that it shares the Aquatic Animals Commission's concern about declining amphibian populations, but is of the view that the issue goes beyond trade in amphibians. Declines in amphibian populations, where they are noticed, are mostly investigated by ecologists, not aquatic health experts, and a large number of papers and web sites have appeared, attributing amphibian declines and malformations to an equally large number of causes, few of which include infective disease agents. Therefore, there needs to be an awareness-raising exercise among Competent Authorities to engage with biologists and ecologists in order to have putative disease events reported.

Australia also drew attention to the issue of the possible transmission of iridoviruses from fish to amphibians and suggested that trade in ornamental fish may be of more concern by amphibian health than trade in amphibians.

At its meeting in October 2004, the Bureau of the Commission reiterated its request that Member Countries provide information on trade in amphibians (nationally and internationally) and on the occurrence of diseases of amphibians within their territories. No such information had been received from Member Countries, but as agreed at the Commission meeting in June 2003, FAO provided production figures (aquaculture and wild capture). Prof. Hill has also managed to obtain some trade figures for the import of live amphibians into the EU via Heathrow Airport, and FAO is endeavouring to obtain figures for trade in live amphibians elsewhere in the world.

The Commission proposed a new *ad hoc* Group on amphibian diseases, which will also provide a revised questionnaire for Member Countries. The Commission defers a decision on whether or not to include amphibians within its remit until the *ad hoc* Group has provided a report with recommendations.

7. OIE Reference Laboratories

Community position

The Community supports the change of expert in the OIE Reference Laboratory for Crayfish plaque.

7.1. Updating the list of OIE Reference Laboratories

The OIE has been notified of the following change of expert at an OIE Reference Laboratory: Prof. Rudolf Hoffmann to replace Dr Birgit Oidtmann at the OIE Reference Laboratory for Crayfish plague in Munich (Germany). The Aquatic Animals Commission recommends its acceptance.

The Commission identified the need for a Reference Laboratory for Infection with *Xenohaliotis californiensis* and invites nominations from Member Countries.

8. Any other business

Community position

The Community would reiterate its comment on the need for including in the work plan the project of developing/drafting more disease specific surveillance guidelines which would supplement the general surveillance chapter in Appendix XII.

8.1. Update of the Commission's web pages

Dr Hill reported that all the changes identified as necessary at the October 2004 meeting have been made. A new page listing the past and future scheduled meetings of the Commission has been added.

The Commission draws Member Countries' attention to the new arrangement for Commission reports:

- an unofficial version of Commission reports, in English only, is to be circulated by e-mail to Delegates and placed on the Delegates' Web site, as soon as possible after each meeting. At the same time, these reports are to be sent by e-mail to international organisations with which the OIE has a formal agreement;
- after translation into French and Spanish, the official versions of Commission reports (in the three languages) are to be circulated by e-mail and mail to Delegates and to the international organisations with which the OIE has a formal agreement, and placed on the OIE public Web site;
- after each General Session, a report of any changes agreed by the International Committee (for example the relevant Resolution(s)) is to be placed on the OIE public Web site adjacent to the relevant Commission reports.

8.2. Permanent Advisory Network for Diseases in Aquaculture (PANDA)

Dr Hill drew attention to the development of an international network of aquatic animal health specialists as part of the EU-funded project "PANDA". The project has identified the Commission as an "associated organisation" (along with FAO, NACA, EAFP[2], and others) for participation in the networking, and has put a link from the PANDA web site to the Commission's pages on the OIE web site. The Commission agreed that such a network might be useful for involving a broader base of experts and will inform the network of the publication of Commission's reports on the OIE web site.

8.3. Review of Aquatic Animals Commission work plan for 2005

The Commission reviewed its work plan for 2005, which is presented at Appendix XIII.

8.4. Shipment of fish pathogens

The OIE received a request from the EU Community Reference Laboratory for Fish Diseases to provide some clarification on the applicability of the current IATA[3] regulations in the context of shipping cultivated aquatic animals pathogens. The Commission will await the outcome of the Biological Standards Commission meeting scheduled for 26-28 of January 2005, where discussions on the transport of samples, according to the latest regulations, will take place.

8.5. Date of the next meeting

The Bureau of the Aquatic Animals Commission will meet from 1 to 5 August 2005.

.../Appendices

[2] EAFP: European Association of Fish Pathologists
[3] IATA: International Air Transport Association

Appendix I

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13–19 January 2005

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Agenda

1. Member Countries' comments on the report of the meeting of the Bureau of the Commission (October 2004)

2. *Aquatic Animal Health Code*

2.1. Definitions (Chapter 1.1.1.)
2.2. Revision of Chapter 1.1.2. on disease listing and notification criteria
2.3. Revision of the list of diseases (Chapter 1.1.3.)
2.4. Revision of Chapter 1.2.1. on notifications and epidemiological information
2.5. Harmonisation of the structure of disease chapters for future editions of the *Aquatic Code*
2.6. Appendix on general recommendations on disinfection

3. *Manual of Diagnostic Tests for Aquatic Animals*

3.1. Update on preparation of the fifth edition of the *Aquatic Manual*
3.2. Review of the scope of the *Manual of Diagnostic Tests for Aquatic Animals*
3.3. Revision of Chapter 1.1.4. on requirements for surveillance for international recognition of freedom from infection
3.4. Revision of chapters on disinfection of fish aquaculture establishments
3.5. OIE procedure for validation of diagnostic tests

4. Joint meeting with the Terrestrial Animal Health Standards Commission

4.1. Continuing work on harmonisation of horizontal chapters in the *Aquatic* and *Terrestrial Codes*
  4.1.1. Requirements for surveillance for declaration of freedom from disease
  4.1.2. Compartmentalisation
  4.1.3. Listing criteria for emerging diseases
4.2. Report of the OIE ad hoc Group on antimicrobial resistance
4.3. Report of the OIE Working Group on Animal Welfare

5. Joint meeting with the Animal Health Information Department

5.1. Update on implementation of new notification system

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

6.1. Third Annual General Meeting of NACA's Asia Regional Advisory Group on Aquatic Animal Health, November 2004, Bangkok
6.2. Conferences of OIE Regional Commissions
6.3. Implementation of recommendations adopted by the OIE Regional Commission for Asia, the Far East and Oceania in 2003, and endorsed by the International Committee of the OIE in 2004
6.4. Proposal to hold a Global Conference

Appendix I (contd)

6.5. International meetings
  6.5.1. Disease of Asian Aquaculture VI in Colombo, Sri Lanka, October 2005
  6.5.2. ISVEE XI Symposium in Cairns (Australia) in August 2005
6.6. OIE Regional Representation for the Americas
6.7. Including diseases of amphibians in the remit of the Commission

7. OIE Reference Laboratories

7.1. Updating the list of Reference Laboratories

8. Any other business

8.1. Update of the Commission's web pages

8.2. Permanent Advisory Network for Diseases in Aquaculture (PANDA)

8.3. Review of Aquatic Animals Commission work plan for 2005

8.4. Shipment of fish pathogens

8.5. Date of the next meeting

Appendix II

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13–19 January 2005

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Appendix III

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1.

Community position

The Community generally agrees with the proposed amendments. There is however a need for further clarifications and improvements as some of the proposed definitions results in a contradiction between Article 1.1.1.1 and other Chapters of the Code.

1) As a general comment, the Community believes it is necessary to further consider the several definitions, which contains requirements. The requirements should be laid down in the relevant Chapters and Articles in the Code and not in the definitions. As an example, the definition of "Zone", where the first part of that definition (points a-e) are not a definition, but examples of geographical areas that comply with the definition. Consequently the said text should be moved from the definition and introduced into Chapter 1.4.4 (preferably under Article 1.4.4.3 point 1).

The following definitions are other examples of definitions which contain requirements:
- Basic biosecurity conditions
- Compartment
- Container
- Early detection system
- Fallowing
- Fish slaughtering premises
- Infected zone
- Inspection
- Laboratory
- Self declaration of freedom from disease
- Stamping out policy
- Zone

2) The Community would reiterate its comment with respect to the harmonisation of the OIE definition of Aquaculture with the definition of FAO, as no justification for not aligning the definition has been given in the report.

3) The Community invites the OIE to reconsider some of the definitions, as they seem not to appear in the different Chapters and Articles of the Code (for example "Lot"). Some definitions are only used in other definitions (for example "Marketing").

4) The Community propose to delete the definition of "veterinary administration" as the substance is already included in the definition of competent authority, and a double definition may lead to some inconsistency.

5) Definition of buffer zone

It could be understood that buffer zones is only applicable in relation to infected zones. It is the Community position that a buffer zone is also relevant to protect a declared disease free zone. The definition should therefore read

"means an area established and maintained using measures based on the epidemiology of the *disease* under consideration, to prevent spread of the *disease agent* into a disease free zone or out of an *infected zone"*

The second sentence of the definition is not a definition *per se*, but rather a requirement. Consequently

the Community propose to move that sentence to Article 1.4.4.3 of the Code.

These proposed amendments will ensure consistency between Article 1.1.1.1 and Chapter 1.4.4.

Furthermore, the Community would reiterate its earlier comment with respect to including the words : "for which required surveillance and control measures are applied and *basic biosecurity conditions* are met for the purpose of *international trade"*. **By introducing this requirement in the definition, it could be understood that the definition in Article 1.1.1.1 only applies to disease free zones, which must not be the case. If the said sentence is maintained, there will be a contradiction between Article 1.1.1.1 and Chapter 1.4.4.**

Then the remaining definition of zone should read:

"A clearly defined geographical area that consists of a contiguous hydrological system with a distinct health status with respect to a specific *disease* or *diseases* ~~for which required surveillance and control measures are applied and *basic biosecurity conditions* are met for the purpose of *international trade*~~. All areas of the zone must have the same health status. ~~The zones must be clearly documented (e.g. by a map or other precise locators such as GPS co-ordinates) by the *Competent Authority(ies)*~~"

6) Definition of susceptible species

Taking into account the oral explanation given by OIE AAC members during the preparation of these comments, with respect to the justification for deleting Macquarie perch, silver perch, mountain galaxias, mosquito fish and other species belonging to the family Poeciliidae **as susceptible species to EHN, it has become clear that the definition of "susceptible species" must be re-written to be consistent with the explanation given – that only species where natural infections occur should be considered as susceptible species.**

This change of definition will also result in amendments of the list of susceptible species for other diseases, for which the Community reserves its right to comment before the General Session.

Aquaculture ~~***Aquacultural***~~ ***activities***

any activity concerning farming, including *marketing*, ~~*processing*~~, ~~etc,~~ of *aquatic animals*.

Buffer zone[4]

means an area established and maintained using measures based on the epidemiology of the *disease* under consideration, to prevent spread of the *disease agent* out of the *infected zone.*

The *buffer zone* should be established by the *Competent Authority(ies)* concerned and subjected to *surveillance* to confirm there has been no spread from the *infected zone.*

Compartment

one or more *aquaculture establishments* under a common biosecurity management system containing an aquatic animal population with a distinct health status with respect to a specific *disease* or *diseases* for which required surveillance~~,~~ and control ~~and biosecurity~~ measures are applied and *basic biosecurity conditions* are met ~~applied~~ for the purpose of international trade. Such *compartments* must be clearly documented by the *Competent Authority(ies).*

Diseases listed by the OIE

diseases that ~~fulfil the criteria outlined~~ are listed in Chapter 1.1.~~2~~3. of this *Aquatic Code.*

Free compartment

means a *compartment* that fulfils the requirements for freedom from the *disease* under consideration,

[4] The text highlighted in yellow shows changes made to the text at the January 2005 meeting of the Commission.

according to the relevant chapter in this *Aquatic Code.*

Free country

means a country that fulfils the requirements for freedom from the *diseases* under consideration ~~*listed by the OIE*~~ according to the relevant chapter in this *Aquatic Code*. ~~and approved as such by a *Competent Authority*.~~

Free zone

means a *zone* that fulfils the requirements for freedom from the *diseases* under consideration ~~*listed by the OIE*~~ according to the relevant chapter in this *Aquatic Code*. ~~and approved as such by a *Competent Authority*.~~

***Infected zone* – current definition (Code 2004)**

~~means a clearly defined *zone* in which a *disease* of *aquatic animals* included in this *Aquatic Code* has been diagnosed. This area must be clearly defined and decreed by the *Competent Authority* in accordance with the environment, the different ecological and geographical factors, the epidemiological factors and the type of aquacultural activity being practised.~~

~~Within and at the border of an *infected zone,* there must be official veterinary control of *aquatic animals* and *aquatic animal products,* their *transportation* and *slaughtering*.~~

~~The time during which the infected zone designation remains in effect will vary according to the *disease* and to the sanitary measures and control methods applied.~~

***Infected zone* – definition proposed**

means a *zone* in which a *disease* has been diagnosed. The *infected zone* must be clearly defined by the *Competent Authority(ies)* concerned and may be separated from the rest of a country by a *buffer zone.*

Infection

means the presence of a multiplying or otherwise developing ~~the~~ *disease agent* in a ~~the~~ host.

Notification

the procedure by which:

a) the *Veterinary Administration* informs the *Central Bureau*,

b) the *Central Bureau* informs the *Veterinary Administrations* of Member Countries

of the ~~suspicion or~~ confirmation of a *disease outbreak*, according to the provisions of Section 1.2. of this *Aquatic Code*.

Water catchment

an area or basin of land bounded by natural features such as hills or mountains, into ~~from~~ which all run-off water flows.

***Zone* – current definition (Code 2004)**

~~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*.~~

***Zone* – definition proposed**

a portion of one or more countries comprising:

a) an entire *water catchment* from the source of a waterway to the estuary or lake, or

b) more than one *water catchment*, or

c) part of a *water catchment* from the source of a waterway to a barrier that prevents the introduction

of specific *disease* or *diseases*, or

d) part of a coastal area with a precise geographical delimitation, or

e) an estuary with a precise geographical delimitation,

that consists of a contiguous hydrological system with a distinct health status with respect to a specific *disease* or *diseases* for which required surveillance and control measures are applied and *basic biosecurity conditions* are met for the purpose of *international trade*. All areas of the zone must have the same health status. The zones must be clearly documented (e.g. by a map or other precise locators such as GPS co-ordinates) by the *Competent Authority(ies)*.

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Appendix IV

CHAPTER 1.1.2.

DISEASE LISTING AND NOTIFICATION CRITERIA

Community position

The Community observes that the proposal for refining the explanatory note to criterion 1, has not been taken into account. However, the justification given in the report for not doing so, refers to the comment given by the Community in October 2003. The comment given in January 2005, was not the same as indicated by the OIE, and the Community therefore invites the OIE to reconsider, its position.

The Community agrees with the proposed amendment to criterion 6.

The Community would raise its concern that the deletion of the reference to the disease specific surveillance chapters is not a indication of giving the work of drafting the disease-specific surveillance chapters a lower priority.

The Community agrees with the proposed criteria in Articles 1.1.2.2. and 1.1.2.3, but would invite the OIE to consider the replace the word "pathogenic agent" in Criterion B 1 of Article1.1.2.3, as with "disease agent" as the latter is defined in Article Chapter 1.1.1, while the first is not.

UNOFFICIAL VERSION

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.		The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in *susceptible* species*, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.
2.	Or	The disease has been shown to or scientific evidence indicates that it is likely to negatively affect wild aquatic animal populations that are an asset worth protecting for economic or ecological reasons.	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 or an aquatic animal potentially endangered by the disease.
3.	Or	The agent is of public health concern.	

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
		And **B. Spread**	
4.		Infectious aetiology of the disease is proven.	
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~~ or fomites ~~inanimate objects~~.	International trade in aquatic animal species *susceptible* to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is a likely risk.
7.	And	Several countries or countries with *zones* may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 ~~as well as the relevant disease chapter~~ of the *Aquatic Manual*.	*Free countries/zones* 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 *broodstock* from widespread diseases, or the protection of the last remaining *free zones* 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 OIE *Manual of Diagnostic Tests for Aquatic Animals*) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

UNOFFICIAL VERSION

Article 1.1.2.2.

Criteria for listing an emerging aquatic animal disease

A newly recognised disease or a known disease behaving differently may be listed if it meets the following criteria:

No.	Parameters that support a listing	Explanatory notes
1	Infectious aetiology of the disease is proven.	
or		
2	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.
and		
3	The agent is of public health concern.	
or		
4	Significant spread in naive populations	The disease has exhibited significant morbidity, mortality or production losses at a national or multinational (zonal or regional) level.

Article 1.1.2.~~2.~~3.

Criteria for ~~urgent~~ immediate notification of aquatic animal diseases

A. For listed diseases	
1.	First occurrence or re-occurrence of a *disease* in a country or *zone or compartment* of a country, if the country or *zone or compartment* of the country was previously considered to be free of that particular *disease*; or
2.	Occurrence in a new host species; or
3.	New pathogen strain or new disease manifestation; or
4.	~~Potential~~ Increased risk for international spread of the disease; or
5.	Newly recognised zoonotic potential.
B. For non-listed diseases	
1.	Emerging disease/pathogenic agent if there are findings that are of epidemiological significance to other countries.

* 'Susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'

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Appendix V

CHAPTER 1.1.3.

DISEASES LISTED BY THE OIE

Community position

The Community agrees with the proposed amendment to Chapter 1.1.3.

The Community appreciates that the OIE AAC have taken the request for further study of BKD, IPN and Koi herpes virus disease into account, and is looking forward to receive the outcome of those studies.

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Article 1.1.3.1.

The following diseases of fish are listed by the OIE:

– Epizootic haematopoietic necrosis

– Infectious haematopoietic necrosis

– ~~*Oncorhynchus masou* virus disease~~

– Spring viraemia of carp

– Viral haemorrhagic septicaemia

– ~~Channel catfish virus disease~~

– ~~Viral encephalopathy and retinopathy~~

– ~~Infectious pancreatic necrosis~~ [under study]

– Infectious salmon anaemia

– Epizootic ulcerative syndrome

– ~~Bacterial kidney disease (*Renibacterium salmoninarum*)~~ [under study]

– ~~Enteric septicaemia of catfish (*Edwardsiella ictaluri*)~~

– ~~Piscirickettsiosis (*Piscirickettsia salmonis*)~~

– Gyrodactylosis (*Gyrodactylus salaris*)

– Red sea bream iridoviral disease

– ~~White Sturgeon iridoviral disease~~

– Koi herpesvirus disease [under study].

Article 1.1.3.2.

The following diseases of molluscs are listed by the OIE:

– Infection with *Bonamia ostreae*

– Infection with *Bonamia* ~~*exitiosus*~~ *exitiosa*

– ~~Infection with *Mikrocytos roughleyi*~~

– ~~Infection with *Haplosporidium nelsoni*~~

– Infection with *Marteilia refringens*

– ~~Infection~~ with ~~*Marteilia sydneyi*~~

- Infection with Mikrocytos mackini

– Infection with Perkinsus marinus

– Infection with *Perkinsus olseni*~~*/ atlanticus*~~

– ~~Infection with *Haplosporidium costale*~~

– Infection with ~~Candidatus~~ *Xenohaliotis californiensis.*

Article 1.1.3.3.

The following diseases of crustaceans are listed by the OIE:

– Taura syndrome

– White spot disease

– Yellowhead disease

– Tetrahedral baculovirosis (*Baculovirus penaei*)

– Spherical baculovirosis (*Penaeus monodon*-type baculovirus)

– Infectious hypodermal and haematopoietic necrosis

– Crayfish plague (*Aphanomyces astaci*)

– ~~Spawner-isolated mortality virus disease~~

= Necrotising hepatopancreatitis

– ~~Infection with Mourilyan virus~~

= Infectious myonecrosis

– ~~White tail disease~~

– ~~Infection with hepatopancreatic parvovirus.~~

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Appendix VI

Comments on the EU *ad hoc* Group's "Assessment for OIE Listing of Koi Herpesvirus Disease (KHVD)" by the *ad hoc* Advisory Group (Finfish Subgroup) to the OIE Fish Disease Commission

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Summary

The Finfish Subgroup wishes to thank the individuals of the *ad hoc* EU Group who have carefully compiled the "Assessment for OIE Listing of Koi herpesvirus disease (KHVD)". In general, the Finfish Subgroup agrees that many of the criteria needed for listing of a disease by OIE are met. However, in addition to the criteria presented to the subgroup, there are several other features of the disease (KHVD) and the agent (KHV) that we believe require consideration or further clarification prior to a recommendation for listing by OIE.

Perhaps paramount among the considerations is that KHVD would be the first OIE-listed disease that is primarily a disease of ornamental fish. Thus, a complex and currently unregulated or poorly regulated network of pathways for fish (and pathogen) movements would have to be addressed. It is unclear whether there would be the mechanisms or the willingness in many OIE Member Countries to create the necessary framework for the required surveillance for issuance of health certificates for international trade in ornamental carp.

Secondly, although it is certain that farmed (pond or cage cultured) populations of common carp have been seriously affected by KHVD, evidence for negative impacts on wild populations is only just emerging. The most recent events in Japan are suggestive that such impacts can occur but the principal host involved in the large majority of disease outbreaks however is, and will most likely continue to be, koi (ornamental, fancy, coloured, etc. carp).

Lastly, features of the biology of KHVD and KHV remain unresolved and could severely complicate programmes aimed at control and containment of the disease, and surveillance programmes to demonstrate freedom. Examples of these features include the current uncertainty about the establishment of "carriers" and whether fish with anti-KHV antibodies or KHV DNA detected by PCR can indeed transmit the virus. Also, vaccination is likely to be a key focus for potential control, particularly in the principal regions from which most koi are exported. Vaccination is apt to render one of the more important tools for detecting prior virus exposure (potential carriers?) that being the presence of serum anti-KHV antibodies.

The Finfish Subgroup is of the view that certain considerations for listing of KHVD are similar to those of currently OIE-listed diseases but others are clearly different and this makes it important to consult further prior to reaching a conclusion on the EU proposal for listing of KHVD. The Subgroup proposes further deliberations among experts and consideration of comments from more OIE Member Countries on the justification for and the consequences/impacts and practicality of listing KHVD, before a recommendation is made.

Particular Comments from the Finfish Subgroup on the "Assessment/proposal"

In the following section the Subgroup comments on particulars in the proposal by the group of EU experts that prepared the "Assessment for OIE Listing of KHVD" and in particular the section of that assessment marked "Evaluation of Koi Herpesvirus (KHV) Disease and Proposal for Future Listing by the OIE" (from hereon referred to as the "Assessment").

Appendix VI (contd)

A. Consequences

1. Significant production losses at a national or multinational level

Large-scale production losses of farmed koi and/or common carp have been reported from Israel, Japan, Germany, Indonesia and Poland and these are well documented in the Assessment, prior literature, and a recent review of KHV by Haenen *et al.* (2004). Significant losses among smaller scale koi producers, wholesalers, and retailers have also occurred in numerous countries worldwide and the economic costs of that mortality likely exceeds that at the production scale level. Proper evaluations of the losses due to KHVD are easily complicated by other factors as concurrent infections (e.g. *F. columnare* or a range of ectoparasites) are often observed in fish from which KHV is identified. The events in Indonesia provide a noteworthy example. Despite serious losses among cultured common carp populations in 2002, outbreaks were rare in 2004 and conclusions from a FAO sponsored investigation of the 2002 losses suggest that factors other than KHV may have been involved in the large-scale losses observed in 2002.

The Subgroup does agree that preventing the spread of KHV to cultured populations of common carp in major production areas of Central and Eastern Europe and Asia is important. We suggest that at a minimum, regional or national programmes aimed at this goal be established.

2. Affects wild fish populations

The most recent and compelling example that wild populations of common carp may be affected by KHVD comes from Japan in 2003. Significant losses among wild common carp were reported from Lake Biwa in the spring of 2003 with estimates of losses as high as 70% of the wild stock in the lake. Further studies on the longer-term impacts of KHV on these wild carp stocks are underway.

In other locations, the role of KHV in mortality among wild carp populations are under evaluation (e.g. in the United Kingdom [UK] and the United States of America [USA]) and the information collected should provide insights into the potential for the virus to cause negative population impacts. It should be indicated that the carp sport fishery in the UK, which involves catch and release approaches in somewhat confined environments, may not represent the impacts on more naturally occurring common carp populations. It has recently been reported by Dr. John Grizzle, Auburn University, Alabama (personal communication) that KHV is present in wild common carp populations in the Southeastern USA. KHV specific DNA sequences were detected by PCR and confirmed by sequencing in the absence of large-scale fish losses or clinical signs of KHVD.

Based upon the fragmentary data collected to date, the Finfish Subgroup agrees that KHVD does pose some risk to wild common carp populations. However, additional data that includes a more rigorous epidemiologic approach to outbreak investigation is needed to confirm the association between virus infections and population impacts. This is critical because KHV infections alone may not always be the sole cause of mortality observed (e.g. many cases in Indonesia). Also, the longer-term impacts of the virus on wild carp populations are uncertain. Recent data from Japan on the apparent acquisition of a "herd-like" immunity has been proposed as one potential reason for the absence of continuing mortality among wild common carp in areas where outbreaks had been reported in the prior year (Miwa S., personal communication). Lending further evidence to support this hypothesis was the presence of anti-KHV antibodies detected in the sera of samples taken from these wild common carp.

3. Public health concern

No comments.

4. Infectious aetiology proven

No comments.

5. Infectious agent associated but aetiology not proven

No comments.

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6. Potential for international spread via live animals and their products

The Subgroup agrees that the extensive and often unregulated movements of koi, through the international ornamental fish trade (and even by individual hobbyists), provides a major network for spread of KHV. The experience in Japan also demonstrated the dangers associated with large scale national movements from central common carp rearing facilities in the rapid and comprehensive spread of KHV in 2003 (Sano *et al.*, 2004).

7. Several countries/zones may be declared free

Until a more comprehensive surveillance programme is developed, and certain countries may be unwilling to initiate such exercises, most information on the geographic distribution of KHVD will come from outbreak reports. It is clear that the virus is now widely spread and perhaps continuing to spread as a result of the trade in live koi. The known geographic distribution of KHV is apt to significantly expand as ornamental fish hobbyists become more aware about the disease and as more countries develop laboratory capabilities to detect the virus or evidence of the virus by PCR or ELISA.

8. A repeatable and robust means of detection/diagnosis exists

The current approach to detection and diagnosis are mentioned in the Assessment. Isolation of virus has proven to be difficult and several different PCR tests are in use, some with more and others with less field-testing or validation. Serological approaches, in particular ELISA detection of serum anti-KHV antibodies, do appear to be a good indicator of prior exposure to the virus. Both field and laboratory studies on the ability of these diagnostic methods to detect not only acute but latent or inapparent infections with the virus are underway. Generally accepted at this time is that PCR positive tests can be used to confirm acute infections when the appropriate signs and environmental conditions are present among koi or common carp undergoing losses. A positive test by ELISA from koi or common carp following natural exposures to the virus is viewed as an indicator of the "potential" for in apparent or latent infections or at a minimum, an increased risk for disease transmission.

REFERENCES IN ADDITION TO THOSE PROVIDED IN THE ASSESSMENT

SANO M., ITO T., KURITA J., YANAI T., WATANABE N., MIWA S. & IIDA T. (2004). First detection of koi herpesvirus in cultured common carp *Cyprinus carpio* in Japan. *Fish Pathology*, **39** (3), 165–168.

Reantaso, M et al. (2004). An Emergency Disease Control Task Force on a Serious Disease of Koi and Common Carps in Indonesia (subsequently referred to as 'Task Force' in this document), organized by NACA in cooperation with ACIAR and AAHRI.

Bulletin of Fisheries Research Agency (Supplement 2) – March 2005

The entire volume of papers currently "in press" from the March 2004 international meeting on KHVD in Yokohama, Japan. These should be available in March 2005 – Contact Dr. Shigeo Hayashe, NRI, Japan (xhayase@fra.affrc.go.jp).

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Appendix VII

CHAPTER 1.2.1.

NOTIFICATIONS AND EPIDEMIOLOGICAL INFORMATION

Community position

The Community agrees with the proposals for Chapter 1.2.1.

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Article 1.2.1.1.

For the purposes of this *Aquatic Code* and in terms of Articles 5, 9 and 10 of the Statutes, every Member Country of the OIE shall recognise the right of the *Central Bureau* to communicate directly with the *Veterinary Administration* of its *territory* or *territories*.

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

Article 1.2.1.2.

1) Countries shall make available to other countries, through the OIE, whatever information is necessary to minimise the spread of ~~important~~ aquatic animal *diseases* and their aetiological agents and to assist in achieving better world-wide control of these *diseases*.

2) To achieve this, countries shall comply with the reporting requirements specified in Article 1.2.1.3.

3) To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the current OIE disease reporting format.

4) Recognising that scientific knowledge concerning the relationship between *disease agents* and *diseases* is constantly evolving and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, countries shall ensure through their reports that they comply with the spirit and intention of paragraph 1 above. This means that the presence of an infectious agent, even in the absence of clinical *disease*, should be reported.

5) In addition to *notifying* ~~new~~ findings in accordance with Article 1.2.1.3., countries shall also provide information on the measures taken to prevent the spread of *diseases*, including possible quarantine measures and restrictions on the movement of *aquatic animals*, *aquatic animal products*, *biological products* and other miscellaneous objects that could by their nature be responsible for transmission of *disease*. In the case of *diseases* transmitted by vectors, the measures taken against such vectors shall also be ~~reported~~ described.

Article 1.2.1.3.

Veterinary Administrations shall send to the OIE:

1) Immediate *notification* (within 24 hours) by fax ~~telegram~~ or electronically ~~mail~~, of any of the following events:

   a) for *diseases listed by the OIE*, the first occurrence or re-occurrence of a *disease* in a country or *zone* or *compartment* of the country, if the country or *zone* or *compartment* of the country was previously considered to be free of that particular *disease*; or

Appendix VII (contd)

b) for *diseases listed by the OIE*, if the *disease* has occurred in a new host species; or

c) for *diseases listed by the OIE*, if the *disease* has occurred with a new pathogen strain or in a new *disease* manifestation; or

d) for *diseases listed by* the OIE, if there is ~~potential~~ increased risk for international spread of the *disease*; or

e) for *diseases listed by the OIE*, if the *disease* has newly recognised zoonotic potential; or

f) for diseases not listed by the OIE, if there is a case of an *emerging disease* or pathogenic agent should there be findings that are of epidemiological significance to other countries.

In deciding whether findings justify immediate *notification* (within 24 hours), countries must ensure that they comply with the obligations of Section 1.3. of this *Aquatic Code* (especially Article 1.3.1.1.), to report developments that may have implications for *international trade*.

2) ~~Monthly~~ Weekly reports by fax ~~telegram~~ or electronically ~~mail~~ subsequent to a *notification* under paragraph 1 above, to provide further information on the evolution of an incident that justified ~~urgent~~ immediate *notification*. These reports should continue until the *disease* has been eradicated or the situation has become sufficiently stable that ~~annual~~ six-monthly reporting under paragraph 3 will satisfy the obligation of the country to the OIE; in each case, a final report on the incident should be submitted.

3) ~~Annual~~ Six-monthly reports on the absence or presence and evolution of *diseases listed by the OIE*, and findings of epidemiological ~~importance~~ significance to other countries with respect to *diseases* that are not listed.

4) An annual questionnaire concerning any other information of significance to other countries.

Article 1.2.1.4.

1) The *Veterinary Administration* ~~or other *Competent Authority*~~ of a *territory* in which an *infected zone* or *compartment* was located shall inform the *Central Bureau* when this *zone* or *compartment* is free from the *disease*.

2) An *infected zone* or *compartment* of a determined *disease* shall be considered as such until a period exceeding the known *infective period* for the *disease* in question has elapsed after the last reported *outbreak* and when full prophylactic and appropriate sanitary measures have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in the various chapters of Parts 2, 3 or 4 of this *Aquatic Code*.

3) A country may *declare itself free* ~~be considered to be~~ again ~~free~~ from a specific *disease* when it can show that all the conditions given in the corresponding chapters of Parts 2, 3 or 4 of this *Aquatic Code* have been implemented ~~fulfilled~~.

4) The *Veterinary Administration* ~~or other *Competent Authority*~~ of a country that sets up one or several *free zones* or *compartments* shall inform the OIE, giving necessary particulars of the *zones* or *compartments* and describing their location (e.g. by a map or other precise locators such as GPS co-ordinates) ~~on a map of the country~~.

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~~Article 1.2.1.5.~~

~~*Veterinary Administrations* shall communicate to the OIE the provisions of their importation and exportation aquatic animal health regulations.~~

~~They shall also communicate any amendments to their regulations as soon as they are made and, at the latest, before the annual General Session of the OIE International Committee.~~

Article 1.2.1.5~~6~~.

1) The *Central Bureau* shall send by fax ~~telegram~~ or electronically ~~mail~~ to the *Veterinary Administration* concerned, all *notifications* received as provided in Articles 1.2.1.2–1.2.1.4.

2) The *Central Bureau* shall notify Member Countries through *Disease Information* of any event of exceptional epidemiological significance reported by a Member Country.

~~3) The *Central Bureau*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of this *Aquatic Code* and its effects on *international trade*.~~

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Appendix VIII

CHAPTER X.X.X.

INFECTION WITH *MARTEILIA REFRINGENS*

Community position

The Community agrees in general with the proposals in Appendix VIII.

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Article X.X.X.1.

~~For the purposes of this *Aquatic Code*, infection with *Marteilia refringens* means infection only with *Marteilia refringens*.~~

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

Article X.X.X.2.

Susceptible species

For the purposes 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*), Blue Mussel (*Mytilus edulis*) and Mediterranean Mussel (*M. galloprovincialis*).

~~Infection with *Marteilia refringens* can also cause *subclinical* infection in these species.~~

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

Article X.X.X.3.

Commodities

1) When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Marteilia refringens* related conditions, regardless of the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*:

   [under study]

   ~~a) gametes, eggs and larvae of molluscs;~~

   ~~b) processed non-viable molluscs (cooked, canned, smoked);~~

   ~~c) fresh non-viable half-shell oysters.~~

2) When authorising import or transit of the following *commodities* of a species listed in Article X.X.X.2., *Competent Authorities* should require the conditions prescribed in Articles X.X.X.7. to X.X.X.11. of this Chapter, relevant to the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment:*

a) *aquatic animals*;

b) *aquatic animal products*.

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of *Marteilia refringens*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Marteilia refringens*, and the potential consequences, associated with importation of the *commodity*, prior to a decision. The outcome of this assessment should be made available to the *exporting country*.

Article X.X.X.4.

***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) or 4) below.

If a country shares a *water catchment* or coastal *zone* ~~water resource~~ with one or more other countries, it can only declare itself a *Marteilia refringens* free country if all the areas covered by the shared water ~~resource~~ are declared *Marteilia refringens free zones* (see Article X.X.X.5.).

1) A country where none of the species listed in Article X.X.X.2. is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been ~~in place~~ met continuously in the country for at least the past 3 years[5] ~~and infection is not known to be established in wild populations~~.

OR

2) A country where the species listed in Article X.X.X.2. are present but there has never been any observed occurrence of the disease for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been ~~in place~~ met continuously in the country for at least the past 3 years and infection with *Marteilia refringens* is not known to be established in wild populations.

OR

3) A country where the last known clinical occurrence was within the past 10 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 X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when:

a) ~~it meets~~ *basic biosecurity conditions* have been met continuously for at least the past 3 years; and

b) *targeted surveillance* as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* has been in place for at least the last 2 of the past 3 years[6] without detection of *Marteilia refringens*.

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5 Infection with *Marteilia refringens* is a seasonal disease that is usually clinically expressed in the 2nd year of infection. Therefore, 3 years of biosecurity measures is the optimal period to enable the detection of cases of infection with *Marteilia refringens* in molluscs.

6 Starting the *targeted surveillance* in the 2nd year of the biosecurity measures ensures that new cases of infection with *Marteilia refringens* are more likely to be detected.

OR

4) A country that had declared itself free from *Marteilia refringens* but in which the *disease* is detected may not declare itself free from *Marteilia refringens* again until the following conditions have been met:

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

b) a *stamping-out policy* has been implemented in the *infected zone*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

In the meantime, other areas of the remaining *territory* may be declared one or more *free zones*, provided that they meet the conditions in point 3) of Article X.X.X.5.

Article X.X.X.5.

***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 infection with *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) or 4) 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 X.X.X.2. is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been ~~in place~~ met continuously in the *zone* or *compartment* for at least the past 3 years[7] ~~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 X.X.X.2. are present but there has never been any observed occurrence of the disease for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been ~~in place~~ met continuously in the *zone* or *compartment* for at least the past 3 years and infection with *Marteilia refringens* is not known to be established in wild populations.

[7] Starting the *targeted surveillance* in the 2nd year of the biosecurity measures ensures that new cases of infection with *Marteilia refringens* are more likely to be detected.

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Appendix VIII (contd)

OR

3) A *zone* or *compartment* where the last known clinical occurrence was within the past 10 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 X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when:

   a) ~~meets~~ *basic biosecurity* conditions have been met continuously for at least the past 3 years; and

   b) *targeted surveillance* as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* has been in place for at least the last 2 of the past 3 years[8] without detection of *Marteilia refringens*.

OR

4) A *zone* previously declared free from *Marteilia refringens* but in which the *disease* is detected may not be declared free from *Marteilia refringens* again until the following conditions have been met:

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

   b) a *stamping-out policy* has been implemented in the *infected zone*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

Article X.X.X.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Marteilia refringens* following the provisions of points 1) or 2) of Articles X.X.X.4. or X.X.X.5., respectively, may maintain its status as *Marteilia refringens* free 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 X.X.X.4. or X.X.X.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Marteilia refringens* free provided that conditions that are conducive to clinical expression of infection with *Marteilia refringens*, as described in Chapter X.X.X. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

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[8] Starting the *targeted surveillance* in the 2nd year of the biosecurity measures ensures that new cases of infection with *Marteilia refringens* are more likely to be detected.

However, for declared free *zones* or *compartment* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Marteilia refringens*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article X.X.X.7.

Importation of live animals from a country, zone or compartment declared free from *Marteilia refringens*

When importing live *aquatic animals* of the species listed in Article X.X.X.2., other than *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* declared free from *Marteilia refringens*, 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 X.X.X.4. or X.X.X.5. (as applicable), whether 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. [X] given in Part 6 of this *Aquatic Code*.

Article X.X.X.8.

Importation of live animals for aquaculture activities from a country, zone or compartment not declared free from *Marteilia refringens*

When importing for *aquaculture activities*, *aquatic animals* of the species listed in Article X.X.X.2., ~~for *aquaculture activities*~~, other than those *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as ~~require that~~:

1) the consignment is ~~be~~ delivered directly into and held in ~~approved~~ *quarantine* ~~secure rearing~~ facilities; and

2) the imported *aquatic animals* ~~and their first generation progeny~~ are ~~be~~ continuously isolated from the local environment; and

3) all effluent and waste material is ~~be~~ treated in a manner that ensures inactivation of *Marteilia refringens*.

Article X.X.X.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from *Marteilia refringens*

When importing for processing and/or human consumption, *aquatic animals* of the species listed in Article X.X.X.2. ~~for processing and/or human consumption~~, other than those live *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as ~~require that~~:

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Appendix VIII (contd)

1) the consignment is ~~be~~ delivered directly to and held in ~~approved~~ *quarantine* ~~secure holding~~ facilities for a short period before processing and/or consumption; and

2) all effluent and waste material is ~~be~~ treated in a manner that ensures inactivation of *Marteilia refringens*.

Article X.X.X.10.

Importation of products from a country, zone or compartment free from *Marteilia refringens*

When importing *aquatic animal products* of the *species* listed in Article X.X.X.2., other than *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* free from *Marteilia refringens*, 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 X.X.X.4. or X.X.X.5. (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. [X] given in Part 6 of this *Aquatic Code*.

Article X.X.X.11.

Importation of products from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animal products* of the species listed in Article X.X.X.2., other than those *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures. ~~such as require that:~~

~~1) the consignment is be delivered directly to and held in approved *quarantine* secure storage facilities, and be processed only in approved processing plants, and~~

~~2) all effluent and waste material is be treated in a manner that ensures inactivation of *Marteilia refringens*.~~

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Appendix IX

CHAPTER 4.1.2.

WHITE SPOT DISEASE

Community position

The Community agrees in general with the proposals in Appendix IX.

However, the Community disagrees with the requirement in Article 4.1.2.5 point 4 b and c. It is the Community's position that where possible, disease free status could be regained for an individual compartment provided the compartments has been emptied, where appropriate disinfected and fallowed, and then restocked with animals from a disease free population.

It also seems to be an editorial mistake in Article 4.1.2.5 point 4, as it currently only refers to "Zone", but should – as already included in points 1, 2 and 3 of the same article – refer to "Zone or compartment"

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Article 4.1.2.1.

For the purposes of this *Aquatic Code*, white spot disease (WSD) means infection with the viral species *White spot syndrome virus* (WSSV) in the genus *Whispovirus* of the family Nimaviridae. Common synonyms are listed in Chapter 4.1.2. of the *Aquatic Manual*.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 4.1.2.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for WSD are all decapod (order *Decapoda*) crustaceans from marine and brackish or freshwater sources. ~~In addition, Bivalves, rotifers, the non-decapodal crustacean *Artemia salina*, krill, copepods, and aquatic arthropods, sea slaters (*Isopoda*) and *Euphydradae* insect larvae, can accumulate high concentrations of viable WSSV although there is no evidence of replication in these species.~~

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

Article 4.1.2.3.

Commodities

1) When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any WSD related conditions, regardless of the WSD status of the *exporting country*, *zone* or *compartment*:

[under study]

~~a) cooked, canned or dried crustaceans (or molluscs as mechanical vectors) for direct human consumption;~~

~~b) chitin prepared from crustaceans shell by chemical extraction;~~

~~c) heat dried or sun dried crustacean by products intended for use in animal feeds or dry pelleted animal feeds containing crustacean by products;~~

~~c) *Artemia* cysts;~~

~~d) chemically preserved (and rendered non infectious) specimens of the species listed in Article 4.1.2.2.~~

2) When authorising import or transit of the following *commodities* of a species listed in Article 4.1.2.2., *Competent Authorities* should require the conditions prescribed in Articles 4.1.2.7. to 4.1.2.11. of this Chapter, relevant to the WSD status of the *exporting country*, *zone* or *compartment*:

   a) *aquatic animals*;

   b) *aquatic animal products*.

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of WSD, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of WSSV, and the potential consequences, associated with importation of the *commodity*, prior to a decision. This assessment should be made available to the *exporting country*.

Article 4.1.2.4.

WSD free country

A country may declare itself free from WSD if it meets the conditions in point 1), 2) or 3) or 4) below.

If a country shares a *water catchment* or coastal *zone* ~~water resource~~ 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 WSD free countries or zones (see Article 4.1.2.5.).

1) A country where none of the species listed in Article 4.1.2.2. is present may declare itself free from WSD when *basic biosecurity conditions* have been ~~in place~~ met continuously in the country for at least the past 2 years[9].

OR

2) A country where the species listed in Article 4.1.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from WSD when *basic biosecurity conditions* have been ~~in place~~ met continuously in the country for at least the past 2 years.

OR

3) A country where the last observed occurrence of the *disease* was within the past 10 years or where the infection status prior to *targeted surveillance* was unknown, for example because of the absence of

[9] The typical life cycle for susceptible species is 2 years or less. Under conditions conducive to disease expression, this period is required because it would cover the time period in which the most susceptible life stage (i.e. juvenile) is present.

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conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from WSD when:

a) ~~it has met~~ *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance* as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* has been in place for at least the past 2 years without detection of WSSV.

OR

4) A country that had declared itself free from WSD but in which the *disease* is detected may not declare itself free from WSD again until the following conditions have been met:

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

b) a *stamping-out policy* has been implemented in the *infected zone*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of WSSV.

In the meantime, other areas of the remaining *territory* may be declared one or more *free zones*, provided that they meet the conditions in point 3) of Article 4.1.2.5.

Article 4.1.2.5.

WSD free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from WSD may be 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), 2) or 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a WSD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1) A *zone* or *compartment* where none of the species listed in Article 4.1.2.2. is present may be declared free from WSD when *basic biosecurity conditions* have been ~~in place~~ met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2) A *zone* or *compartment* where the species listed in Article 4.1.2.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from WSD when *basic biosecurity conditions* have been ~~in place~~ met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3) A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 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 X.X.X. of the *Aquatic Manual*, may declare itself free from WSD when:

a) ~~it has met~~ *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance* as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* has been in

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place, throughout the *zone* or *compartment*, for at least the past 2 years without detection of WSSV.

OR

4) A *zone* previously declared free from WSD but in which the *disease* is detected may not be declared free from WSD again until the following conditions have been met:

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

b) a *stamping-out policy* has been implemented in the *infected zone*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of WSSV.

Article 4.1.2.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from WSD following the provisions of points 1) or 2) of Articles 4.1.2.4. or 4.1.2.5., 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 3) of Articles 4.1.2.4. or 4.1.2.5., 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 X.X.X. 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 of WSD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 4.1.2.7.

Importation of live animals from a country, zone or compartment declared free from WSD

When importing *aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* declared free from WSD, 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*, certifying that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), 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. [X] in Part 6 of this *Aquatic Code*.

Article 4.1.2.8

Importation of live animals for aquaculture activities from a country, zone or compartment not declared free from WSD

When importing for *aquaculture activities*, *aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as ~~require that~~:

1) the consignment is ~~be~~ delivered directly into and held in ~~approved~~ *quarantine* ~~secure rearing~~ facilities;

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and

2) the imported *aquatic animals* and their first generation progeny are ~~be~~ continuously isolated from the local environment; and

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3) all effluent and waste material is ~~be~~ treated in a manner that ensures inactivation of WSSV.

If the intention of the introduction is the establishment of new genetic lines, international standards, such as the the Guidelines of the International Council for the Exploration of the Seas (ICES) should be followed.

For the purposes of this *Aquatic Code*, the ICES Guidelines may be summarised to the following main points:

1) identify stock of interest (cultured or wild) in its current location;

2) evaluate stock's health/disease history;

3) take and test samples for WSSV, pests and general health/disease status;

4) import and *quarantine* in a secure facility a founder (F-0) population;

5) produce F-1 generation from the F-0 stock in *quarantine*;

6) culture F-1 stock and at critical times in its development (life cycle) sample and test for WSSV and perform general examinations for pests and general health/disease status;

7) if WSSV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet *basic biosecurity conditions* of the importing *compartment*, *zone*, or country the F-1 stock maybe defined as WSD free or specific pathogen free (SPF) for WSSV;

8) release SPF F-1 stock from *quarantine* for aquaculture or stocking purposes in the *compartment*, *zone*, or country.

Article 4.1.2.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from WSD

When importing for processing and/or human consumption, *aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as ~~require that~~:

1) the consignment is ~~be~~ delivered directly to and held in ~~approved~~ *quarantine* ~~secure holding~~ facilities for a short period before processing and/or consumption, and

2) all effluent and waste material is ~~be~~ treated in a manner that ensures inactivation of WSSV.

Article 4.1.2.10.

Importation of products from a country, zone or compartment free from WSD

When importing *aquatic animal products* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* free from WSD, 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*, certifying that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), 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. [X] in Part 6 of this *Aquatic Code*.

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Appendix IX (contd)

Article 4.1.2.11

Importation of products from a country, zone or compartment not declared free from WSD

When importing *aquatic animal products* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures. ~~such as require that:~~

~~1) the consignment is be delivered directly to and held in approved secure storage facilities, and be processed only in approved processing plants; and~~

~~2) all effluent and waste material is be treated in a manner that ensures inactivation of WSSV.~~

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Appendix X

CHAPTER 2.1.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

Community position

The Community agrees in general with the proposals in Appendix X.

In addition, the Community disagrees with the requirement in Article 2.1.1.5 point 4 b and c. It is the Community's position that where possible, disease free status could be regained for an individual compartment provided the compartments has been emptied, where appropriate disinfected and fallowed, and then restocked wit animals from a disease free population.

It also seems to be an editorial mistake in Article 2.1.1.5 point 4, as it currently only refers to "Zone", but should – as already included in points 1, 2 and 3 of the same article – refer to "Zone or compartment"

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Article 2.1.1.1.

For the purposes of this *Aquatic Code*, epizootic haematopoietic necrosis (EHN) means infection with the viral species EHN virus (EHNV) in the genus *Ranavirus* of the family Iridoviridae.

Methods for surveillance and diagnosis are provided in the *Aquatic Manual*.

Article 2.1.1.2.

Susceptible species

For the purposes 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 (*Gambusa affinis*) and other species belonging to the family Poeciliidae.~~

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

Article 2.1.1.3.

Commodities

1) When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any EHN related conditions, regardless of the EHN status of the *exporting country*, *zone* or *compartment*:

[under study]

~~a) leather made from fish skin via a full curing process;~~

~~b) fish by-products, such as flame-dried or sun-dried meals, and ensilaged fish;~~

~~c) dead eviscerated fish of a species listed in Article 2.1.1.2. (chilled, sun-dried, smoked or frozen) not intended for further processing prior to retail sale;~~

~~d) dead fish of non-susceptible species, eviscerated or non-eviscerated;~~

~~e) canned fish;~~

~~f) chemically preserved (and rendered non-infectious) specimens of the species listed in Article 2.1.1.2.~~]

2) When authorising import or transit of the following *commodities* of a species listed in Article 2.1.1.2., *Competent Authorities* should require the conditions prescribed in Articles 2.1.1.7. to 2.1.1.11. of this Chapter, relevant to the EHN status of the *exporting country*, *zone* or *compartment*:

a) *aquatic animals*;

b) *aquatic animal products*.

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of EHN, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of EHNV, and the potential consequences, associated with importation of the *commodity*, prior to a decision. This assessment should be made available to the *exporting country*.

Article 2.1.1.4.

EHN free country

A country may declare itself free from EHN if it meets the conditions in point 1), 2) or 3) or 4) below.

If a country shares a *water catchment* ~~water resource~~ with one or more other countries, it can only declare itself an EHN free country if all the areas covered by the shared water ~~resource~~ are declared EHN free countries or zones (see Article 2.1.1.5.).

1) A country where none of the species listed in Article 2.1.1.2. is present may declare itself free from EHN when *basic biosecurity conditions* have been ~~in place~~ met continuously in the country for at least the past 2 years.

OR

2) A country where the species listed in Article 2.1.1.2. 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 X.X.X. of the *Aquatic Manual*, may declare itself free from EHN when *basic biosecurity conditions* have been ~~in place~~ met continuously in the country for at least the past 10 years.

OR

3) A country where the last observed occurrence of the *disease* 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 X.X.X. of the *Aquatic Manual*, may declare itself free from EHN when:

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a) ~~it has met~~ *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance* as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* has been in place for at least the past 2 years without detection of EHNV.

OR

4) A country that had declared itself free from EHN but in which the *disease* is detected may not declare itself free from EHN again until the following conditions have been met:

a) on detection of the disease, the affected area was declared an infected zone and a buffer zone was established; and

b) a *stamping-out policy* has been implemented in the *infected zone*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of EHNV.

In the meantime, other areas of the remaining territory may be declared one or more *free zones*, provided that they meet the conditions in point 3) of Article 2.1.1.5.

Article 2.1.1.5.

EHN free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from EHN may be 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), 2) or 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared an EHN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1) A *zone* or *compartment* where none of the species listed in Article 2.1.1.2. is present may be declared free from EHN when *basic biosecurity conditions* have been ~~in place~~ met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2) A *zone* or *compartment* where the species listed in Article 2.1.1.2. are present but in which 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 X.X.X. of the *Aquatic Manual*, may be declared free from EHN when *basic biosecurity conditions* have been ~~in place~~ met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

3) A *zone* or *compartment* where the last observed occurrence of the *disease* 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 X.X.X. of the *Aquatic Manual*, may declare itself free from EHN when:

a) ~~it has met~~ *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance* as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* has been in place for at least the past 2 years without detection of EHNV.

OR

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4) A *zone* previously declared free from EHN but in which the *disease* is detected may not be declared free from EHN again until the following conditions have been met:

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

b) a *stamping-out policy* has been implemented in the *infected zone*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of EHNV.

Article 2.1.1.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from EHN following the provisions of points 1) or 2) of Articles 2.1.1.4. or 2.1.1.5., 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 3) of Articles 2.1.1.4. or 2.1.1.5., 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 X.X.X. 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 of EHN, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.1.7.

Importation of live animals from a country, zone or compartment declared free from EHN

When importing *aquatic animals* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* declared free from EHN, 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*, certifying that, on the basis of the procedures described in Articles 2.1.1.4. or 2.1.1.5. (as applicable), 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. [X] in Part 6 of this *Aquatic Code*.

Article 2.1.1.8.

Importation of live animals for aquaculture activities from a country, zone or compartment not declared free from EHN

When importing for *aquaculture activities*, *aquatic animals* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as ~~require that~~:

1) the consignment is ~~be~~ delivered directly into and held in ~~approved~~ *quarantine* ~~secure rearing~~ facilities; and

2) the imported *aquatic animals* and their first generation progeny are ~~be~~ continuously isolated from the local environment; and

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3) all effluent and waste material is ~~be~~ treated in a manner that ensures inactivation of EHNV.

Article 2.1.1.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from EHN

When importing for processing and/or human consumption, *aquatic animals* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as ~~require that~~:

1) the consignment is ~~be~~ delivered directly to and held in ~~approved~~ *quarantine* ~~secure holding~~ facilities for a short period before processing and/or consumption; and

2) all effluent and waste material is ~~be~~ treated in a manner that ensures inactivation of EHNV.

Article 2.1.1.10.

Importation of products from a country, zone or compartment free from EHN

When importing *aquatic animal products* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* free from EHN, 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*, certifying that, on the basis of the procedures described in Articles 2.1.1.4. or 2.1.1.5. (as applicable), 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. [X] in Part 6 of this *Aquatic Code*.

Article 2.1.1.11.

Importation of products from a country, zone or compartment not declared free from EHN

When importing *aquatic animal products* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures. ~~require that:~~

~~1) the consignment be delivered directly to and held in approved secure storage facilities, and be processed only in approved processing plants; and~~

~~2) all effluent and waste material be treated in a manner that ensures inactivation of EHNV.~~

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Appendix XI

APPENDIX 5.2.1.

GENERAL RECOMMENDATIONS ON DISINFECTION

Community position

The Community agrees with the proposals in Appendix XI.

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(Showing amendments)

Article 5.2.1.1.

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

~~Article 5.2.1.2.~~

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 into and from an *aquaculture establishment*.~~ *Disinfection* procedures should be part of a *disinfection* programme designed for a specific purpose. *Disinfection* may ~~consequently~~ be used ~~as a routine practice~~ in biosecurity programmes ~~designed~~ to eradicate or exclude specific diseases from *aquaculture establishments*, as well as a routine sanitary measure ~~employed~~ to reduce *disease* incidence within *aquaculture establishments*.

Disinfection of installations and equipment and transport units ~~(including *vehicles* and boats)~~ should be carried out ~~in areas where and according to~~ using procedures ~~and methods such~~ that prevent the ~~risk of contaminating~~ contamination of other water and other aquatic animal populations with infectious material ~~is avoided~~. ~~For example, organic material generated/removed during the cleaning process, such as pond sludge, etc., should be disposed of 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~~ procedures for washing and disinfecting installations or equipment~~, including vehicles and boats, that can be~~ used in *aquaculture establishments* or for treating effluents, and wastes from *quarantine* and *processing* plants. The decision on which product to use should take into account ~~correct choice of such products will depend on~~ their microbiocidal efficacy, their safety for ~~potential effect on~~ *aquatic animals* and the environment~~al impact, and costs~~ induced by their use. ~~*Disinfection* procedures should be part of a *disinfection* programme that establishes 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 5.2.1.2~~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.~~

These have a corrosive and irritant effect on surfaces and mucosa. The iodine present in iodophores is associated with other elements that improve their action by giving them the humectant properties of detergents.

2) *Disinfectants* of with selective actions (quaternary ammonia, phenols, formaldehyde and alcohol) that act 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.

The efficacy of *disinfection* is affected by various factors, including temperature, pH, and the presence of organic matter,. and The manufacturer's instructions for effective use of a *disinfectant* under aquaculture conditions should be followed. Disinfectants to be used in aquaculture should be evaluated/tested against relevant aquatic pathogens under relevant conditions. Approved procedures for the use of *disinfectants* in aquaculture should be established.

The efficacy of *disinfection* is affected by various factors, including temperature, pH, and the presence of organic matter. Temperature is a determinant factor in the action of disinfectants. At high temperatures, the disinfecting action is faster as long as the decomposition of the *disinfectant* does not occur. limit of the product is not reached. At low temperatures the biocidal efficacy of most disinfectants decrease. Similarly, pH also affects the action of *disinfectants*. Many disinfectants have an optimum pH range/level, and product choice should depend on the pH of the diluent (water). For example, quaternary ammonia is more efficient at alkaline pH while iodine and iodophores are more efficient at neutral or acid pH. The presence of organic material and greasy substances may significantly reduce the efficacy of a *disinfectant*. Therefore, surfaces should be cleaned thoroughly before applying *disinfectants*.

Special attention ought to should be paid to organic matters material and greasy substances that can significantly reduce the efficacy of the *disinfectant*. Therefore, surfaces should be It is recommended to cleaned thoroughly the surfaces to be disinfected before applying *disinfectants*, as their actions can drastically decrease due to the presence of these elements.

The safe use of *disinfectants* may require entails the implementation of measures to protect personnel, and cultured *aquatic animals* and to mitigate the environment.; al effects and The manufacturer's instructions for safe use and disposal should be followed. 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 or 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 the *disinfection* effectiveness against target pathogens, toxicological and ecotoxicological properties of the *disinfectants*.

Article 5.2.1.4. (move to the *Aquatic Manual*)

The choice of *disinfection* procedures depends on the size, type and nature of the materials and facilities to be disinfected. The range of surfaces to be disinfected consists of fabric or woven material (clothes, nets), hard surfaces (plastic, cement) or permeable materials (earth, gravel). *Disinfection* is more difficult on permeable surfaces and requires more time.

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, and effluent waters) and their association to equipment 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

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~~cleaning programme that is designed to eliminate all the remaining organic matter adhering to the surfaces, the use of *disinfectants* on equipment and installations and a final neutralisation step 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 that 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.~~

Article 5.2.1.3.

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

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Appendix XI (contd)

APPENDIX 5.2.1.

GENERAL RECOMMENDATIONS ON DISINFECTION

(Clean text)

Article 5.2.1.1.

Disinfection is employed as a common disease management tool in aquaculture. *Disinfection* procedures should be part of a *disinfection* programme designed for a specific purpose. *Disinfection* may be used in biosecurity programmes to eradicate or exclude specific diseases from *aquaculture establishments*, as well as a routine sanitary measure to reduce *disease* incidence within *aquaculture establishments*.

Disinfection of installations and equipment and transport units should be carried out using procedures that prevent the contamination of other water and other aquatic animal populations with infectious material. There is a great variety of products and procedures for washing and disinfecting installations or equipment used in *aquaculture establishments* or for treating effluents, and wastes from *quarantine* and *processing* plants. The decision on which product to use should take into account their microbiocidal efficacy, their safety for *aquatic animals* and the environment.

Article 5.2.1.2.

The manufacturer's instructions for effective use of a *disinfectant* under aquaculture conditions should be followed. Disinfectants to be used in aquaculture should be evaluated/tested against relevant aquatic pathogens under relevant conditions. Approved procedures for the use of *disinfectants* in aquaculture should be established.

The efficacy of *disinfection* is affected by various factors, including temperature, pH, and the presence of organic matter. At high temperatures, the disinfecting action is faster as long as the decomposition of the *disinfectant* does not occur. At low temperatures the biocidal efficacy of most disinfectants decrease. Many disinfectants have an optimum pH range/level, and product choice should depend on the pH of the diluent (water). For example, quaternary ammonia is more efficient at alkaline pH while iodine and iodophores are more efficient at neutral or acid pH. The presence of organic material and greasy substances may significantly reduce the efficacy of a *disinfectant*. Therefore, surfaces should be cleaned thoroughly before applying *disinfectants*.

The use of *disinfectants* may require measures to protect personnel, *aquatic animals* and the environment. The manufacturer's instructions for safe use and disposal should be followed.

Article 5.2.1.3.

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

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Appendix XII

APPENDIX X.X.X.

GENERAL GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE

Community position

The Community agrees with the proposals in Appendix XII.

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Article X.X.X.1.

Introduction and objectives

1) In general, surveillance is aimed at demonstrating the absence of *disease* or *infection*, determining the occurrence or distribution of *disease* or *infection*, while also detecting as early as possible exotic or *emerging diseases*. The type of surveillance applied depends on the desired outputs needed to support decision-making. The following guidelines may be applied to all *diseases*, their agents and susceptible species as listed in this *Aquatic Code*, and are designed to assist with the development of surveillance methodologies. Except where a specific surveillance method for a certain *disease* or *infection* is already described in this *Aquatic Code*, the guidelines in this Appendix may be used to further refine the general approaches described for a specific *disease* or *infection*. Where detailed *disease/infection*-specific information is not available, suitable approaches should be based on the guidelines in this Appendix.

2) *Aquatic animal* health surveillance is an essential component necessary to detect diseases, to support claims for freedom from disease, to provide data to support the risk analysis process, and to substantiate the rationale for sanitary measures. Surveillance data underpin the quality of disease status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for internal decision-making.

3) Essential prerequisites to enable a Member Country to provide information for the evaluation of its *aquatic animal* health status are:

   a) that the particular Member Country complies with the provisions of Chapter 1.4.3. of this *Aquatic Code* on the evaluation of *Competent Authorities*;

   b) that surveillance data, where possible, be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

   c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.2.1. of this *Aquatic Code*.

4) The objectives of this Appendix are to:

   a) provide guidance to the type of outputs that a surveillance system should generate;

   b) provide guidelines to assess the quality of disease surveillance systems.

Article X.X.X.2.

Definitions

The following definitions apply for the purposes of this Appendix.

Bias: A tendency of an estimate to deviate in one direction from a true value.

Case definition: A case definition is a set of criteria used to classify an *aquatic animal* or epidemiological unit as a case.

Confidence: In the context of demonstrating freedom from *infection*, confidence is the probability that the type of surveillance applied would detect the presence of *infection* if the population were infected. The confidence depends on, among other parameters, the assumed level of *infection* in an infected population. The term refers to our confidence in the ability of the surveillance applied to detect *disease*, and is equivalent to the sensitivity of the surveillance system.

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 of activating diagnostic investigation with minimal delay. Such a system should 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* and *emerging 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*.

Epidemiological unit: A group of animals with a defined epidemiological relationship that share approximately the same likelihood of exposure to a pathogen. This may be because they share a common aquatic environment (e.g. fish in a pond, caged fish in a lake, mollusc rearing units, shrimp ponds), or because of common management practices. In some circumstances, the epidemiological unit may be a single such unit, or group of such units, on the same farming site.

Outbreak definition: An outbreak definition is a set of criteria used to classify the occurrence of one or more cases in a group of animals or units as an outbreak.

Probability sampling: A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sample: The group of elements (sampling units) drawn from a population, on which tests are performed or parameters measured to provide surveillance information.

Sampling units: The unit that is sampled, either in a random survey or in non-random surveillance. This may be an individual animal or a group of animals (e.g. an epidemiological unit). Together, they comprise the sampling frame.

Sensitivity: The proportion of true positive tests given in a diagnostic test, i.e. the number of true positive results divided by the number of true positive and false negative results.

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Specificity: The probability that absence of infection will be correctly identified by a diagnostic test (i.e. the number of true negative results divided by the number of true negative and false positive results).

Study population: The population from which surveillance data is derived. This may be the same as the target population or a subset of it.

Surveillance: Means a systematic series of investigations of a given population of *aquatic animals* to detect the occurrence of *disease* for control purposes, and which may involve testing samples of a population.

Surveillance system: A method of surveillance that may involve one or more component activities that generates information on the health, disease or zoonosis status of animal populations.

Survey: An investigation in which information is systematically collected, usually carried out on a sample of a defined population group, within a defined time period.

Target population: The population about which conclusions are to be inferred.

Test: A procedure used to classify a unit as either positive, negative or suspect with respect to an *infection* or *disease*.

Test system: A combination of multiple tests and rules of interpretation which are used for the same purpose as a test.

Article X.X.X.3.

Principles of surveillance

1) Types of surveillance

   a) Surveillance may be based on many different data sources and can be classified in a number of ways, including:

      i) the means by which data are collected (active versus passive surveillance);

      ii) the disease focus (pathogen-specific versus general surveillance); and

      iii) the way in which units for observation are selected (structured surveys versus non-random data sources).

   b) In this Appendix, surveillance activities are classified as being based either on:

      i) structured population-based surveys, such as:

         – systematic sampling at slaughter;

         – random surveys; or

      ii) structured non-random surveillance activities, such as:

         – disease reporting or notifications;

         – control programmes/health schemes;

         – targeted testing/screening;

         – ante-mortem and post-mortem inspections;

         – laboratory investigation records;

         – biological specimen banks;

         – sentinel units;

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– field observations;

– farm production records.

2) Surveillance data

In addition, surveillance data should be supported by related information, such as:

a) data on the epidemiology of the infection, including environmental, host population distribution, and climatic information;

b) data on animal movements and trading patterns for animals and animal products;

c) history of imports of potentially infected material; and

d) biosecurity measures in place.

The sources of evidence should be fully described. In the case of a structured survey, this should include a description of the sampling strategy used for the selection of units for testing. For structured non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any biases that may be inherent in the system.

3) Critical elements

In assessing the quality of a surveillance system, the following critical elements need to be addressed over and above quality of *Competent Authorities* (Chapter 1.3.4.).

a) Populations

Surveillance should be carried out in such a way as to take into account all *aquatic animal* species susceptible to the *infection* in a country, *zone* or *compartment*. The surveillance activity may cover all individuals in the population or part of them. In the latter case, care should be taken regarding the inferences made from the results.

Definitions of appropriate populations should be based on the specific recommendations of the disease chapters of this *Aquatic Code*.

b) Epidemiological unit

The relevant epidemiological unit for the surveillance system should be defined and documented to ensure that it is representative of the population. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

c) Clustering

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a population. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a *zone* or *compartment*). Clustering should be taken into account in the design of surveillance activities and the statistical analysis of surveillance data, at least at what is judged to be the most significant level of clustering for the particular animal population and *infection*.

d) Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for

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each pathogen under surveillance, using, where they exist, the standards in this *Aquatic Code*.

e) Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real-life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be documented and supported by references to the OIE Standards, to the scientific literature and other sources, including expert opinions. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

f) Testing

Surveillance involves the detection of *disease* or *infection* by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance and should be taken into account in the design of surveillance systems and analysis of surveillance data.

The values of sensitivity and specificity for the tests used should be specified, and the method used to determine or estimate these values should be documented. Where values for sensitivity and/or specificity for a particular test are specified in the *Aquatic Manual*, these values may be used without justification.

Samples from a number of animals or units may be pooled together and subjected to a single test. The results should be interpreted using sensitivity and specificity values that have been determined or estimated for that particular pool size and testing procedure.

g) Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

h) Validation

Results from animal health surveillance systems are subject to one or more potential biases. When assessing the results, care should be taken to identify potential biases that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

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Appendix XII (contd)

i) Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during disease control interventions, inspections for movement control or during disease eradication schemes), the consistency of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

i) the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;

ii) the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;

iii) maintenance of disaggregated data rather than the compilation of summary data;

iv) minimisation of transcription during data processing and communication.

Article X.X.X.4.

Principles for surveys

In addition to the general principles for surveillance discussed above, the following guidelines should be used when planning, implementing and analysing surveys.

1) Types of surveys

Surveys may be conducted on the whole target population (i.e. a census) or on a sample. A sample may be selected in either of the two following manners:

a) non-probability-based sampling methods, such as:

i) convenience;

ii) expert choice;

iii) quota;

b) probability-based sampling methods, such as:

i) simple random selection;

ii) cluster sampling;

iii) stratified sampling.

2) Systematic selection

Periodic or repeated surveys conducted in order to document disease freedom must be done using probability-based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of units for testing. Also, consideration should be made of any biases that may be inherent in the survey design.

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3) Survey design

The population of epidemiological units should first be clearly defined where after sampling units appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the population being studied, the epidemiology of the infection and the resources available.

4) Sampling

The objective of sampling from a population is to select a subset of units from the population that is representative of the population with respect to the object of the study, such as the presence or absence of *infection*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production systems. In order to detect the presence of an *infection* in a population of unknown disease status, targeted sampling methods that optimise the detection of *infection* can be used. In such cases, care should be taken regarding the inferences made from the results.

5) Sampling methods

When selecting epidemiological units from within a population, a formal probability sampling method (e.g. simple random sampling) should be used. When this is not possible, sampling should provide the best practical chance of generating a sample that is representative of the target population.

In any case, the sampling method used at all stages should be fully documented and justified.

6) Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *infection*) or to estimate a parameter (e.g. the prevalence of *infection*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Article X.X.X.5.

Principles for structured non-random surveillance

Surveillance systems routinely use structured non-random data, either alone or in combination with surveys. There is a wide variety of non-random data sources that can be used.

1) Common non-random surveillance sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from *infection*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes).

a) Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. Effective laboratory support is an important component of any reporting system. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a good specificity.

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b) Control programmes/health schemes

Aquatic animal disease control programmes or health schemes, while focusing on the control or eradication of specific diseases, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to structured surveillance.

c) Targeted testing/screening

This may involve testing targeted to selected sections of the population (sub-populations), in which disease is more likely to be found. Examples include testing culled animals, weak animals (often at the water outlet or on the water surface) and recently-dead animals.

d) Ante-mortem and post-mortem inspections

Inspections of *aquatic animals* at harvesting, slaughtering and processing premises may provide valuable surveillance data. The sensitivity and specificity of such inspections for the detection of *disease* will be influenced by:

i) the level of training and experience of the staff doing the inspections, and the ratio of staff of different levels of training;

ii) the involvement of the *Competent Authorities* in the supervision of ante-mortem and post-mortem inspections;

iii) the quality of construction of the slaughtering and processing premises, speed of the slaughter chain, lighting quality, etc.; and

iv) staff morale.

Inspections of *aquatic animals* at harvesting, slaughtering and processing premises are likely to provide good coverage only for particular age groups and geographical areas. Statistical biases are likely to be more frequent for infected animals originating from larger, better managed farms rather than for animals originating from smallholder or backyard farms, as well as for healthy rather than diseased animals.

Both for traceback in the event of detection of disease and for analysis of spatial and farm-level coverage, there should be, if possible, an effective identification system that relates each batch of *aquatic animals* in the slaughtering or processing premises to its property of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with inspections of fish slaughtering premises, there needs to be a mechanism to relate specimens to the farm of origin.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *infection*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

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g) Sentinel units

Sentinel units/sites involve the identification and regular testing of one or more of animals of known health/immune status in a specified geographical location to detect the occurrence of disease (usually serologically). They are particularly useful for surveillance of diseases with a strong spatial component, such as diseases with an intermediate host. Sentinel units provide the opportunity to target surveillance depending on the likelihood of *infection* (related to intermediate host habitats and host population distribution), cost and other practical constraints. Sentinel units may provide evidence of freedom from *infection*, or provide data on prevalence and incidence as well as the distribution of *disease*.

h) Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the rearing unit level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

2) Critical elements for structured non-random surveillance

There is a number of critical factors which should be taken into account when using structured non-random surveillance data such as coverage of the population, duplication of data, and sensitivity and specificity of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to structured surveys.

3) Analytical methodologies

Different methodologies may be used for the analysis of non-random surveillance data.

Analytical methodologies based on the use of step-wise probability estimates to describe the surveillance system may determine the probability of each step either by:

a) the analysis of available data, using a scientifically valid methodology; or where no data are available;

b) the use of estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology.

4) Combination of multiple sources of data

The methodology used to combine the evidence from multiple data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times may provide cumulative evidence of *aquatic animal* health status. Such evidence gathered over time may be combined to provide an overall level of confidence. For instance, repeated annual surveys may be analysed to provide a cumulative level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources may be able to achieve the same level of confidence in just one year.

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Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take the decreased value of older information into account.

Article X.X.X.6.

Demonstration of freedom from disease

1) Introduction

A surveillance system to demonstrate freedom from *disease* should meet the following requirements in addition to the general requirements for surveillance outlined in point 2) of this Article.

Freedom from *disease* implies the absence of the *disease agent* in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *disease*. Demonstrating freedom from *disease* involves providing sufficient evidence to demonstrate the *disease agent* is not present in a population. In practice, it is not possible to prove (i.e. be 100% confident) that a population is free from *disease* (unless every member of the population is examined simultaneously with a perfect test with both sensitivity and specificity equal to 100%). Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *disease*, if present, is present in less than a specified proportion of the population.

However, finding evidence of infection at any level in the target population automatically invalidates any freedom from infection claim.

Evidence from non-random data sources as stated below, may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared with structured surveys.

2) Self-declaration of freedom from disease

This point provides general principles for declaring a country, *zone* or *compartment* free from *disease* in relation to the time of last occurrence and in particular for the recognition of historical freedom.

The provisions of this point are based on Articles X.X.X.1., X.X.X.2. and X.X.X.3. of this Appendix and the following assumptions:

a) in the absence of *disease* and vaccination, the *aquatic animal population* would become susceptible over a period of time; and

b) the *disease agents* to which these provisions apply are likely to produce identifiable clinical signs in *susceptible aquatic animals*; and

c) *Competent Authorities* will be able to investigate, detect, diagnose and report *disease*, if present; and

d) the absence of *disease* over a long period of time in a *susceptible* population can be substantiated by effective disease investigation and reporting by the *Competent Authorities* of an OIE Member Country.

3) Additional requirements to declare a country, zone or compartment free from disease without targeted surveillance

a) Historically free

Unless otherwise specified in the relevant disease chapter, a country, *zone* or *compartment* may be declared free from *disease* without applying a *targeted surveillance* programme when:

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i) there has never been any observed occurrence of *disease*; or

ii) eradication has been achieved or the *disease* has not been observed for at least 25 years,

provided that for at least the past 10 years:

iii) it has been a notifiable disease; and

iv) an early detection system has been in place; and

v) measures to prevent *disease* introduction have been in place; and

vi) the *disease* is not known to be established in wild populations within the country or *zone* intended to be declared free. (A country or *zone* cannot be declared historically free if there is any evidence of the *disease* in wild populations.)

b) Last occurrence within the previous 25 years

Countries, *zones* or *compartments* that have achieved eradication (or in which the disease has ceased to occur) within the previous 25 years, should follow the *targeted surveillance* requirements in this *Aquatic Code* if they exist. In the absence of specific requirements for surveillance in this *Aquatic Code*, countries should follow these general guidelines for surveillance. To demonstrate free status, the following must have been in place continuously for at least the past 10 years:

i) the *disease* has been a *notifiable* disease; and

ii) an early detection system has been in place; and

iii) measures to prevent *disease* introduction have been in place; and

iv) the *disease* is not known to be established in wild populations within the country or *zone* intended to be declared free. (A country or *zone* cannot be declared historically free if there is any evidence of the *disease* in wild populations.)

c) Guidelines for the discontinuation of *targeted surveillance* after declaration of freedom from disease

A country, *zone* or *compartment* that has been *declared free* from *disease* following the provisions of this *Aquatic Code* may discontinue *targeted surveillance* while maintaining the disease-free status provided that:

i) the *disease* remains notifiable; and

ii) an early detection system remains in place; and

iii) measures to prevent *disease* introduction remain in place.

Article X.X.X.7.

Surveillance for determining occurrence and distribution of disease

Surveillance for occurrence and distribution of *disease* or of other relevant health-related events is widely used to assess progress in the control or eradication of selected diseases and pathogens and an aid to decision making.

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Appendix XII (contd)

In contrast to surveillance to demonstrate freedom from *disease*, surveillance used to assess progress in control or eradication of selected diseases and pathogens is usually designed to collect data about a number of variables of *aquatic animal* health relevance, for example:

1) prevalence or incidence of *infection*;

2) morbidity and mortality rates;

3) frequency of *disease*/*infection* risk factors and their quantification when the risk factors are expressed by continuous (real numbers) or discrete (integers) variables;

4) frequency distribution of population sizes or the sizes of other epidemiological units;

5) frequency distribution of antibody titres;

6) proportion of immunised animals after a vaccination campaign;

7) frequency distribution of the number of days elapsing between suspicion of infection and laboratory confirmation of the diagnosis and/or to the adoption of control measures;

8) farm production records, etc.

All of the listed data may also have relevance for the risk analysis.

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Appendix XIII

COMMISSION WORK PLAN FOR 2005
Aquatic Animal Health Code
• Ongoing review of the list of diseases
• Revise disease chapters for EHN, infection with *Marteilia refringens* and white spot disease, with the assistance of *ad hoc* groups and other experts, especially to identify commodities

• Harmonise horizontal chapters with those in the *Terrestrial Code*
  • Chapter 1.1.2 Diseases listing and notification criteria
  • Chapter 1.2.1 Notification and epidemiological information
  • Chapter 1.4.4 Zoning (and compartmentalisation)
  • Chapter on aquatic animal health surveillance

Manual of Diagnostic Tests for Aquatic Animals
• Ask authors for preparation of updates of disease chapters for the fifth edition of the *Manual*, using the new template
• Revise the specific *Manual* Chapters on disinfection of fish and of mollusc *aquaculture establishments*
• Revise current Chapter 1.1.4 with the assistance of *ad hoc* groups and other experts
Meetings
• Preparation of the OIE Global Conference on Aquatic Animal Health
• Make presentations on the activities of the Aquatic Animals Commission at the Conferences of the OIE Regional Commissions for Africa; the Middle-East; Asia, the Far East and Oceania
• Assist in the implementation of recommendations adopted by the OIE Regional Commission for Asia, the Far East and Oceania in 2003, and endorsed by the International Committee of the OIE in 2004
Other issues
• Update the Commission's web pages
• Consider new candidates for OIE Reference Laboratories for listed diseases
• Develop a new template for annual reports of Reference Laboratory activities
• Evaluate annual reports (2004) of OIE Reference Laboratories and Collaborating Centre for aquatic animal diseases
• Ask diagnostic chapter authors to update disease cards for listed diseases
• With the assistance of *ad hoc* groups and other experts, redesign and distribute to Member Countries the questionnaire on diseases of amphibians

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OIE listed aquatic diseases

Evaluation of the infection with *Mikrocytos mackini* by EU-ad hoc group

A. CONSEQUENCES

1. Significant losses due to morbidity, mortality or product quality

There can be significant production losses of marketable oysters due to the presence of this disease organism. Growers have had product refused by processors due to 10-80% prevalence of oysters with pustules. This is particularly important for European countries where the ecologic conditions required for the expression of the disease in *Crassostrea gigas* may be met.

Conclusion: + (criterion applies)

2. Affects wild fish populations

The European flat oyster (*Ostrea edulis*), a commercially valuable native bivalve mollusc species throughout the EU, is susceptible to infection and is in fact more sensitive to *M. mackini* than *C. gigas* (Refs 9, 13). Field trials have confirmed that flat oysters are susceptible to infection by natural exposure. The negative rating is based on the temperature requirements for the disease to develop but there is a very real concern that Pacific oysters carrying the disease could easily be introduced (as a species not susceptible to *Bonamia* or *Marteilia*) either directly, or indirectly from elsewhere in the EU, to parts of the EU where the temperature requirements would be met and where the disease would become manifest in native oysters. Although it is stated in the original justification for de-listing that there have not been any reports of epizootics in oyster species, other than *C. gigas*, there is strong circumstantial evidence that commercial stocks of another ostreid species, *Ostrea concaphila*, in British Columbia became drastically reduced through infection with *M. mackini* from Pacific oysters introduced for cultivation (15).

Conclusion: + (criterion applies)

3. Public health concern

There is no evidence to suggest that Mikrocytos may create public health concern.

Conclusion: - (criterion does not apply)

B. SPREAD

4. Infectious aetiology proven

Conclusion: + (criterion applies)

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5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

The expert on *M. mackini*, Dr Susan Bower believes that the parasite could be a major problem in countries with cold climates.

Conclusion: + (criterion applies)

7. Several countries/zones may be declared free

Except for British Columbia, Canada, and the northwestern USA, all other countries that culture, or have wild stocks of *C. gigas*, appear to be free of *M. mackini*.

Conclusion: + (criterion applies)

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C. DIAGNOSIS

8. A repeatable and robust means of detection/diagnosis exists

Conclusion: + (criterion applies)

Table: summary of this evaluation of the infection with Mikrocytos mackini related to the OIE criteria

Agent	1	2	3	4	5	6	7	8	Conclusion
M. mackini	+	+	-	+	N/A	+	+	+	**Retain on List**

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