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**Draft written comments of the Community on the report of the meeting of the OIE
[World Organisation for Animal Health] Aquatic Animals Health Standards
Commission [Paris August 2005] to be submitted for consideration before the General
Session in May 2006**

ANNEX A



EUROPEAN UNION

Brussels
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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 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

Dr. B. Vallat

Directeur général OIE

12 Rue de Prony

F-75017 PARIS



Original: English
August 2005

**REPORT OF THE MEETING OF THE
OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 1–5 August 2005**

The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 1 to 5 August 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 informed the Commission that the OIE now had increased funding to support the activities of *ad hoc* groups and the participation of experts, especially from developing countries.

Dr Vallat invited the Commission to designate a member to participate in a discussion on compartmentalisation that will be held during the September 2005 meeting of the OIE *ad hoc* group on Epidemiology. Unfortunately, the unavailability of members during that time precluded direct participation, and the Commission decided to prepare a brief paper on compartmentalisation issues for aquatic animals, for use by the *ad hoc* group.

Dr Vallat informed the Commission that the Government of Brazil had kindly offered to host the First International Conference of OIE Reference Laboratories and Collaborating Centres in November 2006. He advised that the conference would focus on policy issues and on ways to improve the efficiency of the networks. The Commission confirmed that the participation of the aquatic Reference Laboratories and Collaborating Centre would strengthen interaction among the OIE designated experts for aquatic animal diseases and enhance linkages with the Commission.

Dr Vallat asked the Commission to consider changing its meeting schedule: after the General Session the Commission would meet to develop the proposals for adoption at the next General Session. Member Countries would have until early 2006 to comment on these draft proposals. Comments would be considered at the next meeting of the Commission, which would be held in March 2006. Proposals for adoption at the General Session in May 2006 would not be changed just prior to the General Session. This new schedule would give Member Countries more time to consider draft texts for adoption. The Commission agreed that this is an improvement on past arrangement and will hold its next meeting in March 2006.

Dr Vallat clarified that diseases are listed for reporting purposes. However, there may be chapters in the OIE *Codes* and *Manuals* for diseases that are not listed, as is currently the case for certain *Terrestrial Manual* chapters.

Dr Vallat thanked the members of the Commission for their continuing good work.

The Agenda and the List of Participants are given at [Appendices I](#) and [II](#), respectively.

Member Countries are strongly encouraged to send comments on Appendices III to XXI to the OIE Headquarters by 1 February 2006. These Appendices constitute the texts which the Commission plans to propose for adoption at the 2006 General Session.

Community comment

The Community appreciates the efforts done by the OIE AAC with respect to submitting the report in a reasonable time after the AAC meeting, and support the new meeting schedule proposed by the Director General of the OIE.

However, the Community expects the OIE to submit the outcome of the March 2006 meeting as soon as possible after the meeting, in order to allow OIE Member Countries to establish their position before the General Session in May 2006.

1. Member Country comments on the report of the meeting of the Commission (January 2005)

The Aquatic Animals Commission was appreciative of the Member Countries that had responded to the request for comments: Australia, Canada, Chile, European Community (EC), India, Japan, New Zealand, Poland, Portugal, Romania, Russia, Thailand and the United States of America.

For Chapter 1.1.2 on disease listing and notification criteria in the *Aquatic Code*, India had suggested including the quantification of production losses as a listing criteria in Article 1.1.2.1. The Commission noted that this issue had already been addressed in the report of the Commission meeting in January 2004 as follows:

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

The Commission continues to hold this view.

The EC had suggested replacing the term ‘pathogenic agent’ with the term ‘disease agent’ in criterion B1 in Article 1.1.2.3, because the latter term is defined in the *Aquatic Code*. The Commission clarified that this Article pertains to non-listed diseases, and that the term ‘disease agent’, which is defined for listed diseases, can therefore not be used in this context.

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

2. Aquatic Animal Health Code

Prof Tore Håstein, a member of the OIE Working Group on Animal Welfare and past President of the Commission, joined the meeting for agenda items 2.6 and 2.7.

Community comment

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 accepts the proposals in Appendixes IV, V. However, the Community expects the approach recommended by the OIE AAC in relation to *M. mackini* and *H. nelsoni* is also applied to the fish diseases IPN and BKD, i.e. that these two chapters are maintained in the Code and Manual in line with the existing Chapters in the 2003 Manual and 2005 Code, as this will be valuable for those OIE Member Countries wishing to maintain their national measures against these diseases even though they are not notifiable to the OIE. In that context, the OIE may consider for the future a general (non-

diseases specific) Chapter in the Code, which could give guidance to Member Countries wishing to ask for animal health guarantees for diseases not listed by the OIE. Such chapter could ensure a scientific safe and sound approach to such claims under the terms of the SPS Agreement.

With regard to the ongoing assessment by the Ad Hoc group on the future listing of KHV, the Community will draw the attention of OIE to the outcome of the EAFP workshop in September 2005 (where a summary of the KHV workshop is *in press* and to a similar workshop held in Sri Lanka in October 2005. The OIE Ad Hoc group will find the outcome of these discussions valuable in their assessment.

In relation to the inclusion of new susceptible species to certain diseases, the Community are concerned about the fact that it seems that the OIE AAC have included new susceptible species for several diseases solely based on a literature-review, without consulting the appropriate OIE Reference laboratory. The Community would advice the OIE AAC not to include any new species as susceptible to any disease without the advice of the Reference laboratory (in line with the third paragraph of Article 2 in each disease Chapter), due to the possible economic impact to operators.

With regard to the proposals in Appendixes III, VI, VI, VII, VIII, IX, X, XI, XII and XIII the Community have further comments that it would like to see taken into account and asks for clarification on certain issues before it can give its support.

The Community cannot agree with the proposal in Appendix XIV, XV, XVI, XVII, XVIII, XIX, XX, and XXI unless the comments in the specific Chapters are being taken into account.

As a general remark to the Code, the Community would ask the OIE AAC to consider a statement either in relation to the definition of aquatic animal, or in the foreword, that the recommendations of the Code does not apply to ornamental aquatic animals. However, if it is the intention of the OIE AAC that ornamental aquatic animals are covered by the Code, the Community reserves its agreement to all disease chapters, as due to their intended use and the possibility of introducing internal measures to prevent the such commodities being used for other purposes than ornamental use, commodities comprising ornamental aquatic animals poses less risk than aquatic animals for farming purposes, which should be reflected in the Code.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters.

Finally, as a horizontal comment to all disease chapters, the Community would reiterate its previous comment about freedom due to the absence of susceptible species, and where appropriate climatic or other physical/chemical reasons absence of pathogen. This will also be relevant for maintaining freedom. As, for example, Article 2.1.5.6 ("Maintenance of freedom") is written, a country in the tropics where VHSV cannot survive must retain targeted surveillance to maintain their freedom. This seems unjustified.

2.1. Report on the 73rd OIE General Session

The Commission addressed issues raised by Member Countries during the General Session in the relevant sections below.

2.2. Definitions

The Commission addressed outstanding Member Countries' comments and proposed the amendments attached in Appendix III.

The Aquatic Animals Commission considered Member Countries' comments regarding the usage of the terms *veterinary administration* and *competent authority*. In addressing these comments, the Commission decided to further harmonise the *Aquatic Code* with the *Terrestrial Code* by proposing for adoption the relevant definitions used in the *Terrestrial Code*.

After discussions with the Head of the OIE Information Dept, the Commission decided not to modify at the present time the definition of *notification* but would work with Dr Ben Jebara on whether to include ‘national aquatic contact point’ in the definition.

The Aquatic Animals Commission modified the definition of *buffer zone* to take into account the current definition in the *Terrestrial Code*.

The Aquatic Animals Commission did not modify the definition of *water catchment* as suggested by New Zealand; the Commission considered that artificially impounded water in man-made structures is included in the current definition.

The Commission modified the definitions of *susceptible species*, *infection* and *zone*, in line with several Member Countries’ comments.

2.3. The OIE list of aquatic animal diseases

The Aquatic Animals Commission addressed Member Countries’ comments in amending Chapter 1.1.2., as shown in [Appendix IV](#).

The report of the OIE *ad hoc* group on the list of aquatic animal diseases (finfish and mollusc diseases teams) is appended as [Appendix XXII](#) for the information of Member Countries.

The Chair of the finfish diseases team reported that the team had met electronically and that agreement had been reached on the delisting of infectious pancreatic necrosis (IPN) and bacterial kidney disease (BKD); one member of the team did not agree with the team’s recommendation that koi herpesvirus disease met the criteria for listing, and instead proposed that the issue be debated further at an international forum. The Aquatic Animals Commission noted that the Sixth International Symposium on Diseases in Asian Aquaculture presented an opportunity for the listing of koi herpesvirus disease to be discussed. At the present time, the Commission agreed that, based on comments received from Member Countries and the majority view of the fish team, koi herpesvirus disease would be proposed for listing; however, the Aquatic Animals Commission would review that decision depending on the outcome of the final report of the finfish team. The Aquatic Animals Commission supported the recommendations that IPN and BKD be removed from the list.

The Chair of the mollusc team reported that the team had reached consensus on all issues discussed. It maintained its recommendation that ‘Infection with *Mikrocytos mackini*’ should be delisted and that ‘Infection with *Perkinsus olseni*’ should be maintained on the list. In addition, the team recommended the listing of ‘abalone viral mortality’ as an emerging disease. The team provided detailed information on this emerging disease (<http://library.enaca.org/Health/DiseaseLibrary/Abalone-Disease.pdf>). The Chair of the team brought to the Commission’s attention the sabellid worm (*Terebrasabella heterouncinata* - which is a shell parasite of importance in international trade) and noted that the mollusc team had recommended that the worm be placed on the list of diseases. The Aquatic Animals Commission agreed with the recommendations of the mollusc team regarding ‘Infection with *Mikrocytos mackini*’, ‘Infection with *Perkinsus olseni*’ and ‘abalone viral mortality’; it requested the mollusc team to develop a full assessment for the sabellid worm (*T. heterouncinata*) in time for the March 2006 meeting of the Commission.

The Chair of the crustacean team indicated that the team would meet in October 2005 and produce a report for the meeting of the Aquatic Animals Commission in March 2006.

The proposed revised Chapter 1.1.3. is attached in [Appendix V](#).

2.4. New and revised chapters for fish and mollusc diseases

The Commission addressed the reports of the *ad hoc* Group on fish disease chapters of the OIE *Aquatic Animal Health Code* (hereafter referred to as the fish *ad hoc* group) and of the *ad hoc* group on chapters for mollusc diseases of the OIE *Aquatic Animal Health Code* (hereafter referred to as the mollusc *ad hoc* group). The Chairs of these two *ad hoc* groups presented their work to the Commission. These two reports are appended as [Appendix XXIII](#) and [Appendix XXIV](#) for the information of Member Countries.

While agreeing with the Chairs of the *ad hoc* groups that proposals should be supported, as far as possible, by scientific evidence or expert opinion to ensure transparency for Member Countries, the Commission acknowledged the paucity of scientific literature on the survival of aquatic pathogens in internationally traded commodities. The Commission agreed with the risk-based pathways approach used by the *ad hoc* groups, which stressed the importance of commodities not being diverted from their intended end use in order to minimise the likelihood of exposure of pathogens to susceptible populations. The Aquatic Animals Commission acknowledged that such an approach may necessitate Member Countries introducing internal measures to prevent the commodity being used for any purpose other than the intended one.

The report of the fish *ad hoc* group raised some basic issues for consideration by the Aquatic Animals Commission. The Commission addressed these issues as follows:

- With regard to targeted surveillance as a tool to re-establish freedom in previously infected areas (as referred to in Articles X.X.X.4 and X.X.X.5), the Commission believed that surveillance should focus on the infected zone. However, depending on the epidemiology of the disease and the circumstances of the outbreak, targeted surveillance may need to be extended to the buffer zone. More details will be provided in the relevant *Aquatic Manual* chapters.
- With regard to the time when aquatic animals should be considered suitable for release from quarantine (Article X.X.X.8), the Aquatic Animals Commission believed that the Article should be modified to put more emphasis on the desired outcome i.e. minimisation of the risk of spread of the disease agent, rather than to specify a time period for each disease. The Commission therefore amended the relevant article in each chapter.
- With regard to the differentiation between viral haemorrhagic septicaemia (VHS) virus genotypes the Aquatic Animals Commission acknowledged that differences exist regarding their virulence, an issue that has previously been raised by several Member Countries. The same situation applies to other diseases, e.g. yellowhead disease (YHD). The Aquatic Animals Commission considered that this complex issue should be addressed at a generic level before specific consideration may be given to individual diseases. A good opportunity to discuss the issue will arise in the forthcoming international conference of OIE Collaborating Centres and Reference Laboratories to be held in Brazil in November 2006 (see Agenda Item 8.3). It is suggested that a special session be devoted at this forum to addressing the recurrent question of how the case definition can be used for listed diseases caused by strains or variants of different virulence, e.g. VHS and YHD. The Commission will develop a position paper to identify the problems and propose some guidelines.

In addressing the issues raised in the report of the meeting of the *ad hoc* group on mollusc diseases, the Aquatic Animals Commission agreed with the following recommendations:

- that the chapters ‘Infection with *Haplosporidium nelsoni*’ and ‘Infection with *Mikrocytos mackini*’ be included in the next edition of the *Aquatic Code*, despite the removal of these diseases from the OIE list of diseases;
- that the chapters on ‘Infection with *Mikrocytos roughleyi*’, ‘Infection with *Haplosporidium costale*’ and ‘Infection with *Marteilia sydneyi*’ be removed from the *Aquatic Code*;

In the context of the provisions of Articles x.x.x.4 and x.x.x.5 in each chapter, the Chair of the *ad hoc* group on mollusc diseases raised the situation where a pathogen such as *Perkinsus olseni* with a very wide host range needs to be compared to pathogens with a narrow range of susceptible species (due to high host-specificity) such as *Haplosporidium nelsoni*. The Aquatic Animals Commission agreed that, as a matter of principle, the pathway for a self-declaration of freedom based on the absence of susceptible species should only apply to pathogens with a known narrow host range. This principle has been applied in the proposed chapters for relevant fish and mollusc diseases.

The Aquatic Animals Commission agreed that, for diseases in the *Aquatic Code*, an updated corresponding chapter in the *Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual)* should be retained.

With regard to the text on ‘historical freedom’ in Articles X.X.X.4 and X.X.X.5 of the proposed chapters, the Commission considered previous comments from Member Countries on the inconsistencies in the time periods specified. The Commission recognised that the generic time periods were arbitrary, but recalled that the time periods for specific diseases were intended to be

modified in line with information available.

In relation to the comment from Canada on the use of bioassays with sentinel animals to demonstrate freedom from infection, the Commission identified some potential difficulties inherent in this suggestion, including the limited availability of appropriate sentinels and the problems associated with the introduction of exotic species and potentially their disease agents. The Commission drew Canada's attention to the alternative of surveys using targeted surveillance.

The proposed new and revised chapters are attached in Appendices VI to XXI.

2.5. Appendix on general guidelines for aquatic animal health surveillance

The Aquatic Animals Commission decided to ask the Director-General to set up an OIE *ad hoc* group on aquatic animal health surveillance. This *ad hoc* group would need to meet prior to the next meeting of the Aquatic Animals Commission. The Aquatic Animals Commission saw some advantage in the *ad hoc* group's meeting overlapping that of the existing OIE *ad hoc* group on epidemiology (which operates under the Scientific Commission for Animal Diseases).

2.6. New draft guidelines on the handling and disposal of carcasses and wastes of aquatic animals

The Commission expressed its appreciation to Prof Tore Håstein for his paper on the handling and disposal of carcasses and wastes of aquatic animals. Prof Håstein reported on the source documents and the approach he had used in developing the draft. The Aquatic Animals Commission reviewed the draft and decided to examine whether a summary could be placed in the *Aquatic Code* with the full document placed elsewhere. Due to time constraints, the Aquatic Animals Commission decided to defer a detailed discussion and preparation of the summary to its next meeting in March 2006.

2.7. New draft chapters on aquatic animal welfare

Prof Tore Håstein briefed the Commission on the outputs of two *ad hoc* groups on aquatic animal welfare - general principles, the transport of finfish by land and water, and the slaughter/killing of finfish. The Aquatic Animals Commission noted that the texts were on the agenda of the September 2005 meeting of the Working Group on Animal Welfare. The Commission reviewed the proposed guidelines but decided to defer a detailed discussion until its next meeting in March 2006, after the Working Group on Animal Welfare had examined the documents.

2.8. New work on antimicrobial resistance in the field of aquatic animals

The Commission had insufficient time to address the issue but noted its importance. The Aquatic Animals Commission deferred a detailed discussion to its next meeting in March 2006.

2.9. Recommendations on the use of aquatic animal feedstuffs

The Chair of the *ad hoc* group on fish diseases drew to the attention of the Commission the need to address the safety of the international trade in fishmeal. The *ad hoc* group had recommended that the various commercial methods of processing meal be placed [under study] to determine their effectiveness in inactivating pathogens. The Aquatic Animals Commission recognised the lack of scientific evidence supporting the safety of such commodities and decided to ask the Director General to form an *ad hoc* group, to address the safety for aquatic animals of the various aquatic animal meals traded. This was agreed by the Director-General.

3. Manual of Diagnostic Tests for Aquatic Animals

3.1. Update on preparation of the 5th edition of the *Aquatic Manual*

Community comment

The Community awaits the proposals for the new chapters on disease surveillance.

Ms Sara Linnane briefed the Commission on the status of the *Aquatic Manual* and indicated that draft chapters would be sent to Member Countries for comment in October 2005. It is planned that the fifth edition be presented for adoption at the 74th General Session in May 2006. At this stage, chapters on diseases that have been removed from the list will be retained in the fifth edition of the *Aquatic Manual*, but will not have been updated from the fourth edition. The Commission considers it useful that chapters be updated for those diseases that are no longer listed for reporting purposes in chapter 1.1.3 of the *Aquatic Code* but that are still relevant for international trade. The Aquatic Animals Commission will consider further whether chapters for diseases removed from the list that have no trade implications or those with negligible impact should be deleted from the *Aquatic Manual*.

The Aquatic Animals Commission considered options for providing Member Countries with information on diseases proposed for listing. The purpose would be to provide information on such items as case definition, available diagnostic methods, host species, published literature, etc., and to facilitate the eventual preparation and adoption of a formal chapter for inclusion in the *Aquatic Manual*.

3.2. Revision of chapters on surveillance (chapters 1.1.4 and chapters I.1, I.2 and I.3)

The Commission noted that an updated version of Chapter 1.1.4 would not be available in time for the fifth edition of the *Aquatic Manual*. The proposed OIE *ad hoc* group on aquatic animal health surveillance would need to address this chapter as well as assist in the preparation of chapters I.1, I.2 and I.3.

In the meantime, the Commission will amend chapters I.1, I.2 and I.3, which will be circulated to Member Countries in October for comment.

3.3. Revision of chapter on disinfection of fish and of mollusc aquaculture establishments (Chapter 1.1.5)

The chapter is currently being updated and will be sent to Member Countries in October 2005 with the other draft chapters.

4. Joint meeting with the Terrestrial Animal Health Standards Commission

Community comment

The Community raises its concern about what seems to be an unwanted consequence of the drive towards harmonisation of the different disease chapters, both within the Aquatic Code and Terrestrial Code.

With the current approach, all mollusc chapters have – with very few exemptions – an identical text. This applies also to the fish chapters. As a consequence, it seems that the OIE Code is moving towards one mollusc chapter – applicable to all mollusc diseases, one fish chapter – applicable to all fish diseases and finally one crustacean chapter – applicable to all crustacean diseases. This approach is not supported by the Community, since the characteristics of the different diseases is lost.

Dr Alex Thiermann, President of the Terrestrial Code Commission, participated in this agenda item..

4.1. Compartmentalisation

Dr Thiermann addressed the Commission on the OIE's work on compartmentalisation, including the concept paper produced by the Scientific Commission for Animal Diseases. As no member of the

Aquatic Animals Commission will be available for the upcoming meeting of the *ad hoc* group on epidemiology at which the concept paper is to be discussed, the Commission indicated that it would produce a paper outlining its views for that *ad hoc* group meeting.

The Commission addressed the EC comment regarding a compartment regaining its free status after an outbreak. The meeting agreed that this would result in the compartment losing its free status and would necessitate the compartment following an agreed procedure in order to regain free status. This procedure may be more complex than the comparative procedure for a zone.

4.2. Updating Code and Manual chapters

The meeting discussed the need to ensure that each chapter or appendix in the OIE Codes and Manuals reflect the latest scientific information, even when it addresses a disease not currently listed for notification purposes. It was noted that, due to the current heavy workload of the Commissions, priority would be given to listed diseases; however, the meeting acknowledged the OIE's obligation to keep all chapters and appendices in the OIE standards up to date. Dr Thiermann also advised of discussions in the Working Group on Animal Production Food Safety regarding diseases important for food safety, but without disease implications for animal health eg listeriosis, and how an alternative approach to mandatory notification may be appropriate for such diseases. The meeting also noted the implication for Member Countries' SPS obligations of the removal of chapters and appendices from the OIE standards, and the need for agreed criteria for adding or removing chapters or appendices.

The meeting agreed that it was desirable that each chapter and appendix displays the date of its most recent significant revision.

4.3. Traded commodities

The meeting discussed the new approach regarding commonly traded commodities in the disease chapters in the *Aquatic Code* being proposed by the Aquatic Animals Commission for adoption. The meeting noted the desirability of emphasising the safety, or otherwise, of commodities commonly traded for a particular end use, and Dr Thiermann indicated that the approach of the Aquatic Animals Commission would be discussed at the upcoming meeting of the Terrestrial Code Commission in September.

5. Joint meeting with the Animal Health Information Department

Dr Karim Ben Jebara, Head of the Animal Health Information Department, participated in this agenda item.

5.1. Revision of chapter 1.1.2 on disease listing and notification criteria

Dr Ben Jebara suggested that further harmonisation may be possible between this chapter and the matching chapter in the *Terrestrial Code*. Regarding the criteria for immediate notification (Article 1.1.2.3), he drew the Commission's attention to the fact that these criteria are also used for the disease reporting forms, and referred to the aim of harmonising the terrestrial and aquatic forms as far as possible. The Commission agreed to undertake a detailed comparison of the *Aquatic Code* chapter with the one in the *Terrestrial Code* at their next meeting.

5.2. Harmonisation of the new aquatic and terrestrial notification systems

The meeting compared the aquatic and the terrestrial animal disease forms for immediate notification and noted minor differences, for example in the choice of the 'disease control measures' between the two forms. Also, some of the 'disease control measures' identified on the aquatic form are currently not defined. The Commission agreed to undertake a detailed comparison of the two forms and provide definitions for the 'disease control measures' at its next meeting.

5.3. National contact persons for aquatic animal diseases

The Commission asked Dr Ben Jebara about Member Countries' uptake of the Director General's invitation to nominate 'national contact persons' for aquatic animal diseases, for the purpose of

dealing with aquatic animal health issues (including reporting), under the authority of the national delegate. Dr Ben Jebara reported that to date 38 Member Countries had provided contact details. The meeting agreed that it would be timely to circulate a reminder to delegates.

5.4. OIE World Animal Health Information System

Dr Ben Jebara provided an update on the state of development of the OIE's new animal health information system, including the mapping application. He clarified that, while there are delays with the electronic on-line components, testing commenced 2 months ago. Member Countries have been advised either to use the hard copy forms for submitting the first six-monthly report (January-June 2005) by 31 July 2005, or to report on-line (pending completion of the system) by 1 October 2005.

6. Joint meeting with the Publications Department

The meeting was joined by Ms Annie Souyri, Deputy Head of the Publications Department.

6.1. OIE Scientific and Technical Review: issue on aquatic animal health

Ms Souyri recalled that an aquatic animal health issue in the OIE *Scientific and Technical Review* series had been planned some time ago but had not proceeded. The Commission agreed that such an issue would be timely now, given that the last issue on an aquatic topic (*Preventing the spread of aquatic animal diseases*) dates back to 1996. Ms Souyri clarified the anticipated date of publication (2007) and the schedule leading up to that date. The size of the publication would be approximately 15 papers (300 pages). The Commission agreed on 'management of aquatic animal disease emergencies' as the scope of the publication. The President of the Commission offered the assistance of her co-workers in Australia for the preparation of a draft list of topics and potential authors, in consultation with the Commission.

7. The role and activities of the OIE in the field of aquatic animal health

Dr Rohana Subasinghe, FAO, participated in this agenda item.

7.1. Global conference on aquatic animal health in September 2006

Dr Alejandro Schudel, Head of the Scientific and Technical Department, provided a briefing on the background to the Conference. Later in the week, Dr Christianne Bruscke joined the meeting with Prof. Tore Håstein, who attended as a member of the Scientific Committee for the Conference.

The meeting discussed the scope and objectives of the Conference, and identified five themes for the programme. The Scientific Committee of the Conference will provide a more detailed draft programme to the Steering Committee with the view that the first announcement will be made in the near future.

7.2. International meetings

7.2.1. Diseases in Asian Aquaculture VI in Colombo, Sri Lanka, October 2005

Dr Rohana Subasinghe reported on three events to be held in Colombo, Sri Lanka in October/November 2005. They are; (a) NACA Asia Regional Advisory Group on Aquatic Animal Health (22-24 October); (b) Asian Fisheries Society Fish Health Section Sixth Symposium on Diseases in Asian Aquaculture – DAA VI - (25-28 October); and (c) FAO Expert Workshop for the Preparation of the Technical Guidelines for Health Management for Responsible Movement of Live Aquatic Organisms. All arrangements are progressing well. Members of the Commission will participate in all three events. Dr. Subasinghe mentioned that, considering the expected wide participation of experts from all over the world, DAA VI would be an ideal opportunity to discuss issues such as a listing of koi herpesvirus disease and the global conference on aquatic animal health. The Commission agreed to the suggestion and requested Dr. Subasinghe to look into arranging appropriate discussion time on the above mentioned issues during the DAA VI.

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

The Commission noted that calls for abstracts have been issued by the organisers of the ISVEE XI symposium and that aquatic animal epidemiology is one of the themes. The Commission plans to send a representative to attend the symposium to present new chapters on aquatic animal surveillance for expert comment. These comments will be considered by the Commission at its subsequent meeting.

7.2.3. Regional Commission Conferences

Prof. Eli Katunguka-Rwakishaya represented the Commission at the Conference of the OIE Regional Commission for Africa, which took place in Khartoum, Sudan, 7-10 February 2005. The Conference was attended by 23 Member Countries, and six international organisations gave presentations. The presentation covered the activities of the Aquatic Animals Commission and emphasised the need for dialogue between veterinarians and fisheries authorities in the African region. The presentation of Prof. Katunguka-Rwakishaya was well received and provoked extensive debate.

Prof. Barry Hill will give a presentation at the 8th Conference of the OIE Regional Commission for the Middle East, which will be held in Bahrain, 26-29 September 2005. At the 24th Conference of the Regional Commission for Asia, the Far East and Oceania, which will take place in Seoul, Korea (Rep. of), 16-19 November 2005, the President of the Commission will provide an update on the implementation of the recommendations on aquatic animal health from that Regional Commission's 23rd Conference, in Noumea, New Caledonia, and on recent developments in OIE aquatic animal health standards.

7.2.4. Regional meeting: Ad hoc Group for the Americas on Aquatic Animals

The Commission noted the Mission Report on the first meeting of the *ad hoc* group for the Americas on Aquatic Animals provided by Dr Luis Barcos, OIE Regional Representative for the Americas. The Commission looks forward to being informed of further developments.

7.3. Inclusion of diseases of amphibians in the remit of the Commission

Since the Commission's last meeting, the Director General has approved the Commission's proposal for a new *ad hoc* group on amphibian diseases, which will provide a revised questionnaire for Member Countries. The Commission deferred the decision on whether or not to propose including amphibians within its remit until the *ad hoc* group has provided a report with recommendations. The Commission will prepare terms of reference and a proposed membership of the *ad hoc* group.

8. OIE Reference Laboratories

8.1. Updating the list of Reference Laboratories

The Commission reviewed the application for OIE Reference Laboratory status from the University of Washington, School of Aquatic and Fishery Sciences, USA, for infection with *Xenohaliotis californiensis*, with Dr Carolyn Friedman as the expert. The Commission recommended its acceptance.

8.2. New proposed template for annual reports

The Commission revised the template for annual reports of Reference Laboratory activities which will now be passed to the OIE Biological Standards Commission for consideration. The purpose of the changes to the current annual report format is to improve the usefulness of the information requested and to simplify the reporting requirements, while emphasising the major epidemiological events for each disease in the reporting period.

8.3. First International Conference of OIE Reference Laboratories and Collaborating Centres

The Commission identified a number of issues that could be usefully brought to the attention of this Conference. Among these would be to review the purpose and the contents of the annual reports, the validation of diagnostic tests, the question of whether OIE Reference Laboratories for aquatic animal diseases should be retained for diseases that are no longer listed and whether laboratories should be appointed for diseases that are proposed for listing.

One of the important issues to be addressed is that of strain differentiation (see Agenda Item 2.4).

9. Any other business

9.1. Date of the next meeting

The Aquatic Animals Commission will meet on 13-17 March 2006.

.../Appendices

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

Paris, 1-5 August 2005

Agenda

- 1. Member Country comments on the report of the meeting of the Commission (January 2005)**
- 2. *Aquatic Animal Health Code***
 - 2.1. Report on the 73rd OIE General Session
 - 2.2. Definitions (chapter 1.1.1.)
 - 2.3. The OIE list of aquatic animal diseases (chapter 1.1.3.)
 - 2.4. New and revised chapters for fish and mollusc diseases
 - 2.5. Appendix on general guidelines for aquatic animal health surveillance
 - 2.6. New draft guidelines on the handling and disposal of carcasses and wastes of aquatic animals
 - 2.7. New draft chapters on aquatic animal welfare
 - 2.8. New work on antimicrobial resistance in the field of aquatic animals
 - 2.9. Recommendations on the use of aquatic animal feedstuffs
- 3. *Manual of Diagnostic Tests for Aquatic Animals***
 - 3.1. Update on preparation of the 5th edition of the *Aquatic Manual*
 - 3.2. Revision of chapters on surveillance (chapters 1.1.4 and chapters I.1, I.2 and I.3)
 - 3.3. Revision of chapters on disinfection of fish and of mollusc aquaculture establishments (chapter 1.1.5)
- 4. Joint meeting with the Terrestrial Animal Health Standards Commission**
 - 4.1. Compartmentalisation
 - 4.2. Updating Code and Manual chapters
 - 4.3. Traded commodities
- 5. Joint meeting with the Animal Health Information Department**
 - 5.1. Revision of chapter 1.1.2 on disease listing and notification criteria
 - 5.2. Harmonisation of the new aquatic and terrestrial notification systems
 - 5.3. National contact persons for aquatic animal diseases
 - 5.4. OIE World Animal Health Information System
- 6. Joint meeting with the Publications Department**
 - 6.1. OIE Scientific and Technical Review: issue on aquatic animal health

Appendix I (contd)**7. The role and activities of the OIE in the field of aquatic animal health**

- 7.1. Global Conference on Aquatic Animal Health (Norway) September 2006
- 7.2. International meetings
 - 7.2.1. Diseases of Asian Aquaculture VI in Colombo (Sri Lanka) October 2005
 - 7.2.2. ISVEE XI symposium in Cairns (Australia) August 2006
 - 7.2.3. Regional Commission Conferences
 - 7.2.4. Regional meeting: *ad hoc* group for the Americas on Aquatic Animals
- 7.3. Including diseases of amphibians in the remit of the Commission

8. OIE Reference Laboratories

- 8.1. Updating the list of Reference Laboratories
- 8.2. New proposed template for annual reports
- 8.3. First International Conference of OIE Reference Laboratories and Collaborating Centres (Brazil) November 2006

9. Any other business

- 9.1. Date of the next meeting
-

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

Paris, 1–5 August 2005

List of participants

MEMBERS OF THE COMMISSION

Dr Eva-Maria Bernoth

(President)

Office of the Chief Veterinary Officer,
Department of Agriculture, Fisheries and
Forestry – Australia, GPO Box 858,
Canberra ACT 2601
AUSTRALIA
Tel.: (61-2) 62.72.43.28
Fax: (61-2) 62.73.52.37
Email: eva-maria.bernoth@daff.gov.au

Prof. Barry Hill

(Vice-President)

CEFAS – Weymouth Laboratory
Barrack Road, The Nothe
Weymouth, Dorset DT4 8UB
UNITED KINGDOM
Tel.: (44-1305) 20.66.25
Fax: (44-1305) 20.66.27
E-mail: b.j.hill@cefass.co.uk

Dr Ricardo Enriquez

(Secretary General)

Patología Animal / Ictiopatología
Universidad Austral de Chile
Casilla 567 - Valdivia
CHILE
Tel.: (56-63) 22.11.20
Fax: (56-63) 21.89.18
E-mail: renrique@uach.cl

Dr Franck Berthe

Canada Research Chair
Department of Pathology & Microbiology
Atlantic Veterinary College - UPEI
550 University Ave.
Charlottetown
Prince Edward Island, C1A 4P3
CANADA
Tel: + (1-902) 566-0668
Fax: +(1-902) 566-0851
Email: fberthe@upe.ca

Prof. Eli Katunguka-Rwakishaya

Director
School of Graduate Studies
Makerere University,
P.O. Box 7062,
Kampala
UGANDA
Tel.: (256.41) 53.0983
54.0564
Fax: (256-41) 533809
email: erkatunguka@vetmed.mak.ac.ug
mupgs@muspgs.mak.ac.ug

OTHER PARTICIPANTS

Dr Alejandro Thiermann

*(President of the OIE Terrestrial Animal
Health Standards Commission)*
US Mission to the Organisation for
Economic Co-operation and Development
19, rue de Franqueville
75016 Paris
FRANCE
Tel: 33-(0)1 44 15 18 69
Fax: 33-(0)1 42 67 09 87
E-mail: a.thiermann@oie.int

Prof. Donald V. Lightner

(Crustacean disease expert)
Aquaculture Pathology Section,
Department of Veterinary Science &
Microbiology,
University of Arizona, Building 90,
Room 202,
Tucson, AZ 85721
UNITED STATES OF AMERICA
Tel.: (1.520) 621.84.14
Fax: (1-520) 621.48.99
E-mail: dvl@u.arizona.edu

Prof. Tore Håstein

*(Member of the OIE Animal Welfare
Working Group)*
National Veterinary Institute
Ullevålsveien 68
P.O. Box 8156 Dep.
0033 Oslo
NORWAY
Tel. : (47-23) 21 61 50
Fax : (47-23) 21 60 01
E-mail : tore.hastein@vetinst.no

Dr Rohana P. Subasinghe

Senior Fishery Resources Officer
Fisheries Department
FAO
Viale delle Terme di Caracalla
00100 Rome
ITALY
Phone: + 39 06 570 56473
Fax: + 39 06 570 53020
E-mail: Rohana.Subasinghe@fao.org

Appendix II (contd)**OIE HEADQUARTERS**

Dr Bernard Vallat

Director General
OIE
12, rue de Prony
75017 Paris
FRANCE
Tel: 33 - (0)1 44 15 18 88
Fax: 33 - (0)1 42 67 09 87
E-mail: oe@oie.int

Dr David Wilson

Head
International Trade Department
OIE
Tel.: 33 - (0)1 44.15.18.80
Fax: 33 - (0)1 42.67.09.87
E-mail: d.wilson@oie.int

Dr Alejandro Schudel

Head
Scientific and Technical Department
OIE
Tel.: 33 (0)1 44.15.18.88
Fax: 33 (0)1 42.67.09.87
E-mail: a.schudel@oie.int

Dr Karim Ben Jebara

Head
Animal Health Information Department
OIE
Tel.: 33 (0)1 44.15.18.88
Fax: 33 (0)1 42.67.09.87
E-mail: k.benjebara@oie.int

Dr Francesco Berlingieri

Deputy
International Trade Department
OIE
Tel.: 33 (0)1 44.15.18.88
Fax: 33 (0)1 42.67.09.87
E-mail: f.berlingieri@oie.int

Dr Christianne Brusckhe

Charge de Mission
Scientific and Technical Department
OIE
Tel.: 33 (0)1 44.15.18.88
Fax: 33 (0)1 42.67.09.87
E-mail: c.brusckhe@oie.int

Ms Sara Linnane

Scientific Editor
Scientific and Technical Department
OIE
Tel.: 33 (0)1 44.15.18.88
Fax: 33 (0)1 42.67.09.87
E-mail: s.linnane@oie.int

Annie Souyri

Deputy Head
Publications Department
OIE
Tel.: 33 (0)1 44.15.18.88
Fax: 33 (0)1 42.67.09.87
E-mail: a.souyri@oie.int

CHAPTER 1.1.1.

DEFINITIONS

Community comment

The Community questions the necessity of the introduction of the definitions of Veterinarian, Veterinary authority, Veterinary Services, and Veterinary Statutory Body, as they all seem only to be used in other definitions. The Community has raised its concerns about the extensive use of definitions only for the purpose of use in other definitions earlier, and asked the OIE AAC to consider the necessity of such definitions. In reply to this concern, the OIE proposes to increase the number of definitions whose purpose is only to be used in other definitions, a development to which the Commission again must express its concern.

The Community supports the other proposals.

Article 1.1.1.1.

Buffer zone

means a zone established to protect the health status of aquatic animals in a free country or free zone, from those in a country or zone of a different animal health status, using measures based on the epidemiology of the disease under consideration to prevent spread of the disease agent into a free country or free zone.

~~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.~~

Competent Authority

means the Veterinary Services, or other Authority of a Member Country, having the responsibility and competence for ensuring or supervising the implementation of the aquatic animal health measures or other standards in the Aquatic Code and Aquatic Manual.

~~means the National Veterinary Services, or other Authority of a Member Country, having the responsibility and competence for ensuring or supervising the implementation of the aquatic animal health measures recommended in the Aquatic Code.~~

Free compartment

means a compartment that fulfils the requirements for self declaration of freedom from disease with respect to the disease(s) freedom from the disease under consideration, according to the relevant chapter(s) in this Aquatic Code.

Free country

means a country that fulfils the requirements for self declaration of freedom from disease with respect to the disease(s) freedom from the diseases under consideration according to the relevant chapter(s) in this Aquatic Code.

Free zone

means a zone that fulfils the requirements for self declaration of freedom from disease with respect to the

disease(s) freedom from the ~~diseases~~ under consideration according to the relevant chapter(s) in this *Aquatic Code*.

Infection

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

Susceptible species

means a species of *aquatic animal* in which *infection* by a *disease agent* ~~can multiply or otherwise develop~~ has been demonstrated by natural cases or by experimental *infection* that mimics the natural pathways.

Veterinarian

means a person registered or licensed by the relevant *Veterinary statutory body* of a country to practise veterinary medicine/science in that country.

Veterinary Administration

means the governmental *Veterinary Service* having authority in the whole country for implementing the animal health measures and international veterinary certification process which the OIE recommends, and supervising or auditing their application.

means the National Veterinary Service (or other official entity) in a country having the authority to implement and carry out aquatic animal health measures (i.e. *stamping out, fallowing, disinfection* etc.); and certification as recommended in the *Aquatic Code*. (If an authority other than the *Veterinary Administration* acts as the *Competent Authority* for matters related to aquaculture and protection of the health of farmed and wild populations of fish, molluscs and crustaceans, the *Veterinary Administration* nonetheless remains the body that is responsible for liaison with the OIE in terms of Section 1.2. of the *Aquatic Code*.)

Veterinary Authority

means a *Veterinary Service*, under the authority of the *Veterinary Administration*, which is directly responsible for the application of animal health measures in a specified area of the country. It may also have responsibility for the issuing or the supervision of the issuing of international veterinary certificates in that area.

Veterinary Services

means the *Veterinary Administration*, all the *Veterinary Authorities*, and all persons authorised, registered or licensed by the *Veterinary statutory body*.

Veterinary statutory body

means an autonomous authority regulating *veterinarians* and *veterinary para-professionals*.

Zone

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)*.

— text deleted

CHAPTER 1.1.2.

DISEASE LISTING AND NOTIFICATION CRITERIA

Community comment

The Community supports the proposed amendments.

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. Such proposals should be accompanied by a case definition for the disease under consideration.

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 <i>susceptible* species</i> , 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 populations of <i>aquatic animal</i> 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.	
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.

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
6.	And	Potential for international spread, including via live animals, their products or fomites.	International trade in aquatic animal species <i>susceptible</i> 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 <i>zones</i> may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 of the <i>Aquatic Manual</i> .	<i>Free countries/zones</i> could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible, however, individual countries that run a control programme on such a disease can demand its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of <i>broodstock</i> from widespread diseases, or the protection of the last remaining <i>free zones</i> from a widespread disease.
And C. Diagnosis			
8.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see <i>OIE Manual of Diagnostic Tests for Aquatic Animals</i>) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

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 proposed for listing if it meets the following criteria (1 or 2, and 3 or 4): Such proposals should be accompanied by a case definition for the disease under consideration.

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 of wild or cultured <i>aquatic animals</i> .	The disease has exhibited significant morbidity, mortality or production losses at a <i>zone, compartment</i> or country level. “Naïve” means animals previously unexposed either to a new disease or a new form of a known disease.

Article 1.1.2.3.

Criteria for immediate notification of aquatic animal diseases

A. For listed diseases	
1.	First occurrence or re-occurrence of a <i>disease</i> in a country or <i>zone</i> or <i>compartment</i> of a country, if the country or <i>zone</i> or <i>compartment</i> of the country was previously considered to be free of that particular <i>disease</i> ; or
2.	Occurrence in a new host species; or
3.	New pathogen strain or new disease manifestation; or
4.	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'.

— text deleted

Appendix V

CHAPTER 1.1.3.

DISEASES LISTED BY THE OIE

Community comment

The Community can accept amendments proposed to the disease list, provided the comment under point 2 of the meeting report is taken duly into account.

The Community agrees with the inclusion of abalone viral mortality as an emerging disease.

Article 1.1.3.1.

The following diseases of fish are listed by the OIE:

- Epizootic haematopoietic necrosis
- Infectious haematopoietic necrosis
- Spring viraemia of carp
- Viral haemorrhagic septicaemia
- ~~Infectious pancreatic necrosis~~[†]
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- ~~Bacterial kidney disease (*Renibacterium salmoninarum*)~~[†]
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease
- Koi herpesvirus disease²

Article 1.1.3.2.

The following diseases of molluscs are listed by the OIE:

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- ~~Infection with *Mikrocytos mackini*~~[‡]
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*[‡]
- Infection with *Xenobalotus californiensis*.

= Abalone viral mortality

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*)
- Necrotising hepatopancreatitis²
- Infectious myonecrosis².

¹ ~~Listing of this disease is under study.~~

² Listing of this disease is under study.

— text deleted

CHAPTER 3.1.5.

INFECTION WITH *MARTEILIA REFRINGENS***Community comment**

The Community agrees with the proposed chapter, but would ask the OIE AAC to consider the comments included under the specific Articles.

Article 3.1.5.1.

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 3.1.5.2.

Community comment

If all species of the genera *Ostrea* and *Mytilus* have shown to be susceptible species as mentioned in the second paragraph, why are they not included in the first paragraph? This approach seems inconsistent.

The Community reads the Article as the species referred to in the 1st paragraph are known susceptible species.

Furthermore, in the 2nd paragraph that all species tested to date have been shown to be susceptible. The Community therefore propose the second paragraph to read:

All species of the genera *Ostrea* and *Mytilus* exposed to *Marteilia refringens* to date have been shown to be susceptible species. Therefore, there is reason to suspect that this applies also to species of these two genera to date not exposed to *M. refringens*. Therefore all species of these two genera should be regarded as potentially susceptible species.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for infection with *Marteilia refringens* are: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean oyster (*O. puelchana*) and Chilean flat oyster (*O. chilensis*), blue mussel (*Mytilus edulis*) and Mediterranean mussel (*M. galloprovincialis*).

To date, all species of the genera *Ostrea* and *Mytilus* exposed to *Marteilia refringens* have been shown to be susceptible species. Therefore, all species of these genera should be regarded as potentially susceptible 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 3.1.5.3.

Community comment

After having been in direct contact with members of the OIE Ad Hoc group for mollusc diseases, the Community could accept the list of safe commodities in point 1. However, the Community would ask the OIE to provide the Member Countries with the justification used by the Ad hoc group when deciding that gametes, eggs and larvae are to be considered as a safe commodity. It would be valuable in the future, that such recommendations by the OIE are always followed by the justification, due to their significance for future trade requirements.

The text “especially those of the genus *Ostrea* and *Mytilus*“ in the second line of point 3 could lead to misunderstandings. Please refer to “species listed in Article 3.1.5.2” The current proposal may cause confusion, as “genera *Ostrea* and *Mytilus*” is already referred to in Article 3.1.5.2.

Commodities

1. When authorising import or transit of the following ~~commodities (under study)~~, *Competent Authorities* should not require any *Marteilia refringens* related conditions, regardless of the *Marteilia refringens* status of the *exporting country, zone* or *compartment*:
 - a) From the species listed in Article 3.1.5.2., for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) Gametes, eggs and larvae;
 - b) The following commodities destined for human consumption from the species listed in Article 3.1.5.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);
 - c) All commodities from *Crassostrea gigas*, including the live aquatic animal.

For the commodities listed in point 1) b), Member Countries should consider introducing internal measures to prevent the commodity being used for any purpose other than for human consumption.

2. When authorising import or transit of the ~~following commodities~~ of a species listed in Article 3.1.5.2., other than commodities listed in point 1 of Article 3.1.5.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.5.7. to 3.1.5.11. 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 any other commodity from bivalve species not listed in Article 3.1.5.2. (especially those of the genera *Ostrea* and *Mytilus*) not listed above nor in Article 3.1.5.3 point 1) c), 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 3.1.5.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

In option 1, please refer to “species listed in Article 3.1.5.2” The current proposal may cause confusion, as “genera *Ostrea* and *Mytilus*” is already referred to in Article 3.1.5.2.

***Marteilia refringens* free country**

A country may declare itself free from *Marteilia refringens* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a ~~water catchment or coastal zone or compartment~~ 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 are declared *Marteilia refringens* free zones (see Article 3.1.5.5.).

1. A country where ~~none of the species of genera *Ostrea* and *Mytilus* listed in Article 3.1.5.2.~~ is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years¹.

OR

2. A country where ~~the~~ any species listed in Article 3.1.5.2. is 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 3.1.5. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been 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) *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 years² without detection of *Marteilia refringens*.

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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3.1.5.5.

Article 3.1.5.5.

Community comment

In option 1, please refer to “species listed in Article 3.1.5.2”. The current proposal may cause confusion, as “genera *Ostrea* and *Mytilus*” is already referred to in Article 3.1.5.2

***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 points 1), 2), 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 ~~one of the~~ species of genera *Ostrea* and *Mytilus* ~~listed in Article 3.1.5.2.~~ is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years².

OR

2. In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where ~~the~~ any species listed in Article 3.1.5.2. is 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 XXX of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been 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.

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) *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 years² 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3.1.5.6.

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 3.1.5.4. or 3.1.5.5., 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 3.1.5.4. or 3.1.5.5., 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 XXX 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 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 3.1.5.7.

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 3.1.5.2., other than *commodities* listed in point 1) of Article 3.1.5.3., 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 3.1.5.4. or 3.1.5.5. (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 the Model Certificate No. 3 in Appendix 6.3.1. given in Part 6. of this *Aquatic Code*.

Article 3.1.5.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e.

both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.5.2., other than those *commodities* listed in point 1) of Article 3.1.5.3., 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:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Marteilia refringens*.

Article 3.1.5.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

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

When importing, for processing ~~and/or~~ for human consumption, *aquatic animals* of the species listed in Article 3.1.5.2., other than ~~any~~ ~~those~~ live *commodities* listed in point 1) of Article 3.1.5.3., from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should require that ~~assess the risk and apply risk mitigation measures such as:~~

1. the consignment is delivered directly to and held in *quarantine* facilities ~~for a short period before~~ until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Marteilia refringens*.

Article 3.1.5.10.

Community comment

The recommendation in Article 3.1.5.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.5.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

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

refringens

When importing *aquatic animal products* of the species listed in Article 3.1.5.2., other than *commodities* listed in point 1) of Article 3.1.5.3., 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 3.1.5.4. or 3.1.5.5. (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 the Model Certificate No. [X] in Appendix 6.3.2. given in Part 6. of this Aquatic Code.

Article 3.1.5.11.

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 3.1.5.2., other than those *commodities* listed in point 1) of Article 3.1.5.3., 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.

- 1- ~~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.~~
- 2- ~~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.~~

 — text deleted

CHAPTER 3.1.2.

INFECTION WITH *BONAMIA EXITOSA*

Article 3.1.2.1.

Community comment

The Community agrees with the proposed chapter, but would ask the OIE AAC to consider the comments included under the specific Articles.

For the purposes of this *Aquatic Code*, infection with *Bonamia exitiosa* means infection only with *Bonamia exitiosa*.

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

Article 3.1.2.2.

Community comment

If all species of the genera *Ostrea* have shown to be susceptible species as mentioned in the second paragraph, why are they not included in the first paragraph? This approach seems inconsistent.

The Community reads the Article as the species referred to in the 1st paragraph are known susceptible species.

Furthermore, in the 2nd paragraph that all species tested to date have been shown to be susceptible. The Community therefore propose the second paragraph to read:

All species of the genera *Ostrea* exposed to *Bonamia exitiosa* to date have been shown to be susceptible species. Therefore, there is reason to suspect that this applies also to species of this genera to date not exposed to *B. exitiosa*. Therefore all species of this genera should be regarded as potentially susceptible species.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for infection with *Bonamia exitiosa* are: Australian mud oyster (*Ostrea angasi*), and Chilean flat oyster (*O. chilensis*).

To date, all species of the genus *Ostrea* exposed to *Bonamia exitiosa* have been shown to be *susceptible species*. Therefore, all species of these genera should be regarded as potentially *susceptible species*. *Bonamia* isolates closely related to *Bonamia exitiosa* have been reported from *O. puelchana* and *Crassostrea ariakensis*.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Bonamia exitiosa* 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 3.1.2.3.

Community comment

After having been in direct contact with members of the OIE Ad Hoc group for mollusc diseases, the Community could accept the list of safe commodities in point 1. However, the Community would ask the OIE to provide the Member Countries with the justification used by the Ad hoc group when deciding that gametes, eggs and larvae are to be considered as a safe commodity. It would be valuable in the future, that such recommendations by the OIE are always followed by the justification, due to their significance for future trade requirements.

The text “especially those of the genus *Ostrea*“ in the second line of point 3 could lead to misunderstandings. Please refer to “species listed in Article 3.1.2.2” The current proposal may cause confusion, as “genera *Ostrea*” is already referred to in Article 3.1.2.2.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Bonamia exitiosa* related conditions, regardless of the *Bonamia exitiosa* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.2.2., for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) *Gametes, eggs and larvae*;
 - b) The following *commodities* destined for human consumption from the species listed in Article 3.1.2.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);
 - c) All *commodities* from *Crassostrea gigas*, *C. virginica* and *Saccostrea glomerata*, including the live *aquatic animal*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.
2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.2.2., other than *commodities* listed in point 1 of Article 3.1.2.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.2.7. to 3.1.2.11. of this Chapter, relevant to the *Bonamia exitiosa* status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any other *commodity* from bivalve species not listed in Article 3.1.2.2. (especially those of the genus *Ostrea*) nor in Article 3.1.2.3 point 1) c), from an *exporting country, zone or compartment* not declared free of *Bonamia exitiosa*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Bonamia exitiosa*, 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 3.1.2.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

In option 1, please refer to “species listed in Article 3.1.2.2” The current proposal may cause confusion, as “genera *Ostrea*” is already referred to in Article 3.1.2.2.

***Bonamia exitiosa* free country**

A country may declare itself free from *Bonamia exitiosa* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Bonamia exitiosa* free country if all the areas covered by the shared water are declared *Bonamia exitiosa* free zones (see Article 3.1.2.5.).

1. A country where no species of the genus *Ostrea* is present may declare itself free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any species listed in Article 3.1.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 3.1.2. of the *Aquatic Manual*, may declare itself free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Bonamia exitiosa* 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 *Bonamia exitiosa* when:
 - a) *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 *Bonamia exitiosa*.

OR

4. A country that had declared itself free from *Bonamia exitiosa* but in which the disease is detected may not declare itself free from *Bonamia exitiosa* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia exitiosa*.

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 3.1.2.5.

Article 3.1.2.5.

Community comment

In option 1, please refer to “species listed in Article 3.1.2.2”. The current proposal may cause confusion, as “genera Ostrea” is already referred to in Article 3.1.2.2

***Bonamia exitiosa* free zone or free compartment**

A *zone* or *compartment* free from *Bonamia exitiosa* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia exitiosa* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia exitiosa* 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 *Bonamia exitiosa*, a *zone* or *compartment* where no species of the genus *Ostrea* is present may declare itself free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia exitiosa*, a *zone* or *compartment* where any species listed in Article 3.1.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – 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 *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia exitiosa* is not known to be established in wild populations.

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 XXX of the *Aquatic Manual*, may declare itself free from *Bonamia exitiosa* when:
 - a) *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 *Bonamia exitiosa*.

OR

4. A *zone* previously declared free from *Bonamia exitiosa* but in which the disease is detected may not be declared free from *Bonamia exitiosa* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia exitiosa*.

Article 3.1.2.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of points 1) or 2) of Articles 3.1.2.4. or 3.1.2.5., respectively, may maintain its status as *Bonamia exitiosa* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of point 3) of Articles 3.1.2.4. or 3.1.2.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Bonamia exitiosa* free provided that conditions that are conducive to clinical expression of infection with *Bonamia exitiosa*, 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 infection with *Bonamia exitiosa*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.2.7.

Importation of live animals from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing live *aquatic animals* of the species listed in Article 3.1.2.2., other than *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* declared free from *Bonamia exitiosa*, 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 3.1.2.4. or 3.1.2.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.2.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.2.2., other than those *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the risk and apply risk

mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia exitiosa*.

Article 3.1.2.9.

Importation of live animals for processing for human consumption from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 3.1.2.2., other than any live *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia exitiosa*.

Article 3.1.2.10.

Community comment

The recommendation in Article 3.1.2.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.2.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

Importation of products from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of the species listed in Article 3.1.2.2., other than *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* free from *Bonamia exitiosa*, 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 3.1.2.4. or 3.1.2.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.2.11.

Importation of products from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of the species listed in Article 3.1.2.2., other than those *commodities*

listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 3.1.1.

INFECTION WITH *BONAMIA OSTREAE***Community comment**

The Community agrees with the proposed chapter, but would ask the OIE AAC to consider the comments included under the specific Articles.

Article 3.1.1.1.

For the purposes of this *Aquatic Code*, infection with *Bonamia ostreae* means infection only with *Bonamia ostreae*.

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

Article 3.1.1.2.

Community comment

If all species of the genera *Ostrea* have shown to be susceptible species as mentioned in the second paragraph, why are they not included in the first paragraph? This approach seems inconsistent.

The Community reads the Article as the species referred to in the 1st paragraph are known susceptible species.

Furthermore, in the 2nd paragraph that all species tested to date have been shown to be susceptible. The Community therefore propose the second paragraph to read:

All species of the genera *Ostrea* exposed to *Bonamia ostreae* to date have been shown to be susceptible species. Therefore, there is reason to suspect that this applies also to species of this genera to date not exposed to *B. ostreae*. Therefore all species of this genera should be regarded as potentially susceptible species.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for infection with *Bonamia ostreae* are: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean flat oyster (*O. puelchana*), Chilean flat oyster (*O. chilensis*), Asiatic oyster (*O. denselammellosa*) and Suminoe oyster (*Crassostrea ariakensis*).

To date, all species of the genus *Ostrea* (except *O. conchaphila*) exposed to *Bonamia ostreae* have been shown to be *susceptible species*. Therefore, all species of these genera should be regarded as potentially *susceptible species*.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Bonamia ostreae* 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 3.1.1.3.

Community comment

After having been in direct contact with members of the OIE Ad Hoc group for mollusc diseases, the Community could accept the list of safe commodities in point 1. However, the Community would ask the OIE to provide the Member Countries with the justification used by the Ad hoc group when deciding that gametes, eggs and larvae are to be considered as a safe commodity. It would be valuable in the future, that such recommendations by the OIE are always followed by the justification, due to their significance for future trade requirements.

The text “especially those of the genus *Ostrea*“ in the second line of point 3 could lead to misunderstandings. Please refer to “species listed in Article 3.1.1.2” The current proposal may cause confusion, as “genera *Ostrea*” is already referred to in Article 3.1.1.2.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Bonamia ostreae* related conditions, regardless of the *Bonamia ostreae* status of the *exporting country, zone* or *compartment*:
 - a) From the species listed in Article 3.1.1.2., for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) *Gametes, eggs* and larvae;
 - b) The following *commodities* destined for human consumption from the species listed in Article 3.1.1.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);
 - c) All *commodities* from *Crassostrea gigas*, *C. virginica*, *Ruditapes decussatus*, *R. philippinarum*, *Mytilus galloprovincialis* and *M. edulis*, including the live *aquatic animal*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.1.2., other than *commodities* listed in point 1 of Article 3.1.1.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.1.7. to 3.1.1.11. of this Chapter, relevant to the *Bonamia ostreae* status of the *exporting country, zone* or *compartment*.
3. When considering the import or transit of any other *commodity* from bivalve species not listed in Article 3.1.1.2. (especially those of the genus *Ostrea*) nor in Article 3.1.1.3 point 1) c), from an *exporting country, zone* or *compartment* not declared free of *Bonamia ostreae*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Bonamia ostreae*, 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 3.1.1.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

In option 1, please refer to “species listed in Article 3.1.1.2” The current proposal may cause confusion, as “genera *Ostrea*” is already referred to in Article 3.1.1.2.

***Bonamia ostreae* free country**

A country may declare itself free from *Bonamia ostreae* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Bonamia ostreae* free country if all the areas covered by the shared water are declared *Bonamia ostreae* free zones (see Article 3.1.1.5.).

1. A country where no species of the genus *Ostrea* is present may declare itself free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any species listed in Article 3.1.1.2. 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 3.1.1. of the *Aquatic Manual*, may declare itself free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Bonamia ostreae* 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 *Bonamia ostreae* when:
 - a) *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 *Bonamia ostreae*.

OR

4. A country that had declared itself free from *Bonamia ostreae* but in which the disease is detected may not declare itself free from *Bonamia ostreae* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia ostreae*.

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 3.1.1.5.

Article 3.1.1.5.

Community comment

In option 1, please refer to “species listed in Article 3.1.1.2”. The current proposal may cause confusion, as “genera *Ostrea*” is already referred to in Article 3.1.1.2

***Bonamia ostreae* free zone or free compartment**

A *zone* or *compartment* free from *Bonamia ostreae* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia ostreae* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia ostreae* 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 *Bonamia ostreae*, a *zone* or *compartment* where no species of the genus *Ostrea* is present may declare itself free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia ostreae*, a *zone* or *compartment* where any species listed in Article 3.1.1.2. 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 *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia ostreae* is not known to be established in wild populations.

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 *Bonamia ostreae* when:

- a) *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 *Bonamia ostreae*.

OR

4. A *zone* previously declared free from *Bonamia ostreae* but in which the disease is detected may not be declared free from *Bonamia ostreae* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia ostreae*.

Article 3.1.1.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of points 1) or 2) of Articles 3.1.1.4. or 3.1.1.5., respectively, may maintain its status as *Bonamia ostreae* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of point 3) of Articles 3.1.1.4. or 3.1.1.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Bonamia ostreae* free provided that conditions that are conducive to clinical expression of infection with *Bonamia ostreae*, 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 infection with *Bonamia ostreae*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.1.7.

Importation of live animals from a country, zone or compartment declared free from *Bonamia ostreae*

When importing live *aquatic animals* of the species listed in Article 3.1.1.2., other than *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* declared free from *Bonamia ostreae*, 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 3.1.1.4. or 3.1.1.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.1.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.1.2., other than those *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia ostreae*.

Article 3.1.1.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

Importation of live animals for processing for human consumption from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 3.1.1.2., other than any live *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia ostreae*.

Article 3.1.1.10.

Community comment

The recommendation in Article 3.1.1.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.1.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

Importation of products from a country, zone or compartment declared free from *Bonamia ostreae*

When importing *aquatic animal products* of the species listed in Article 3.1.1.2., other than *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* free from *Bonamia ostreae*, 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 3.1.1.4. or 3.1.1.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.1.11.

Importation of products from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing *aquatic animal products* of the species listed in Article 3.1.1.2., other than those *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 3.1.4.

INFECTION WITH *HAPLOSPORIDIUM NELSONI***Community comment**

The Community agrees with the proposed chapter, but would ask the OIE AAC to consider the comments included under the specific Articles.

Article 3.1.4.1.

For the purposes of this *Aquatic Code*, infection with *Haplosporidium nelsoni* means infection only with *Haplosporidium nelsoni*.

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

Article 3.1.4.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for infection with *Haplosporidium nelsoni* are: Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*).

Clinical manifestations and disease are mainly observed in *C. virginica*.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Haplosporidium nelsoni* 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 3.1.4.3.

Community comment

After having been in direct contact with members of the OIE Ad Hoc group for mollusc diseases, the Community could accept the list of safe commodities in point 1. However, the Community would ask the OIE to provide the Member Countries with the justification used by the Ad hoc group when deciding that gametes, eggs and larvae are to be considered as a safe commodity. It would be valuable in the future, that such recommendations by the OIE are always followed by the justification, due to their significance for future trade requirements.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Haplosporidium nelsoni* related conditions, regardless of the *Haplosporidium nelsoni* status of the *exporting country*, *zone* or *compartment*:
 - a) From the species listed in Article 3.1.4.2., for any purpose:

- i) Commercially-sterile canned or cooked products;
- ii) *Gametes, eggs and larvae*;
- b) The following *commodities* destined for human consumption from the species listed in Article 3.1.4.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);
- c) All *commodities* from *Crassostrea ariakensis*, including the live *aquatic animal*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.4.2., other than *commodities* listed in point 1 of Article 3.1.4.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.4.7. to 3.1.4.11. of this Chapter, relevant to the *Haplosporidium nelsoni* status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any other *commodity* from bivalve species not listed in Article 3.1.4.2. nor in Article 3.1.4.3 point 1) c), from an *exporting country, zone or compartment* not declared free of *Haplosporidium nelsoni*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Haplosporidium nelsoni*, 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 3.1.4.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

Haplosporidium nelsoni free country

A country may declare itself free from *Haplosporidium nelsoni* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Haplosporidium nelsoni* free country if all the areas covered by the shared water are declared *Haplosporidium nelsoni* free zones (see Article 3.1.4.5.).

1. A country where no species listed in Article 3.1.4.2. are present may declare itself free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any species listed in Article 3.1.4.2. 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 3.1.4. of the *Aquatic Manual*, may declare itself free from *Haplosporidium nelsoni* when *basic biosecurity conditions*

have been met continuously in the country for at least the past 2 years and infection with *Haplosporidium nelsoni* 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 *Haplosporidium nelsoni* when:
 - a) *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 *Haplosporidium nelsoni*.

OR

4. A country that had declared itself free from *Haplosporidium nelsoni* but in which the disease is detected may not declare itself free from *Haplosporidium nelsoni* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Haplosporidium nelsoni*.

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 3.1.4.5.

Article 3.1.4.5.

***Haplosporidium nelsoni* free zone or free compartment**

A *zone* or *compartment* free from *Haplosporidium nelsoni* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Haplosporidium nelsoni* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Haplosporidium nelsoni* 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 *Haplosporidium nelsoni*, a *zone* or *compartment* where none of the species listed in Article 3.1.4.2. is present may declare itself free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Haplosporidium nelsoni*, a *zone* or *compartment* where any species listed in Article 3.1.4.2. 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 *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously

in the *zone* or *compartment* for at least the past 2 years and infection with *Haplosporidium nelsoni* is not known to be established in wild populations.

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 *Haplosporidium nelsoni* when:
 - a) *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 *Haplosporidium nelsoni*.

OR

4. A *zone* previously declared free from *Haplosporidium nelsoni* but in which the disease is detected may not be declared free from *Haplosporidium nelsoni* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Haplosporidium nelsoni*.

Article 3.1.4.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of points 1) or 2) of Articles 3.1.4.4. or 3.1.4.5., respectively, may maintain its status as *Haplosporidium nelsoni* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of point 3) of Articles 3.1.4.4. or 3.1.4.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Haplosporidium nelsoni* free provided that conditions that are conducive to clinical expression of infection with *Haplosporidium nelsoni*, 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 infection with *Haplosporidium nelsoni*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.4.7.

Importation of live animals from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing live *aquatic animals* of the species listed in Article 3.1.4.2., other than *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*, 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 3.1.4.4. or 3.1.4.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.4.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.4.2., other than those *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

Article 3.1.4.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

Importation of live animals for processing for human consumption from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 3.1.4.2., other than any live *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

Article 3.1.4.10.

Community comment

The recommendation in Article 3.1.4.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.4.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

Importation of products from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing *aquatic animal products* of the species listed in Article 3.1.4.2., other than *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* free from *Haplosporidium nelsoni*, 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 3.1.4.4. or 3.1.4.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.4.11.

Importation of products from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing *aquatic animal products* of the species listed in Article 3.1.4.2., other than those *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 3.1.7.

INFECTION WITH *MIKROCYTOS MACKINI***Community comment**

The Community agrees with the proposed chapter, but would ask the OIE AAC to consider the comments included under the specific Articles.

Article 3.1.7.1.

For the purposes of this *Aquatic Code*, infection with *Mikrocytos mackini* means infection only with *Mikrocytos mackini*.

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

Article 3.1.7.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for infection with *Mikrocytos mackini* are: European flat oyster (*Ostrea edulis*), Olympia oyster (*O. conchaphila*), Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*).

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Mikrocytos mackini* 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 3.1.7.3.

Community comment

After having been in direct contact with members of the OIE Ad Hoc group for mollusc diseases, the Community could accept the list of safe commodities in point 1. However, the Community would ask the OIE to provide the Member Countries with the justification used by the Ad hoc group when deciding that gametes, eggs and larvae are to be considered as a safe commodity. It would be valuable in the future, that such recommendations by the OIE are always followed by the justification, due to their significance for future trade requirements.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Mikrocytos mackini* related conditions, regardless of the *Mikrocytos mackini* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.7.2., for any purpose:
 - i) Commercially-sterile canned or other heat treated products;

- ii) *Gametes, eggs and larvae*;
- b) The following *commodities* destined for human consumption from the species listed in Article 3.1.7.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.7.2., other than *commodities* listed in point 1 of Article 3.1.7.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.7.7. to 3.1.7.11. of this Chapter, relevant to the *Mikrocytos mackini* status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any other *commodity* from bivalve species not listed in Article 3.1.7.2. from an *exporting country, zone or compartment* not declared free of *Mikrocytos mackini*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Mikrocytos mackini*, 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 3.1.7.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

Mikrocytos mackini free country

A country may declare itself free from *Mikrocytos mackini* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself a *Mikrocytos mackini* free country if all the areas covered by the shared water are declared *Mikrocytos mackini* free zones (see Article 3.1.7.5.).

1. A country where no species listed in Article 3.1.7.2. are present may declare itself free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any species listed in Article 3.1.7.2. 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 3.1.7. of the *Aquatic Manual*, may declare itself free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Mikrocytos mackini* 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 *Mikrocytos mackini* when:
 - a) *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 *Mikrocytos mackini*.

OR

4. A country that had declared itself free from *Mikrocytos mackini* but in which the disease is detected may not declare itself free from *Mikrocytos mackini* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Mikrocytos mackini*.

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 3.1.7.5.

Article 3.1.7.5.

***Mikrocytos mackini* free zone or free compartment**

A *zone* or *compartment* free from *Mikrocytos mackini* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Mikrocytos mackini* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Mikrocytos mackini* 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 *Mikrocytos mackini*, a *zone* or *compartment* where none of the species listed in Article 3.1.7.2. is present may declare itself free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where any species listed in Article 3.1.7.2. 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 *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

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 *Mikrocytos mackini* when:

- a) *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 *Mikrocytos mackini*.

OR

4. A *zone* previously declared free from *Mikrocytos mackini* but in which the disease is detected may not be declared free from *Mikrocytos mackini* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Mikrocytos mackini*.

Article 3.1.7.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of points 1) or 2) of Articles 3.1.7.4. or 3.1.7.5., respectively, may maintain its status as *Mikrocytos mackini* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of point 3) of Articles 3.1.7.4. or 3.1.7.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Mikrocytos mackini* free provided that conditions that are conducive to clinical expression of infection with *Mikrocytos mackini*, 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 infection with *Mikrocytos mackini*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.7.7.

Importation of live animals from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing live *aquatic animals* of the species listed in Article 3.1.7.2., other than *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, 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 3.1.7.4. or 3.1.7.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1.

Article 3.1.7.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.7.2., other than those *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Mikrocytos mackini*.

Article 3.1.7.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

Importation of live animals for processing for human consumption from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 3.1.7.2., other than any live *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Mikrocytos mackini*.

Article 3.1.7.10.

Community comment

The recommendation in Article 3.1.7.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.7.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

Importation of products from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of the species listed in Article 3.1.7.2., other than *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* free from *Mikrocytos mackini*, 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 3.1.7.4. or 3.1.7.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.7.11.

Importation of products from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of the species listed in Article 3.1.7.2., other than those *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 3.1.9.

INFECTION WITH *PERKINSUS OLSENI***Community comment**

The Community agrees with the proposed chapter, but would ask the OIE AAC to consider the comments included under the specific Articles.

Article 3.1.9.1.

For the purposes of this *Aquatic Code*, infection with *Perkinsus olseni* means infection only with *Perkinsus olseni*.

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

Article 3.1.9.2.

Community comment

If all species of the bivalve and gastrophoda have shown to be susceptible species as mentioned in the second paragraph, why are they not included in the first paragraph? This approach seems inconsistent.

The Community reads the Article as the species referred to in the 1st paragraph are known susceptible species.

Furthermore, in the 2nd paragraph that all species tested to date have been shown to be susceptible. The Community therefore propose the second paragraph to read:

All species of the bivalva and gastrophoda exposed to *Perkinsus olseni* to date have been shown to be susceptible species. Therefore, there is reason to suspect that this applies also to species of these phyla to date not exposed to *P. olseni*. Therefore all species of phyla should be regarded as potentially susceptible species.

Finally, the Community would ask the OIE to justify why *C. gigas* and *C. ariakensis* are proposed to be susceptible species, as they are not regarded as susceptible in the 2005 Code.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for infection with *Perkinsus olseni* are: primarily venerid clams (*Austrovenus stutchburyi*, *Venerupis pullastra*, *V. aurea*, *Ruditapes decussatus*, *R. philippinarum*), abalone (*Haliotis rubra*, *H. laevigata*, *H. cyclobates*, *H. scalaris*) and other species (*Anadara trapezia*, *Barbatia novaezelandiae*, *Macomona liliana*, *Paphies australis*, *Crassostrea gigas*, *Crassostrea ariakensis*).

To date, all species of bivalves and gastropods exposed to *Perkinsus olseni* have been shown to be *susceptible species*. Therefore, all these mollusc species should be regarded as potentially *susceptible species*. Clinical manifestations and disease are mainly observed in the families Veneridae, Haliotidae and Arcidae.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Perkinsus olseni* 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 3.1.9.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Perkinsus olseni* related conditions, regardless of the *Perkinsus olseni* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.9.2., for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - b) The following *commodities* destined for human consumption from the species listed in Article 3.1.9.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals).

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.
2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.9.2., other than *commodities* listed in point 1 of Article 3.1.9.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.9.7. to 3.1.9.11. of this Chapter, relevant to the *Perkinsus olseni* status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any other *commodity* from bivalve and gastropod species not listed in Article 3.1.9.2. from an *exporting country, zone or compartment* not declared free of *Perkinsus olseni*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Perkinsus olseni*, 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 3.1.9.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 in the ingress.

Perkinsus olseni free country

A country may declare itself free from *Perkinsus olseni* if it meets the conditions in points 1), 2) or 3) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Perkinsus olseni* free country if all the areas covered by the shared water are declared *Perkinsus olseni* free zones (see Article 3.1.9.5.).

1. A country where the species listed in Article 3.1.9.2. 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 3.1.9. of the *Aquatic Manual*, may declare itself free from *Perkinsus olseni* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years and infection with *Perkinsus olseni* is not known to be established in wild populations.

OR

2. 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 *Perkinsus olseni* when:
 - a) *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 past 3 years without detection of *Perkinsus olseni*.

OR

3. A country that had declared itself free from *Perkinsus olseni* but in which the disease is detected may not declare itself free from *Perkinsus olseni* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3 years without detection of *Perkinsus olseni*.

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 2) of Article 3.1.9.5.

Article 3.1.9.5.

***Perkinsus olseni* free zone or free compartment**

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Perkinsus olseni* 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 *Perkinsus olseni*, a *zone* or *compartment* where any species listed in Article 3.1.9.2. 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 *Perkinsus olseni* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years and infection with *Perkinsus olseni* is not known to be established in wild populations.

OR

2. 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 *Perkinsus olsenii* when:
- basic biosecurity conditions* have been met continuously for at least the past 3 years; and
 - 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 3 years without detection of *Perkinsus olsenii*.

OR

3. A *zone* previously declared free from *Perkinsus olsenii* but in which the disease is detected may not be declared free from *Perkinsus olsenii* again until the following conditions have been met:
- on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - 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 3 years without detection of *Perkinsus olsenii*.

Article 3.1.9.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Perkinsus olsenii* following the provisions of point 1) of Articles 3.1.9.4. or 3.1.9.5., respectively, may maintain its status as *Perkinsus olsenii* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Perkinsus olsenii* following the provisions of point 2) of Articles 3.1.9.4. or 3.1.9.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Perkinsus olsenii* free provided that conditions that are conducive to clinical expression of infection with *Perkinsus olsenii*, 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 infection with *Perkinsus olsenii*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.9.7.

Importation of live animals from a country, zone or compartment declared free from *Perkinsus olsenii*

When importing live *aquatic animals* of the species listed in Article 3.1.9.2., other than *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* declared free from *Perkinsus olsenii*, 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 3.1.9.4. or 3.1.9.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus olsenii*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.9.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Perkinsus olseni*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.9.2., other than those *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* not declared free from *Perkinsus olseni*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus olseni*.

Article 3.1.9.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

Importation of live animals for processing for human consumption from a country, zone or compartment not declared free from *Perkinsus olseni*

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 3.1.9.2., other than any live *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* not declared free from *Perkinsus olseni*, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus olseni*.

Article 3.1.9.10.

Community comment

The recommendation in Article 3.1.9.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.9.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

Importation of products from a country, zone or compartment declared free from *Perkinsus olseni*

When importing *aquatic animal products* of the species listed in Article 3.1.9.2., other than *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* free from *Perkinsus olseni*, 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 3.1.9.4. or 3.1.9.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus olseni*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.9.11.

Importation of products from a country, zone or compartment not declared free from *Perkinsus olseni*

When importing *aquatic animal products* of the species listed in Article 3.1.9.2., other than those *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* not declared free from *Perkinsus olseni*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures such as:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 3.1.9.3. or other products authorised by the *competent authority*; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus olseni*.

CHAPTER 3.1.8.

INFECTION WITH *PERKINSUS MARINUS***Community comment**

The Community agrees with the proposed chapter, but would ask the OIE AAC to consider the comments included under the specific Articles.

Article 3.1.8.1.

For the purposes of this *Aquatic Code*, infection with *Perkinsus marinus* means infection only with *Perkinsus marinus*.

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

Article 3.1.8.2.

Susceptible species

For the purposes of this *Aquatic Code*, susceptible species for infection with *Perkinsus marinus* are: Eastern oyster (*Crassostrea virginica*), Pacific oyster (*C. gigas*), Suminoe oyster (*C. ariakensis*), soft shell clam (*Mya arenaria*), Baltic clam (*Macoma balthica*) and hard clam (*Mercenaria mercenaria*).

Clinical manifestations and disease are mainly observed in *C. virginica*.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Perkinsus marinus* 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 3.1.8.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Perkinsus marinus* related conditions, regardless of the *Perkinsus marinus* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.8.2., for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - b) The following *commodities* destined for human consumption from the species listed in Article 3.1.8.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially-sterile heat treated products (e.g. ready prepared meals).

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.8.2., other than

commodities listed in point 1) of Article 3.1.8.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.8.7. to 3.1.8.11. of this Chapter, relevant to the *Perkinsus marinus* status of the *exporting country, zone or compartment*.

3. When considering the import or transit of any other *commodity* from bivalve species not listed in Article 3.1.8.2. from an *exporting country, zone or compartment* not declared free of *Perkinsus marinus*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Perkinsus marinus*, 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 3.1.8.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 in the ingress.

Perkinsus marinus free country

A country may declare itself free from *Perkinsus marinus* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself a *Perkinsus marinus* free country if all the areas covered by the shared water are declared *Perkinsus marinus* free zones (see Article 3.1.8.5.).

1. A country where no species listed in Article 3.1.8.2. are present may declare itself free from *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years.

OR

2. A country where any species listed in Article 3.1.8.2. 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 3.1.8. of the *Aquatic Manual*, may declare itself free from *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years and infection with *Perkinsus marinus* 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 *Perkinsus marinus* when:
 - a) *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 past 3 years without detection of *Perkinsus marinus*.

OR

4. A country that had declared itself free from *Perkinsus marinus* but in which the disease is detected may not declare itself free from *Perkinsus marinus* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3 years without detection of *Perkinsus marinus*.

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 3.1.8.5.

Article 3.1.8.5.

***Perkinsus marinus* free zone or free compartment**

A *zone* or *compartment* free from *Perkinsus marinus* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Perkinsus marinus* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

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

1. A country where no species listed in Article 3.1.8.2. are present may declare itself free from *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years.

OR

2. In a country of unknown status for *Perkinsus marinus*, a *zone* or *compartment* where any species listed in Article 3.1.8.2. 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 *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years and infection with *Perkinsus marinus* is not known to be established in wild populations.

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 *Perkinsus marinus* when:
 - a) *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 past 3 years without detection of *Perkinsus marinus*.

OR

4. A *zone* previously declared free from *Perkinsus marinus* but in which the disease is detected may not be declared free from *Perkinsus marinus* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3 years without detection of *Perkinsus marinus*.

Article 3.1.8.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Perkinsus marinus* following the provisions of points 1) or 2) of Articles 3.1.8.4. or 3.1.8.5., respectively, may maintain its status as *Perkinsus marinus* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Perkinsus marinus* following the provisions of point 3) of Articles 3.1.8.4. or 3.1.8.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Perkinsus marinus* free provided that conditions that are conducive to clinical expression of infection with *Perkinsus marinus*, 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 infection with *Perkinsus marinus*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.8.7.

Importation of live animals from a country, zone or compartment declared free from *Perkinsus marinus*

When importing live *aquatic animals* of the species listed in Article 3.1.8.2., other than *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* declared free from *Perkinsus marinus*, 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 3.1.8.4. or 3.1.8.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus marinus*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.8.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Perkinsus marinus*

When importing for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.8.2., other than those *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* not declared free from *Perkinsus marinus*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus marinus*.

Article 3.1.8.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

Importation of live animals for processing for human consumption from a country, zone or compartment not declared free from *Perkinsus marinus*

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 3.1.8.2., other than any live *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* not declared free from *Perkinsus marinus*, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus marinus*.

Article 3.1.8.10.

Community comment

The recommendation in Article 3.1.8.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.8.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

Importation of products from a country, zone or compartment free from *Perkinsus marinus*

When importing *aquatic animal products* of the species listed in Article 3.1.8.2., other than *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* free from *Perkinsus marinus*, 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 3.1.8.4. or 3.1.8.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus marinus*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.8.11.

Importation of products from a country, zone or compartment not declared free from *Perkinsus marinus*

When importing *aquatic animal products* of the species listed in Article 3.1.8.2., other than those *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* not declared free from *Perkinsus marinus*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures such as:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 3.1.8.3. or other products authorised by the *competent authority*; and
 - b) all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus marinus*.
-

CHAPTER 3.1.11.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Article 3.1.11.1.

For the purposes of this *Aquatic Code*, infection with *Xenobaliothis californiensis* means infection only with *Xenobaliothis californiensis*.

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

Article 3.1.11.2.

Community comment

If all species of the genera *Haliotis* have shown to be susceptible species as mentioned in the second paragraph, why are they not included in the first paragraph? This approach seems inconsistent.

The Community reads the Article as the species referred to in the 1st paragraph are known susceptible species.

Furthermore, in the 2nd paragraph that all species tested to date have been shown to be susceptible. The Community therefore propose the second paragraph to read:

All species of the genus *Haliotis* exposed to *Xenobaliothis californiensis* to date have been shown to be susceptible species. Therefore, there is reason to suspect that this applies also to species of this genus to date not exposed to X californiensis. Therefore all species of this genus should be regarded as potentially susceptible species.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for infection with *Xenobaliothis californiensis* are: black abalone (*Haliotis cracherodii*), white abalone (*H. sorenseni*), red abalone (*H. rufescens*), pink abalone (*H. corrugata*), green abalone (*H. fulgens*), flat abalone (*H. wallalensis*) and Japanese abalone (*H. discus-hannai*).

To date, all species of the genus *Haliotis* exposed to *Xenobaliothis californiensis* have been shown to be *susceptible species*. Therefore, all species of these genera should be regarded as potentially *susceptible species*.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Xenobaliothis californiensis* 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 3.1.11.3.

Community comment

The Community would ask for further clarification on the safe commodities in 1 a).

- since there is a “comma” after gametes, is something lost in editing (in point ii) ?

- What is meant by “shells” (in point iii)

The text “especially those of the genus *Haliotis*” in the second line of point 3 could lead to misunderstandings. Please refer to “species listed in Article 3.1.11.2” The current proposal may cause confusion, as “genus *Haliotis*” is already referred to in Article 3.1.11.2.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Xenobaliothis californiensis* related conditions, regardless of the *Xenobaliothis californiensis* status of the *exporting country*, *zone* or *compartment*:
 - a) From the species listed in Article 3.1.11.2., for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) *Gametes*;
 - iii) Shells.
 - b) The following *commodities* destined for human consumption from the species listed in Article 3.1.11.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell, eviscerated abalone (chilled or frozen) packaged for direct retail trade;

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.11.2., other than *commodities* listed in point 1 of Article 3.1.11.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.11.7. to 3.1.11.11. of this Chapter, relevant to the *Xenobaliothis californiensis* status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any other *commodity* from bivalve species not listed in Article 3.1.11.2. (especially those of the genus *Haliotis*) from an *exporting country*, *zone* or *compartment* not declared free of *Xenobaliothis californiensis*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Xenobaliothis californiensis*, 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 3.1.11.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

In option 1, please refer to “species listed in Article 3.1.11.2” The current proposal may cause confusion, as “genus *Haliotis*” is already referred to in Article 3.1.11.2.

***Xenohaliotis californiensis* free country**

A country may declare itself free from *Xenohaliotis californiensis* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Xenohaliotis californiensis* free country if all the areas covered by the shared water are declared *Xenohaliotis californiensis* free zones (see Article 3.1.11.5).

1. A country where no species of the genus *Haliotis* is present may declare itself free from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where any species listed in Article 3.1.11.2. 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 3.1.11. of the *Aquatic Manual*, may declare itself free from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Xenohaliotis californiensis* 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 *Xenohaliotis californiensis* when:
 - a) *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 *Xenohaliotis californiensis*.

OR

4. A country that had declared itself free from *Xenohaliotis californiensis* but in which the disease is detected may not declare itself free from *Xenohaliotis californiensis* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Xenobaliothis californiensis*.

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 3.1.11.5.

Article 3.1.11.5.

Community comment

In option 1, please refer to “species listed in Article 3.1.11.2”. The current proposal may cause confusion, as “genus Haliotis” is already referred to in Article 3.1.11.2

***Xenobaliothis californiensis* free zone or free compartment**

A *zone* or *compartment* free from *Xenobaliothis californiensis* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Xenobaliothis californiensis* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Xenobaliothis californiensis* 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 *Xenobaliothis californiensis*, a *zone* or *compartment* where no species of the genus *Haliotis* is present may declare itself free from *Xenobaliothis californiensis* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Xenobaliothis californiensis*, a *zone* or *compartment* where any species listed in Article 3.1.11.2. 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 *Xenobaliothis californiensis* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Xenobaliothis californiensis* is not known to be established in wild populations.

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 *Xenobaliothis californiensis* when:
 - a) *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 *Xenobaliothis californiensis*.

OR

4. A *zone* previously declared free from *Xenobalictis californiensis* but in which the disease is detected may not be declared free from *Xenobalictis californiensis* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Xenobalictis californiensis*.

Article 3.1.11.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Xenobalictis californiensis* following the provisions of points 1) or 2) of Articles 3.1.11.4. or 3.1.11.5., respectively, may maintain its status as *Xenobalictis californiensis* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Xenobalictis californiensis* following the provisions of point 3) of Articles 3.1.11.4. or 3.1.11.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Xenobalictis californiensis* free provided that conditions that are conducive to clinical expression of infection with *Xenobalictis californiensis*, 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 infection with *Xenobalictis californiensis*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.11.7.

Importation of live animals from a country, zone or compartment declared free from *Xenobalictis californiensis*

When importing live *aquatic animals* of the species listed in Article 3.1.11.2., other than *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* declared free from *Xenobalictis californiensis*, 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 3.1.11.4. or 3.1.11.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Xenobalictis californiensis*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.11.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from ..”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing, for *aquaculture, aquatic animals* of the species listed in Article 3.1.11.2., other than those *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Xenohaliotis californiensis*.

Article 3.1.11.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

Importation of live animals for processing for human consumption from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 3.1.11.2., other than any live *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Xenohaliotis californiensis*.

Article 3.1.11.10.

Community comment

The recommendation in Article 3.1.11.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 3.1.11.9. To request animal health certificates for non-viable molluscs or mollusc products, taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems non-justifiable.

Importation of products from a country, zone or compartment declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of the species listed in Article 3.1.11.2., other than *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* free from *Xenohaliotis californiensis*, 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 3.1.11.4. or 3.1.11.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.11.11.

Importation of products from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of the species listed in Article 3.1.11.2., other than those *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 2.1.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

Community comment

The Community cannot agree with this chapter unless its comments to Articles 2.1.1.3 and 2.1.1.11 are taken into account.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would also ask the OIE AAC to consider the other comments included under the specific Articles.

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~~ of 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*) and rainbow trout (*Oncorhynchus mykiss*).

Suspect cases of natural infection with EHNV 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 2.1.1.3.

Community comment

Taking into account the recent work in EU research project “Fish Egg Trade” which should be known by the OIE, the Community would argue that “disinfected eggs” may be imported regardless of the EHN status of the exporting country, zone or compartment. However, in such cases, the consignment should be accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2. If the OIE is of the opinion that EHN has been transmitted by disinfected egg, the Community would ask the OIE to forward the justification.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Commodities

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

- a) From the species in Article 2.1.1.2., for any purpose:
 - i) Commercially-sterile canned fish;
 - ii) Leather made from fish skin;
- b) The following *commodities* destined for human consumption from the species listed in Article 2.1.1.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
- c) For species other than those in Article 2.1.1.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the ~~following *commodities*~~, of a species listed in Article 2.1.1.2., other than those listed in point 1) of Article 2.1.1.3., *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 any live *commodity* of a species not listed in Article 2.1.1.2. ~~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 EHN, 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 2.1.1.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress

EHN free country

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

If a country shares a *zone* or *compartment* ~~water-catchment~~ with one or more other countries, it can only declare itself an EHN free country if all the areas covered by the shared water 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 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 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:
 - a) *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 last 2 years without detection of EHN.

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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of EHN.

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.

Community comment

The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

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 points 1), 2), 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 *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 declare itself free from EHN when *basic biosecurity conditions* have been 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 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 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) *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 last 2 years without detection of EHN.

OR

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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 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 live *aquatic animals* of the species listed in Article 2.1.1.2., other than *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 the Model Certificate in Appendix 6.1.1. No. 1 given in Part 6. of this *Aquatic Code*.

Article 2.1.1.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *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:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of EHN.

Article 2.1.1.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.1.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.1.2., other than any live *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* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.1.3. or other products authorised by the competent authority; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of EHN

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

When importing, for processing ~~and/or~~ for human consumption, *aquatic animals* of the species listed in Article 2.1.1.2., other than any ~~those~~ live *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 require that ~~assess the risk and apply risk mitigation measures such as:~~

1. the consignment is delivered directly to and held in *quarantine* facilities for ~~a short period before~~ slaughter and processing to one of the products listed in point 1) of Article 2.1.1.3. or

other products authorised by the competent authority; and

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

Article 2.1.1.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.1.9 and 2.1.1.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.1.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.1.9 will also apply to Article 2.1.1.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from EHN

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, aquatic animals of the species listed in Article 2.1.1.2., other than any live 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 require:

1. the consignment is delivered directly to and held in quarantine facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of EHNV.

Article 2.1.1.10.

Community comment

The recommendation in Article 2.1.1.10 seems inconsistent taking into account the definition of aquatic animal products in Chapter 1.1.1. (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.1.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

Importation of products from a country, zone or compartment 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* 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 the Model Certificate in Appendix 6.2.1. No. 2 given in

Part 6. of this *Aquatic Code*.

Article 2.1.1.11.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further processing of fish that has been eviscerated before entering the importing country.

The Community would ask the OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes otherwise to delete the words “whether eviscerated or” from the 2nd paragraph.

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.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in facilities for processing to one of the products listed in point 1) of Article 2.1.14.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of EHN.

 — text deleted

CHAPTER 2.1.2.

INFECTIOUS HAEMATOPOIETIC NECROSIS

Community comment

The Community cannot agree with this chapter unless its comment to Articles 2.1.2.3 and 2.1.2.11 are taken into account.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would also ask the OIE AAC to consider the other comments included under the specific Articles.

Article 2.1.2.1.

Community comment:

Typo in first line, as the disease in question is infectious haematopoietic necrosis and *not* epizootic haematopoietic necrosis

For the purposes of this *Aquatic Code*, epizootic haematopoietic necrosis (IHN) means infection with IHN virus (IHNV) of the genus *Novirhabdovirus* of the family Rhabdoviridae.

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

Article 2.1.2.2.

Community comment:

The Community would argue that eel (*Aguilla anguilla*) may be considered as susceptible species to IHN (see Bergman et al 2003 (Dis Aquat Org Vol 55, p. 205-210), and Enzman et al 2005 (Dis Aquat Org Vol 66, p. 187-195))

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for IHN are: rainbow or steelhead trout (*Oncorhynchus mykiss*), the Pacific salmon species [chinook (*O. tshawytscha*), sockeye (*O. nerka*), chum (*O. keta*), masou (*O. mason*), pink (*O. rhodurus*) and coho (*O. kisutch*)], and Atlantic salmon (*Salmo salar*).

Suspect cases of natural infection with IHNV 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 2.1.2.3.

Community comment

Taking into account the recent work in EU research project “Fish Egg Trade” which should be known by the OIE, the Community would argue that “disinfected eggs” may be imported regardless of the IHN status of the exporting country, zone or compartment, as the risk of vertical transmission of IHN is negligible. However, in such cases, the consignment should be accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2. If the OIE is of the opinion that IHN has been transmitted by disinfected egg, the Community would ask the OIE to forward the justification.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any IHN related conditions, regardless of the IHN status of the *exporting country, zone or compartment*:
 - a) From the species in Article 2.1.2.2., for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following *commodities* destined for human consumption from the species listed in Article 2.1.2.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.2.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.2.2., other than those listed in point 1) of Article 2.1.2.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.2.7. to 2.1.2.11. of this Chapter, relevant to the IHN status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.2.2. from an *exporting country*, *zone* or *compartment* not declared free of IHN, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of IHNV, 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 2.1.2.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

IHN free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an IHN free country if all the areas covered by the shared water are declared IHN free countries or zones (see Article 2.1.2.5.).

1. A country where none of the species listed in Article 2.1.2.2. is present may declare itself free from IHN when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.2.2. 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 IHN when *basic biosecurity conditions* have been 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 IHN when:
 - a) *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 last 2 years without detection of IHNV.

OR

4. A country that had declared itself free from IHN but in which the disease is detected may

not declare itself free from IHN 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of IHNV.

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 2.1.2.5.

Article 2.1.2.5.

Community comment

The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

IHN free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from IHN 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.2.2. is present may declare itself free from IHN when *basic biosecurity conditions* have been 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 2.1.2.2. 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 IHN when *basic biosecurity conditions* have been 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 IHN when:

- a) *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 last 2 years without detection of IHNV.

OR

- 4. A *zone* previously declared free from IHN but in which the disease is detected may not be declared free from IHN 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of IHNV.

Article 2.1.2.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from IHN following the provisions of points 1) or 2) of Articles 2.1.2.4. or 2.1.2.5., respectively, may maintain its status as IHN free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from IHN following the provisions of point 3) of Articles 2.1.2.4. or 2.1.2.5., respectively, may discontinue *targeted surveillance* and maintain its status as IHN free provided that conditions that are conducive to clinical expression of IHN, 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 IHN, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.2.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.2.2., other than *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* declared free from IHN, 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 2.1.2.4. or 2.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IHN.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.2.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.2.2., other than those *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of IHNV.

Article 2.1.2.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.2.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.2.3. or other products authorised by the competent authority; and

2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of IHNV

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.2.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of IHNV.

Article 2.1.2.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.2.9 and 2.1.2.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.2.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.1.9 will also apply to Article 2.1.2.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from IHN

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of IHNV.

Article 2.1.2.10.

Community comment

The recommendation in Article 2.1.2.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.2.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-

justifiable.

Importation of products from a country, zone or compartment declared free from IHN

When importing *aquatic animal products* of the species listed in Article 2.1.2.2., other than those *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* free from IHN, 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 2.1.2.4. or 2.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IHN.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.2.11.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further processing of fish that has been eviscerated before entering the importing country.

The Community would ask the OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes otherwise to delete the words “whether eviscerated or” from the 2nd paragraph.

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

When importing *aquatic animal products* of the species listed in Article 2.1.2.2., other than those *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 2.1.2.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of IHN.

CHAPTER 2.1.4.

SPRING VIRAEMIA OF CARP

Community comment

The Community cannot agree with this chapter unless its comments to Articles 2.1.4.3 and 2.1.4.11 are taken into account.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would also ask the OIE AAC to consider the other comments included under the specific Articles.

Article 2.1.4.1.

For the purposes of this *Aquatic Code*, spring viraemia of carp (SVC) means infection with the viral species SVC virus (SVCV) tentatively placed in the genus *Vesiculovirus* of the family Rhabdoviridae.

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

Article 2.1.4.2.

Community comment:

The Community would argue that pike (*Exos lucius*) may be considered as susceptible species, as this is referred to in Chapter 2.1.4 of the Manual (2003). See also Ahne W. (1985) *Z. Angew. Ichthyol.*, 2, 90-95.

The Community would also ask to OIE to assess Haenen, O.L.M. & Davidse, A., (1993) *Dis.Aquat.Org.* 15, p. 87-92, to see if Roach (*Rutilus rutilus*) may be considered as susceptible species to SVC.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for SVC are: common carp (*Cyprinus carpio carpio*) and koi carp (*Cyprinus carpio koi*), crucian carp (*Carassius carassius*), sheatfish, (also known as European catfish or wels) (*Silurus glanis*), silver carp (*Hypophthalmichthys molitrix*), bighead carp (*Aristichthys nobilis*), grass carp (white amur) (*Ctenopharyngodon idella*), goldfish (*Carassius auratus*), orfe (*Leuciscus idus*), and tench (*Tinca tinca*).

Suspect cases of natural infection with SVCV 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 2.1.4.3.

Community comment

Taking into account the recent work in EU research project “Fish Egg Trade” which should be known by the OIE, the Community would argue that “disinfected eggs” may be imported regardless of the SVC status of the exporting country, zone or compartment, as the risk of vertical transmission of SVC has not been scientifically demonstrated and that such transmission (if at all possible) appears of minor peidemiological importance. However, in such cases, the consignment should be accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2. If the OIE is of the opinion that SVC has been transmitted by disinfected egg, the Community would ask the OIE to forward the justification.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any SVC related conditions, regardless of the SVC status of the *exporting country*, *zone* or *compartment*:
 - a) From the species in Article 2.1.4.2., for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following *commodities* destined for human consumption from the species listed in Article 2.1.4.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.4.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.4.2.,

other than those listed in point 1) of Article 2.1.4.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.4.7. to 2.1.4.11. of this Chapter, relevant to the SVC status of the *exporting country, zone or compartment*.

3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.4.2. from an *exporting country, zone or compartment* not declared free of SVC, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of SVCV, 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 2.1.4.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

SVC free country

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

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself an SVC free country if all the areas covered by the shared water are declared SVC free countries or zones (see Article 2.1.4.5.).

1. A country where none of the species listed in Article 2.1.4.2. is present may declare itself free from SVC when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.4.2. 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 SVC when *basic biosecurity conditions* have been 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 SVC when:
 - a) *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 last 2 years without detection of SVCV.

OR

4. A country that had declared itself free from SVC but in which the disease is detected may not declare itself free from SVC 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of SVCV.

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 2.1.4.5.

Article 2.1.4.5.

Community comment

The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

SVC free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from SVC 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.4.2. is present may declare itself free from SVC when *basic biosecurity conditions* have been 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 2.1.4.2. 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 SVC when *basic biosecurity conditions* have been 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 SVC when:

- a) *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 last 2 years without detection of SVCV.

OR

4. A *zone* previously declared free from SVC but in which the disease is detected may not be declared free from SVC again until the following conditions have been met:
- on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - 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 years without detection of SVCV.

Article 2.1.4.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from SVC following the provisions of points 1) or 2) of Articles 2.1.4.4. or 2.1.4.5., respectively, may maintain its status as SVC free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from SVC following the provisions of point 3) of Articles 2.1.4.4. or 2.1.4.5., respectively, may discontinue *targeted surveillance* and maintain its status as SVC free provided that conditions that are conducive to clinical expression of SVC, 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 SVC, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.4.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.4.2., other than *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* declared free from SVC, 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 2.1.4.4. or 2.1.4.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from SVC.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.4.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.4.2., other than those *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

Article 2.1.4.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.4.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.4.2., other than any live *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.4.3. or other products authorised by the competent authority; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of SVCV

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.4.2., other than any live *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.4.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

Article 2.1.4.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.4.9 and 2.1.4.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.4.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.4.9 will also apply to Article 2.1.4.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from SVC

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.4.2., other than any live *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

Article 2.1.4.10.

Community comment

The recommendation in Article 2.1.4.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.4.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

Importation of products from a country, zone or compartment declared free from SVC

When importing *aquatic animal products* of the species listed in Article 2.1.4.2., other than those *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* free from SVC, 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 2.1.4.4. or 2.1.4.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from SVC.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.4.11.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further processing of fish that has been eviscerated before entering the importing country.

The Community would ask the OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes otherwise to delete the words “whether eviscerated or” from the 2nd paragraph.

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

When importing *aquatic animal products* of the species listed in Article 2.1.4.2., other than those *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 2.1.4.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

CHAPTER 2.1.5.

V I R A L H A E M O R R H A G I C S E P T I C A E M I A

Community comment

The Community cannot agree with this chapter unless its comments to Articles 2.1.5.3 and 2.1.5.11 are taken into account.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would also ask the OIE AAC to consider the other comments included under the specific Articles.

Article 2.1.5.1.

For the purposes of this *Aquatic Code*, viral haemorrhagic septicaemia (VHS) means infection with VHS virus (VHSV, synonym: Egtved virus) of the genus *Novirhabdovirus* of the family Rhabdoviridae.

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

Article 2.1.5.2.

Community comment

The Community will argue that both eel (*Anguilla anguilla*) and lamprey (*Lampetra fluviatilis*) are species susceptible to VHS.

As regards VHS in eels, see Thiery R. et al (2002), Dis Aquat Org. Vol 52 p. 29-37 and Einer-Jensen et al (2004) J Gen Virol, Vol 85, p. 1167-1179

As regards VHS in lamprey, see Finnish disease report to the OIE for 2003. Paper is *in prep*.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for VHS are:

Atlantic salmon (*Salmo salar*), Atlantic cod (*Gadus morhua*), Atlantic herring (*Clupea harengus*), black cod (*Anaplopoma fimbria*), blue whiting (*Micromesistius punctatus*), brook trout (*Salvelinus fontinalis*), brown trout (*Salmo trutta*), chinook salmon (*Oncorhynchus tshawytscha*), coho salmon (*O. kisutch*), common dab (*Limanda limanda*), English sole (*Parophrys vetulus*), flounder (*Platichthys flesus*), golden trout (*Salmo aguabonita*), grayling (*Thymallus thymallus*), Greenland halibut (*Reinhardtius hippoglossoides*), haddock (*Melanogrammus aeglefinus*), Japanese flounder (*Paralichthys olivaceus*), lake trout (*Salvelinus namaycush*), lesser argentine (*Argentina sphyraena*), Norway pout (*Trisopterus esmarkii*), Pacific cod (*Gadus macrocephalus*), Pacific hake (*Merluccius productus*), Pacific herring (*Clupea harengus pallasii*), Pacific mackerel (*Scomber japonicus*), Pacific sandlance (*Ammodytes hexapterus*), pike (*Esox lucius*), pilchard

(*Sardinops sagax*), plaice (*Pleuronectes platessa*), poor cod (*Trisopterus minutus*), rainbow trout (*Oncorhynchus mykiss*), rockling (*Rhinonemus cimbrius*), sea bass (*Dicentrarchus labrax*), shiner perch (*Cymatogaster aggregata*), smelt (*Thaleichthys pacificus*), sprat (*Sprattus sprattus*), surf smelt (*Hypomesus pretiosus pretiosus*), threespine stickleback (*Gasterosteus aculeatus*), turbot (*Scophthalmus maximus*), sand goby (*Pomatoschistus minutus*), walleye pollock (*Theragra chalcogramma*), whitefish (*Coregonus* sp.) and whiting (*Merlangius merlangus*).

Suspect cases of natural infection with VHSV 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 2.1.5.3.

Community comment

Taking into account the recent work in EU research project “Fish Egg Trade” which should be known by the OIE, the Community would argue that “disinfected eggs” may be imported regardless of the VHS status of the exporting country, zone or compartment, as VHS can be effectively prevented by egg disinfection. However, in such cases, the consignment should be accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2. If the OIE is of the opinion that VHS has been transmitted by disinfected egg, the Community would ask the OIE to forward the justification.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any VHS related conditions, regardless of the VHS status of the *exporting country, zone or compartment*:
 - a) From the species in Article 2.1.5.2., for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following *commodities* destined for human consumption from the species listed in Article 2.1.5.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);

- v) Dried eviscerated fish (including air dried, flame dried, sun dried);
- c) For species other than those in Article 2.1.5.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.5.2., other than those listed in point 1) of Article 2.1.5.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.5.7. to 2.1.5.11. of this Chapter, relevant to the VHS status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.5.2. from an *exporting country*, *zone* or *compartment* not declared free of VHS, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of VHSV, 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 2.1.5.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

VHS free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an VHS free country if all the areas covered by the shared water are declared VHS free countries or zones (see Article 2.1.5.5.).

1. A country where the species listed in Article 2.1.5.2. 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 VHS when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

OR

2. 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 VHS when:
 - a) *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 last 2 years without detection of VHSV.

OR

3. A country that had declared itself free from VHS but in which the disease is detected may not declare itself free from VHS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of VHSV.

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 2) of Article 2.1.5.5.

Article 2.1.5.5.

Community comment

The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

VHS free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from VHS 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 points 1), 2) or 3) below.

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

1. A *zone* or *compartment* where the species listed in Article 2.1.5.2. 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 VHS when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

2. 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 VHS when:
 - a) *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 last 2 years without detection of VHSV.

OR

3. A *zone* previously declared free from VHS but in which the disease is detected may not be declared free from VHS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of VHSV.

Article 2.1.5.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from VHS following the provisions of point 1) of Articles 2.1.5.4. or 2.1.5.5., respectively, may maintain its status as VHS free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from VHS following the provisions of point 2) of Articles 2.1.5.4. or 2.1.5.5., respectively, may discontinue *targeted surveillance* and maintain its status as VHS free provided that conditions that are conducive to clinical expression of VHS, 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 VHS, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.5.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.5.2., other than *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* declared free from VHS, 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 2.1.5.4. or 2.1.5.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from VHS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.5.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.5.2., other than those *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

Article 2.1.5.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.5.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.5.2., other than any live *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.5.3. or other products authorised by the competent authority; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of VHSV

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.5.2., other than any live *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.5.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

Article 2.1.5.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.5.9 and 2.1.5.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.5.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.5.9 will also apply to Article 2.1.5.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from VHS

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.5.2., other than any live *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

Article 2.1.5.10.

Community comment

The recommendation in Article 2.1.5.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.5.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

Importation of products from a country, zone or compartment declared free from VHS

When importing *aquatic animal products* of the species listed in Article 2.1.5.2., other than those *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* free from VHS, 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 2.1.5.4. or 2.1.5.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from VHS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.5.11.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further processing of fish that has been eviscerated before entering the importing country. Also, taking the very long list of susceptible species into consideration, almost all imported fish products should be held in quarantine facilities with proper effluent disinfection.

The Community would like to OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes otherwise to delete the words “whether eviscerated or” from the 2nd paragraph.

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

When importing *aquatic animal products* of the species listed in Article 2.1.5.2., other than those *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 2.1.5.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

CHAPTER 2.1.9.

INFECTIOUS SALMON ANAEMIA

Community comment

The Community cannot agree with this chapter unless its comments to Articles 2.1.9.3 and 2.1.9.11 are taken into account.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would also ask the OIE AAC to consider the other comments included under the specific Articles.

Article 2.1.9.1.

For the purposes of this *Aquatic Code*, infectious salmon anaemia (ISA) means infection with ISA virus (ISAV) of the genus *Isavirus* of the family Orthomyxoviridae.

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

Article 2.1.9.2.

Community comment

The Community would argue that rainbow trout (*Onchorynchus mykiss*) may be considered a species susceptible to ISA. ISA has been isolated from rainbow trout in Ireland. This finding is described in Chapter 2.1.9 of the current (2003) Manual.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for ISA are: Atlantic salmon (*Salmo salar*), brown and sea trout (*S. trutta*), pollock (*Pollachius virens*) and cod (*Gadus morhua*).

Suspect cases of natural infection with ISAV 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 2.1.9.3.

Community comment

Taking into account the recent work in EU research project “Fish Egg Trade” which should be known by the OIE, the Community would argue that “disinfected eggs” may be imported regardless of the ISA status of the exporting country, zone or compartment, as ISA can be effectively prevented by egg disinfection. However, in such cases, the consignment should be

accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2. If the OIE is of the opinion that ISA has been transmitted by disinfected egg, the Community would ask the OIE to forward the justification.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any ISA related conditions, regardless of the ISA status of the *exporting country*, *zone* or *compartment*:
 - a) From the species in Article 2.1.9.2., for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following *commodities* destined for human consumption from the species listed in Article 2.1.9.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.9.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.9.2., other than those listed in point 1) of Article 2.1.9.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.9.7. to 2.1.9.11. of this Chapter, relevant to the ISA status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.9.2. from an *exporting country*, *zone* or *compartment* not declared free of ISA, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of ISAV, 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 2.1.9.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

ISA free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an ISA free country if all the areas covered by the shared water are declared ISA free countries or zones (see Article 2.1.9.5.).

1. A country where none of the species listed in Article 2.1.9.2. is present may declare itself free from ISA when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.9.2. 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 ISA when *basic biosecurity conditions* have been 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 ISA when:
 - a) *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 last 2 years without detection of ISAV.

OR

4. A country that had declared itself free from ISA but in which the disease is detected may not declare itself free from ISA 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of ISAV.

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 2.1.9.5.

Article 2.1.9.5.

Community comment

The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

ISA free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from ISA 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.9.2. is present may declare itself free from ISA when *basic biosecurity conditions* have been 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 2.1.9.2. 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 ISA when *basic biosecurity conditions* have been 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 ISA when:

- a) *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 last 2 years without detection of ISAV.

OR

4. A *zone* previously declared free from ISA but in which the disease is detected may not be declared free from ISA 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of ISAV.

Article 2.1.9.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from ISA following the provisions of points 1) or 2) of Articles 2.1.9.4. or 2.1.9.5., respectively, may maintain its status as ISA free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from ISA following the provisions of point 3) of Articles 2.1.9.4. or 2.1.9.5., respectively, may discontinue *targeted surveillance* and maintain its status as ISA free provided that conditions that are conducive to clinical expression of ISA, 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 ISA, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.9.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.9.2., other than *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* declared free from ISA, 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 2.1.9.4. or 2.1.9.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from ISA.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.9.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.9.2., other than those *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

Article 2.1.9.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.9.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.9.2., other than any live *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.9.3. or other products authorised by the competent authority; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of ISAV

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.9.2., other than any live *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.9.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

Article 2.1.9.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.9.9 and 2.1.9.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.9.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.9.9 will also apply to Article 2.1.9.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from ISA

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.9.2., other than any live *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

Article 2.1.9.10.

Community comment

The recommendation in Article 2.1.9.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.9.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

Importation of products from a country, zone or compartment declared free from ISA

When importing *aquatic animal products* of the species listed in Article 2.1.9.2., other than those *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* free from ISA, 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 2.1.9.4. or 2.1.9.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from ISA.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.9.11.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further processing of fish that has been eviscerated before entering the importing country.

The Community would like to OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes otherwise to delete the words “whether eviscerated or” from the 2nd paragraph.

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

When importing *aquatic animal products* of the species listed in Article 2.1.9.2., other than those *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures. In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 2.1.9.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

CHAPTER 2.1.10.

EPIZOOTIC ULCERATIVE SYNDROME

Community comment

The Community cannot agree with this chapter unless its comments to Articles 2.1.1.3 and 2.1.10.11 are taken into account.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would also ask the OIE AAC to consider the other comments included under the specific Articles.

Article 2.1.10.1.

For the purposes of this *Aquatic Code*, epizootic ulcerative syndrome (EUS) means infection with the Oomycete fungus *Aphanomyces invadans*.

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

Article 2.1.10.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for EUS are: yellowfin seabream (*Acantopagrus australis*); climbing perch (*Anabas testudineus*); eels (Anguillidae); bagrid catfishes (Bagridae); silver perch (*Bidyanus bidyanus*); Atlantic menhaden (*Brevoortia tyrannus*); jacks (*Caranx* spp.); catla (*Catla catla*); striped snakehead (*Channa striatus*); mrigal (*Cirrhinus mrigala*); torpedo-shaped catfishes (*Clarius* spp.); halfbeaks flying fishes, (Exocoetidae); tank goby (*Glossogobius giuris*); marble goby (*Oxyeleotris marmoratus*); gobies (Gobiidae); rohu (*Labeo rohita*); rhinofishes (*Labeo* spp.); barramundi and giant sea perch (*Lates calcarifer*); striped mullet (*Mugil cephalus*); mullets [Mugilidae] (*Mugil* spp.; *Liža* spp.); ayu (*Plecoglossus altivelis*); pool barb (*Puntius sophore*); barcoo grunter (*Scortum barcoo*); sand whiting (*Sillago ciliata*); wells catfishes (Siluridae); snakeskin gourami (*Trichogaster pectoralis*); common archer fish (*Toxotes chatareus*); silver barb (*Puntius gonionotus*); spotted scat (*Scatophagus argus*); giant gourami (*Osphronemus gourami*); dusky flathead (*Platycephalus fuscus*); spiny turbot (*Psettodes* sp.); Tairiku-baratanago (*Rhodeus ocellatus*); Ketu-Bangladeshi (*Robtee* sp.); rudd (*Scardinius erythrophthalmus*); therapon (*Terapon* sp.); three-spot gourami (*Trichogaster trichopterus*).

Suspect cases of natural infection with *A. invadans* 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 2.1.10.3.

Community comment

Although not included in the EU research project “Fish Egg Trade”, the Community would ask

the OIE to consider if “disinfected eggs” may be imported regardless of the EUS status of the exporting country, zone or compartment. In such cases, the consignment should be accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any EUS related conditions, regardless of the EUS status of the *exporting country, zone or compartment*:
 - a) From the species in Article 2.1.10.2., for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following *commodities* destined for human consumption from the species listed in Article 2.1.10.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.10.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.10.2., other than those listed in point 1) of Article 2.1.10.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.10.7. to 2.1.10.11. of this Chapter, relevant to the EUS status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.10.2. from an *exporting country, zone or compartment* not declared free of EUS, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *A. invadans*, 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 2.1.10.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

EUS free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an EUS free country if all the areas covered by the shared water are declared EUS free countries or zones (see Article 2.1.10.5.).

1. A country where the species listed in Article 2.1.10.2. 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 EUS when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

OR

2. 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 EUS when:
 - a) *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 last 2 years without detection of *A. invadans*.

OR

3. A country that had declared itself free from EUS but in which the disease is detected may not declare itself free from EUS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of *A. invadans*.

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 2) of Article 2.1.10.5.

Article 2.1.10.5.

Community comment

The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

EUS free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from EUS 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 points 1), 2) or 3) below.

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

1. A *zone* or *compartment* where the species listed in Article 2.1.10.2. 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 EUS when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

2. 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 EUS when:
 - a) *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 last 2 years without detection of *A. invadans*.

OR

3. A *zone* previously declared free from EUS but in which the disease is detected may not be declared free from EUS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of *A. invadans*.

Article 2.1.10.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from EUS following the provisions of point 1) of Articles 2.1.10.4. or 2.1.10.5., respectively, may maintain its status as EUS free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from EUS following the provisions of point 2) of Articles 2.1.10.4. or 2.1.10.5., respectively, may discontinue *targeted surveillance* and maintain its status as EUS free provided that conditions that are conducive to clinical expression of EUS, 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 EUS, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.10.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.10.2., other than *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* declared free from EUS, 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 2.1.10.4. or 2.1.10.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from EUS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.10.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.10.2., other than those *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from

the local environment; and

3. all effluent and waste material are treated in a manner that ensures inactivation of *A. invadans*.

Article 2.1.10.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.10.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.10.2., other than any live *commodities* listed in point 1) of Article 2.1.0.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.10.3. or other products authorised by the competent authority; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of *A. invadans*

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.10.2., other than any live *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.10.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *A. invadans*.

Article 2.1.10.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.10.9 and 2.1.10.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.10.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.10.9 will also apply to Article 2.1.10.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from EUS

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.10.2., other than any live *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *A. invadans*.

Article 2.1.10.10.

Community comment

The recommendation in Article 2.1.10.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.10.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

Importation of products from a country, zone or compartment declared free from EUS

When importing *aquatic animal products* of the species listed in Article 2.1.10.2., other than those *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* free from EUS, 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 2.1.10.4. or 2.1.10.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from EUS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.10.11.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further processing of fish that has been eviscerated before entering the importing country.

The Community would like to OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes otherwise to delete the words “whether eviscerated or” from the 2nd paragraph.

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

When importing *aquatic animal products* of the species listed in Article 2.1.10.2., other than those *commodities* listed in point 1) of Article 2.1.10.3., from a country, ~~zone~~ or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 2.1.10.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of *A. Invadans*.

CHAPTER 2.1.14.

GYRODACTYLOSIS (*Gyrodactylus salaris*)**Community comment**

The Community cannot agree with this chapter.

The chapter does not reflect the fact that *G salaris* is an ectoparasite, unable to survive in seawater, and consequently several of the Articles needs to be considered further with the nature of the pathogen in mind.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would ask the OIE AAC to amend the chapter in line with the comments also included under the specific Articles.

Article 2.1.14.1.

For the purposes of this *Aquatic Code*, Gyrodactylosis means *infection* with the viviparous freshwater ectoparasite *Gyrodactylus salaris* (Platyhelminthes; Monogenea).

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

Article 2.1.14.2.

Community comment

The Community proposes to delete the words “in declining order of susceptibility” as this is irrelevant for the purpose of the Code.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for Gyrodactylosis (in declining order of susceptibility) are: Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), Arctic char (*Salvelinus alpinus*), North American brook trout (*Salvelinus fontinalis*), grayling (*Thymallus thymallus*), North American lake trout (*Salvelinus namaycush*) and brown trout (*Salmo trutta*).

Suspect cases of natural infection with *G. salaris* 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 2.1.14.3.

Community comment

The entire Article 2.1.14.3 must be rewritten to take into account that *G. salaris* is an ectoparasite and not a virus, and which survive neither high salinities nor drying.

Although *G. salaris* is not included in the EU research project “Fish Egg Trade”, the Community would argue that “disinfected eggs” may be imported regardless of the *G. salaris* status of the exporting country, zone or compartment, as the susceptibility of the parasite to common egg disinfectants is well known. However, in such cases, the consignment should be accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2. If the OIE is of the opinion that *G. salaris* has been transmitted by disinfected egg, the Community would ask the OIE to forward the justification.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Furthermore, the Community would argue that fish originating from seawater, should be regarded as a safe commodity, as the parasite is unable to survive under these conditions. Please see report on http://www.europanda.net/m_area/docs/wp2/gsriskanalysis.pdf. However, in such cases, the consignment should be accompanied with a animal health certificate stating that the fish originates from a zone or a compartment with a salinity of more than 25 ppt, and that no live fish of susceptible species have been introduced during the 14 days prior to shipment. This requirement may be included in Point 2, together with the disinfection of eggs.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any Gyrodactylosis related conditions, regardless of the Gyrodactylosis status of the *exporting country, zone or compartment*:
 - a) From the species in Article 2.1.14.2., for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following *commodities* destined for human consumption from the species listed in Article 2.1.14.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.14.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.14.2., other than those listed in point 1) of Article 2.1.14.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.14.7. to 2.1.14.11. of this Chapter, relevant to the Gyrodactylosis status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.14.2. from an *exporting country, zone or compartment* not declared free of Gyrodactylosis, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *G. salaris*, 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 2.1.14.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

The Community would also argue that option 2 is irrelevant for freedom from *G. salaris*. According to Community experience, *G. salaris* -free country, zone or compartment cannot be declared free without a carefully planned targeted surveillance scheme. In areas where the parasite is fully adapted to its host, no disease or symptoms will occur. In addition, strong seasonal fluctuation has been observed. This view is also acknowledged in Chapter 2.1.14 of the current (2003) Manual.

Gyrodactylosis free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an Gyrodactylosis free country if all the areas covered by the shared water are declared Gyrodactylosis free countries or zones (see Article 2.1.14.5.).

1. A country where none of the species listed in Article 2.1.14.2. is present may declare itself free from Gyrodactylosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.14.2. 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 Gyrodactylosis when *basic biosecurity conditions* have been 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 Gyrodactylosis when:

- a) *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 last 2 years without detection of *G. salaris*.

OR

4. A country that had declared itself free from Gyrodactylosis but in which the disease is detected may not declare itself free from Gyrodactylosis 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of *G. salaris*.

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 2.1.14.5.

Article 2.1.14.5.

Community comment

The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

The Community will also claim that, irrespectively of the comment to Article 2.1.14.3, a zone or a compartment located in sea water would by nature comprise a disease free zone or compartment (see also Article 2.1.14.2, point 5, of the 2005 Code).

The Community proposes to include a new point 5 reading

A zone or compartment supplied with sea water with a salinity of at least 20 parts per thousand and no live aquatic animals of species referred to in Article 2.1.14.2 have been introduced for the previous 14 days from a site of a lesser health status

Finally, the Community would also argue that option 2 is irrelevant for freedom from *G. salaris*. According to Community experience *G. salaris* -free country, zone or compartment cannot be declared free without a carefully planned targetted surveillance scheme. In areas where the parasite is fully adapted to its host, no disease or symptoms will occur. In addition, strong seasonal fluctuation has been observed. This view is also acknowledged in Chapter 2.1.14 of the current (2003) Manual.

Gyrodactylus free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from Gyrodactylus 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.14.2. is present may declare itself free from Gyrodactylus when *basic biosecurity conditions* have been 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 2.1.14.2. 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 Gyrodactylus when *basic biosecurity conditions* have been 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 Gyrodactylus when:

- a) *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 last 2 years without detection of *G. salaris*.

OR

4. A *zone* previously declared free from Gyrodactylus but in which the disease is detected may not be declared free from Gyrodactylus 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of *G. salaris*.

Article 2.1.14.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from Gyrodactylus following the provisions of points 1) or 2) of Articles 2.1.14.4. or 2.1.14.5., respectively, may maintain its status

as Gyrodactylosis free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from Gyrodactylosis following the provisions of point 3) of Articles 2.1.14.4. or 2.1.14.5., respectively, may discontinue *targeted surveillance* and maintain its status as Gyrodactylosis free provided that conditions that are conducive to clinical expression of Gyrodactylosis, 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 Gyrodactylosis, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.14.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.14.2., other than *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* declared free from Gyrodactylosis, 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 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from Gyrodactylosis.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.14.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.14.2., other than those *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*.

Article 2.1.14.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.14.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.14.2., other than any live *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from *G. salaris*, the *Competent Authority* of the *importing country* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.14.3. or other products authorised by the competent authority; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of *G. salaris*.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.14.2., other than any live *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should require:

1. a certificate from the *Competent Authority* of the exporting country stating that the fish have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days.

OR

2. a) the consignment is delivered directly to and held in quarantine facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.14.3. or other products authorised by the competent authority; and
 - b) all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*.

Article 2.1.14.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.14.9 and 2.1.14.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.14.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.14.9 will also apply to Article 2.1.14.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from Gyrodactylosis

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.14.2., other than any live *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should require:

1. a certificate from the *Competent Authority* of the exporting country stating that the fish have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days.

OR

2. a) the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.14.3. or other products authorised by the competent authority; and
 - b) all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*.

Article 2.1.14.10.

Community comment

The recommendation in Article 2.1.14.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.14.9 To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

Importation of products from a country, zone or compartment declared free from Gyrodactylosis

When importing *aquatic animal products* of the species listed in Article 2.1.14.2., other than those *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* free from Gyrodactylosis, 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 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from Gyrodactylosis.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.14.11.

Community comment

The Community would argue that this Article may be irrelevant taking into account the nature of the disease in question.

If the OIE wish to maintain the Article, the Community would like the OIE to forward the justifications for its necessity.

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

When importing *aquatic animal products* of the species listed in Article 2.1.14.2., other than those *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 2.1.14.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*;

OR

- c) the *Competent Authority* of the *importing country* should require a certificate from the *Competent Authority* of the *exporting country* attesting that the product was derived from fish which had been held, immediately prior to processing, in water with a salinity of at least 25 parts per thousand for a continuous period of 14 days.

CHAPTER 2.1.15.

RED SEA BREAM IRIDOVIRAL DISEASE

Community comment

The Community cannot agree with this chapter unless its comments to Article 2.1.15.3 and 2.1.15.11 are taken into account.

Furthermore, the Community asks the OIE to justify why freedom for historical reasons in the mollusc chapters has been set to 10 years, while in the fish chapters there are 25 years. The Community proposes 10 years in all chapters

The Community would also ask the OIE AAC to consider the other comments included under the specific Articles.

Article 2.1.15.1.

For the purposes of this *Aquatic Code*, red sea bream iridoviral disease (RSIVD) means infection with red sea bream iridovirus (RSIV) of the family Iridoviridae.

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

Article 2.1.15.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for RSIVD are: red sea bream (*Pagrus major*), yellowtail (*Seriola quinqueradiata*), amberjack (*Seriola dumerili*), sea bass (*Lateolabrax* sp., *Lates calcarifer*), Albacore (*Thunnus thynnus*), Japanese parrotfish (*Oplegnathus fasciatus*), striped jack (*Caranx delicatissimus*), mandarin fish (*Siniperca chuatsi*), red drum (*Sciaenops ocellatus*), mullet (*Mugil cephalus*) and groupers (*Epinephelus* spp.).

Suspect cases of natural infection with RSIV 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 2.1.15.3.

Community comment

Although not included in the EU research project “Fish Egg Trade”, the Community would ask the OIE to consider if “disinfected eggs” may be imported regardless of the RSIVD status of the exporting country, zone or compartment. In such cases, the consignment should be accompanied with a animal health certificate stating that the eggs has been properly disinfected in accordance with relevant chapter in the OIE Code and/or Manual. This requirement may be included in Point 2.

With regard to point 1 b), the Community ask the OIE AAC to justify its opinion that diseases have spread with eviscerated fish through further processing. To the knowledge of the Community, such spreading has not yet been recorded.

The Community therefore proposes to delete the words “packaged for retail sale” from point 1. b) iii), as by evisceration most of the risk, also associated with further processing is mitigated.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any RSIVD related conditions, regardless of the RSIVD status of the *exporting country*, *zone* or *compartment*:
 - a) From the species in Article 2.1.2.2., for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following *commodities* destined for human consumption from the species listed in Article 2.1.2.2. which have been prepared in such a way as to minimise the likelihood of alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.2.2., all *aquatic animal products*.

For the *commodities* listed in point 1) b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.2.2., other than those listed in point 1) of Article 2.1.2.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.2.7. to 2.1.2.11. of this Chapter, relevant to the RSIVD status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.2.2. from an *exporting country*, *zone* or *compartment* not declared free of RSIVD, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of RSIV, 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 2.1.15.4.

Community comment

Please make reference to “compartments” also in the last line of paragraph 2 of the ingress.

RSIVD free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an RSIVD free country if all the areas covered by the shared water are declared RSIVD free countries or zones (see Article 2.1.15.5.).

1. A country where none of the species listed in Article 2.1.15.2. is present may declare itself free from RSIVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.15.2. 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 RSIVD when *basic biosecurity conditions* have been 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 RSIVD when:
 - a) *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 last 2 years without detection of RSIV.

OR

4. A country that had declared itself free from RSIVD but in which the disease is detected may not declare itself free from RSIVD 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of RSIV.

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 2.1.15.5.

Article 2.1.15.5.

<p>Community comment</p> <p>The Community cannot accept that the OIE have not re-introduced the possibility of, where appropriate, disease freedom can be declared or re-declared without 2 years of targeted surveillance.</p>

Consequently, the Community reiterates its request from January 2005 that the OIE ensures that such possibility is reintroduced in line with the text of (as template) Article 2.1.2.5 of the 2005 Code.

RSIVD free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from RSIVD 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.15.2. is present may declare itself free from RSIVD when *basic biosecurity conditions* have been 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 2.1.15.2. 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 RSIVD when *basic biosecurity conditions* have been 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 RSIVD when:
 - a) *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 last 2 years without detection of RSIV.

OR

4. A *zone* previously declared free from RSIVD but in which the disease is detected may not be declared free from RSIVD 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of RSIV.

Article 2.1.15.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from RSIVD following the provisions of points 1) or 2) of Articles 2.1.15.4. or 2.1.15.5., respectively, may maintain its status as RSIVD free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from RSIVD following the provisions of point 3) of Articles 2.1.15.4. or 2.1.15.5., respectively, may discontinue *targeted surveillance* and maintain its status as RSIVD free provided that conditions that are conducive to clinical expression of RSIVD, 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 RSIVD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.15.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.15.2., other than *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* declared free from RSIVD, 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 2.1.15.4. or 2.1.15.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from RSIVD.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.15.8.

Community comment:

The Community believes there is a need for clarification what the OIE mean by “country, zone or compartment not declared free from”

If the meaning is “country, zone or compartment not declared free, but nor known to be infected” the Community could agree to this Article.

However, if the meaning is that susceptible species can be moved from any area not declared free (i.e. both “unknown” and “infected”) for farming under quarantine conditions in a declared disease free area, the Community would reserve its agreement to this Article.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.15.2., other than those *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of RSIV.

Article 2.1.2.9.

Community comment:

The Community would ask the OIE to replace the word “should” in the fourth line of the ingress with the word “may”, since with the proposed amendments, the OIE moves away from “should assess the risk and apply risk mitigation such as” to “should require quarantine”. This change leaves the Member Countries few options, while the original wording left more judgement to the individual Member Country.

In point 1, it seems inappropriate to use the terminology “quarantine”, taking into account the definition of “quarantine” in Chapter 1.1.1. when the intention is to hold animals in “enclosed environments” awaiting slaughter and processing.

Furthermore, requirement in point 2 is already a part of the definition of “quarantine” in Chapter 1.1.1.

Consequently, the Community proposes that Article 2.1.2.9 read:

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* may require that

1. the consignment is delivered directly to and held in *quarantine* facilities awaiting slaughter and processing to one of the products listed in point 1) of Article 2.1.2.3. or other products authorised by the competent authority; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of RSIV.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should require that:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in point 1) of Article 2.1.2.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of RSIV.

Article 2.1.2.9.bis

Community comment:

For the sake of simplification (and taking into account that the requirements of Articles 2.1.2.9 and 2.1.2.9 bis are identical), the Community would ask the OIE to consider merging these two Articles into one Article. Hence, Article 2.1.2.9 bis is superfluous.

If the OIE retains the Article, the comments forwarded in relation to Article 2.1.2.9 will also apply to Article 2.1.2.9 bis.

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from RSIVD

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of RSIV.

Article 2.1.15.10.

Community comment

The recommendation in Article 2.1.15.10 seems inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when this Article is compared with Article 2.1.15.9. To request animal health certificates for fish products, taking into account their intended use and the nature of the commodities, seems non-justifiable.

Importation of products from a country, zone or compartment declared free from RSIVD

When importing *aquatic animal products* of the species listed in Article 2.1.15.2., other than those *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* free from RSIVD, 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 2.1.15.4. or 2.1.15.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from RSIVD.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.15.11.

Community comment

The Community would like to ask the OIE AAC to justify the need for effluent treatment in case of further processing of fish that has been eviscerated before entering the importing country.

The Community would like to OIE to forward any supporting evidence which justifies such risk mitigation.

The Community proposes otherwise to delete the words “whether eviscerated or” from the 2nd paragraph.

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

When importing *aquatic animal products* of the species listed in Article 2.1.15.2., other than those *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in point 1) of Article 2.1.15.3. or other products authorised by the competent authority; and
 - b) all effluent and waste material are treated in a manner that ensures inactivation of RSIV.
-



**REPORT OF THE MEETINGS OF THE TEAMS COMPRISING
THE OIE AD HOC GROUP ON THE LIST OF AQUATIC ANIMAL DISEASES**

Paris, 20-22 July 2005

The OIE *ad hoc* Group on the list of aquatic animal diseases comprises three teams – finfish diseases, mollusc diseases and crustacean diseases.

The report of the initial discussions of the teams were circulated to Member Countries in the report of the meeting of the Bureau of the Aquatic Animals Commission of October 2004.

This report addresses the 2005 meetings of the finfish and mollusc diseases teams; the crustacean diseases team intends to meet later in 2005 and the report of that meeting will be circulated separately.

The report of the finfish diseases team is at [Appendix A](#) and the report of the mollusc diseases team is at [Appendix B](#).

.../Appendices

SECOND REPORT OF THE FINFISH DISEASES TEAM

The OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases - finfish diseases team met electronically.

The membership of the team is as follows:

Chair	Members	
<p>Prof Barry Hill Centre for Environment, Fisheries and Aquaculture Sciences The Nothe Weymouth DT4 8UB UNITED KINGDOM Tel.: + (44-1305) 20.66.26 Fax: + (44-1305) 20.66.27 E-mail: b.j.hill@cefasc.co.uk</p>	<p>Prof Ronald P. Hedrick Department of Medicine and Epidemiology 2108 Tupper Hall University of California One Shields Ave Davis, CA 95616 USA Tel.: + 530-752-3411 Fax: + 530-752-0414 E-mail: rphedrick@ucdavis.edu</p> <p>Dr Motohiko Sano Research Promotion & Development Department, Fisheries Research Agency, Yokohama 220-6115, JAPAN Tel. + 81-45-227-2677 Fax. + 81-45-227-2703 E-mail: sanogen@fra.affrc.go.jp</p>	<p>Dr Jim Winton Chief, Fish Health Section Western Fisheries Research Center 6505 NE 65th Street Seattle, WA 98115-5016 USA Phone: +1-206-526-6587 FAX: +1-206-526-6654 e-mail: jim_winton@usgs.gov</p>

Re-assessment of IPN, BKD and KHV disease for OIE listing

1. INTRODUCTION

During 2004, the finfish diseases team of the OIE *ad hoc* Group evaluated each of the 16 fish diseases listed in the 7th edition (2004) of the OIE *Aquatic Code* with respect to how far they meet, or do not meet, each of the criteria for listing an aquatic animal disease as published in Article 1.1.2.1 of the *Aquatic Code*. Account was taken of information in the International Database on Aquatic Animal Diseases, in the OIE *Aquatic Manual* and in the published scientific literature. Account was also taken of the views of the Aquatic Animals Commission in their assessment presented in Appendix IX of the report of the Commission's meeting in June 2003 on which some OIE Member Countries provided comments. The finfish diseases team report to the Aquatic Animal Commission was appended to the report of the October 2005 meeting of the Bureau of the Commission. The Bureau decided that, based on the report of finfish diseases team of the *ad hoc* Group, 8 fish diseases would be proposed for deletion from the current list. The revised list of fish diseases proposed by the Bureau was appended to the Bureau meeting report and comments from OIE Member Countries were requested.

At its meeting in January 2005, the Commission considered Member Countries' comments on its suggested changes to the list of fish diseases. The Commission accepted some of the comments and decided to retain infectious pancreatic necrosis (IPN) and bacterial kidney disease (BKD) on the list subject to being placed 'under study' for re-assessment. In response to a submission from the European Commission on behalf of the EU Member States providing an assessment of koi herpes virus disease (KHVD) against the listing criteria, the Commission also placed this disease on the list as being 'under study' until a final decision to propose its full addition or not. The amended list of fish diseases was adopted by the International Committee at the OIE General Session in May 2005.

The finfish diseases team was asked to re-assess BKD, IPN and KHVD (currently listed in the 2005 edition of the *Aquatic Animal Health Code* as 'under study') against the aquatic animal disease listing criteria, to recommend whether they should be added to or deleted from the list and to provide documented scientific justification for any recommendations in a report on these findings to the OIE Aquatic Animals Commission by 1 August 2005. To obtain more technical information to assist in their re-assessment of KHVD, the finfish diseases team was enlarged to include an expert from Japan where there have been significant epidemiological developments in wild carp populations since the first outbreak of the disease in that country.

2. APPROACH

In the timescale allowed for the exercise, it did not prove possible for the finfish diseases team members to meet together face to face to discuss the issues in detail, so the work was conducted by email communication only, which limited detailed discussion on some of the finely balanced points, and the information and opinion provided by OIE Member Countries.

In conducting the re-assessments, the finfish diseases team took note of the following comment in the report of the January 2005 meeting of the Commission:

"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."

Appendix XXII (contd)

Appendix A (contd)

The *ad hoc* group was also provided with a set of guidelines from the Aquatic Animals Commission for conducting assessment of the diseases against the listing criteria.

Bearing the above Commission comment and the Commission guidelines in mind, the finfish diseases team considered all the comments from OIE Member Countries and the EU detailed assessments on BKD, IPN and KHVD, in reviewing its original assessments. This second report presents the team's further conclusions and recommendations for these three diseases.

3. DISEASE RE-ASSESSMENTS

a) Bacterial kidney disease (BKD)

In response to the report of the January meeting of the Commission, the EU reiterated its comment on the report of the October 2003 meeting of the Bureau 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 (Appendix I). The Commission referred the EU assessment to the OIE Reference Laboratory for BKD for comment.

Subsequent comments submitted by the Designated Expert at the OIE Reference Laboratory for BKD were as follows:

Regarding arguments by the OIE *ad hoc* group's finfish diseases team for de-listing BKD and the EU *ad hoc* group's case for its retention, there are many points of agreement (criteria 3, 4, 5, 6 and 8). I will not comment on these further except to state that I believe the conclusions are correct. For the areas of disagreement (criteria 1, 2, and 7), I can offer some comments based largely upon personal opinion formed by a combination of scientific evidence, experience, and the opinions of others. Both groups have done a good job of citing relevant literature; however, perceptions about the importance of BKD will ultimately be somewhat unique to each observer based upon the situation in each member country.

For criterion 1, I believe there is little disagreement that BKD can be a very significant disease of cultured salmonids, resulting in substantial mortality in both fresh water and in the marine environment. The initial portion of the explanatory text for criterion 1 states that "There is a general pattern that the disease will lead to losses in susceptible species...." This is typically true, especially for the most susceptible of the salmonid species. What is less certain is the second part of the sentence "...and that morbidity or mortality are related primarily to the agent and not management or environmental factors". While viruses generally fulfill this part of the explanation, there is a substantial body of experience that management actions and environmental factors can greatly alter the severity of BKD or even the likelihood of infection by *R. salmoninarum*. Nevertheless, some management options, including reduction in density or modification of environmental factors, are not practical for commercial use. Examination and culling of positive broodstock to reduce the effects of vertical transmission, approval of new antimicrobials, and progress on vaccines to prevent the disease offer opportunities to reduce, but probably not eliminate, the impact of BKD on salmonids in culture environments.

For criterion 2, there are fewer examples to cite that apply to entirely wild, free-ranging stocks, partly because these are difficult to study; however, there is evidence that BKD continues to affect Pacific salmon after their release from hatcheries operated by various federal, state, provincial and tribal agencies on the Pacific coast of the US and Canada. Some of these populations represent threatened or endangered stocks for which extensive recovery efforts are being mounted, while others support significant commercial and recreational fisheries. The magnitude of these losses and the potential effects of anthropogenic and environmental stressors on the disease process in these wild stocks are not well understood. What is clear is that *R. salmoninarum* is endemic among most, if not all, of the wild stocks of salmonids in this area, including populations that have never experienced hatchery influence.

For criterion 7, there is good evidence that *R. salmoninarum* has always been, or at least has become, endemic among most, if not all, salmonid stocks throughout their traditional range when a sufficient number of animals, collected at an appropriate life stage, are examined using the most highly sensitive methods available. Many of these stocks, especially wild or free-ranging populations of the less-sensitive species, show exceptionally low levels of infection and it has been difficult to determine the environmental or physiological factors that affect the maintenance of *R. salmoninarum* in these stocks. In the explanatory notes for criterion 7, the second sentence "Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible..." probably applies here. The remainder of this sentence restates the option available for diseases formerly listed as Other Significant Diseases in earlier versions of the OIE Code in that "...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". In my view, scientific support should not be difficult if the most sensitive assays are applied to an appropriate set of samples in accordance with procedures in the OIE Manual and I would encourage individual member countries to conduct such surveys and institute appropriate control programs for any disease of concern that is not listed by OIE.

In summary, and in the absence of definitive data regarding certain points, I tend to agree with the conclusions of the EU *ad hoc* group regarding criteria 1 and 2, but remain to be persuaded that any significant portion of the range in which salmonids are resident is entirely free of *R. salmoninarum*, although fish in these areas may be free of the disease it causes or harbor levels of *R. salmoninarum* that are undetectable by less-sensitive methods that are still being used in many laboratories. The nearly universal distribution of *R. salmoninarum* means that the continued listing of BKD will have a significant impact on international trade in salmonids and salmonid eggs and will present a significant reporting burden for member countries with little demonstrable benefit. Intensive surveys by member countries in support of a declaration of freedom from BKD would be welcome, and I remain open to revision of my opinion should such data suggest that significant geographic areas containing susceptible species of fish are free of *R. salmoninarum* as these would merit the attention of the fish health community and protection beyond that available to individual countries.

The finfish diseases team unanimously agreed with the comments of the Designated Expert for BKD and concluded that there is still not sufficient firm scientific evidence available for it to conclude that criterion 7 is fully met for BKD. Therefore the team's original judgement remains unchanged i.e. this disease fails to meet the necessary overall combination of criteria for listing, bearing in mind the guidance given by the Commission on the main purpose of listing a disease (see Section 2 above).

Conclusion: *BKD does not meet all the necessary criteria for listing by OIE.*

Recommendation: *the Aquatic Animals Commission should propose that BKD is removed from the OIE list of fish diseases*

b) Infection pancreatic necrosis (IPN)

The EU re-iterated 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 (Appendix II). The Commission referred the EU assessment to the OIE Reference Laboratory for IPN for comment.

The IPN Reference Laboratory did not disagree with most of the comments in the EU assessment but pointed out that criteria 1 and 2 apply almost exclusively to Atlantic salmon (*Salmo salar*) and not to the many other fish species that are susceptible to IPN virus in many other countries. It made the comment that the EU statements about wild populations of Baltic salmon and some countries or regions of the world being apparently free of IPN are not supported by references to evidence published in the scientific literature or by official self-declaration of freedom to OIE by the countries concerned.

Appendix XXII (contd)Appendix A (contd)

The finfish diseases team's view is that, whilst the EU comments may well be an accurate reflection of the situation concerning apparent freedom of some countries, it is a fact that IPN has a global distribution and occurs in the majority of salmonid farming countries. Significant economic impact of IPN is limited to Atlantic salmon farming countries, the main ones of which are already chronically affected by the disease. Retaining the disease on the OIE list would not help to improve that situation. The arguments put forward for protecting some wild Baltic salmon stocks are not sufficient justification for requiring regular global reporting on the occurrence of IPN in all countries. The OIE Aquatic Animals Commission has made it clear that the principle purpose of listing a disease is for reporting occurrence, meaning that all affected countries would need to report regularly to OIE on the incidence and prevalence of IPN in their territories. This large amount of reporting would not be justified by just a very small number of countries, zones or farms appearing to be free of IPN virus. National measures to protect species worth protecting for conservation reasons are not affected by the disease not being listed by OIE. Therefore the team's original judgement remains unchanged i.e. this disease fails to meet the necessary overall combination of criteria for listing, bearing in mind the guidance given by the Aquatic Animals Commission on the main purpose of listing a disease (see Section 2 above).

Conclusion: *IPN does not meet all the necessary criteria for listing by OIE.*

Recommendation: *the Aquatic Animals Commission should propose that IPN is removed from the OIE list of fish diseases*

c) Koi herpes virus disease (KHVD)

In response to the report of the October 2003 meeting of the Commission, the EU, supported by Norway, invited the Commission to evaluate the EU ad hoc group assessment for listing KHVD. The finfish diseases team agreed with the EU assessment that several of the criteria for listing a disease by the OIE are met for KHVD but concluded that further clarification on some aspects of the assessment was needed (the detailed response submitted by the finfish diseases team to the January meeting of Aquatic Animals Commission is attached as Appendix III). The Commission sought Member Countries' comments on the EU assessment as well as the detailed response of the finfish diseases team of the *ad hoc* Group.

The EU did not provide any scientific/technical comments on the finfish diseases team's response to their initial assessment of KHVD for listing. Some specific technical/scientific comments on the EU and finfish diseases team's KHVD assessments were received from Australia, Thailand, Japan and United States of America (USA).

Australia suggested that a revised assessment, addressing all comments received, be produced for Member Country consideration. Thailand commented that since the pathology and causative agent of KHVD are still unclear, the disease should be further studied before being listed. Japan strongly supported the listing of the disease on the basis of the EU assessment and the experiences with the disease in that country. However, the USA considered that KHVD does not meet the criteria to be an OIE listed disease because of issues such as the robustness of available diagnostic tests, the inability to detect a carrier state and the widespread distribution of the pathogen.

In its further deliberations, the finfish diseases team paid particular attention to criterion 2 concerning the potential of a disease to impact "wild populations". Since the first report that cited the example of a serious outbreak in wild common carp in Japan, there has been an outbreak among wild common carp in the USA in Lake Chautauqua, New York with similar widespread and significant mortality attributed to the virus. Although the studies in Japan and the USA have not been completed, they do demonstrate clearly that KHVD can have a serious impact on wild populations.

The finfish diseases team agreed with the comments from Japan and the EU, and concurred that the case for listing KHVD is compelling. However, one member of the team (Prof Hedrick) considered it would be helpful to have further informed discussions to address some of the issues so that there is a better understanding of the potential implications and consequences of listing, and felt that a forum for discussion/debate amongst KHVD experts still appears to be needed for KHVD prior to a decision on recommendation for listing. He suggested that the subjects to be covered by this forum should include as a minimum:

- 1) a case definition for the disease,
- 2) a better understanding of the current and potentially broad distribution of the associated agent,
- 3) review of past and more currently developed serological tests as sufficient indicators of potential virus carriers (Ronen et al.. 2003. Efficient vaccine against the virus causing a lethal disease in cultured *Cyprinus carpio*. Vaccine 21:4677-4684 and Adkison M.A., Gilad O., Hedrick R.P. 2005. An enzyme linked immunosorbent assay (ELISA) for detection of antibodies to the koi herpesvirus (KHV) in the serum of koi, *Cyprinus carpio*. Fish Pathology 40(2):53-62)
- 4) dependence on PCR as the primary method of confirmation for presence of the associated agent
- 5) resolution of the apparently conflicting laboratory data emerging for the role of cyprinids other than *Cyprinus carpio* (koi or common carp) in the virus life cycle including virus transmission
- 6) capability of member countries to meet the logistical challenges associated with the surveillance programs to demonstrate freedom from KHVD.

The team agreed that this would be a helpful way of resolving the uncertainties and differences of opinion, and hopes that such a forum will be held in the near future so that the outcome can be taken into account for a final conclusion and recommendation on KHVD listing to be included in the Ad hoc group's report to the Commission in February 2006.

Recommendation: KHVD should be kept under study until the outcome of the proposed forum can be taken into account in preparing the final report and recommendations of the finfish diseases team.

Appendix I

Assessment of Bacterial Kidney Disease (*Renibacterium salmoninarum*) by the EU ad hoc group (including the OIE ad hoc group evaluation)

- + criterion applies
- (+) criterion applies but to limited circumstances
- criterion does not apply
- (-) criterion does not apply sufficiently
- ? insufficient information available
- NA not applicable.

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

OIE ad hoc group: The association of *Renibacterium salmoninarum* with disease in farmed and wild salmonid fish is well established (Evelyn, 1993). The presence of the bacterium, in the absence of disease is also commonly encountered (Fryer and Lannan, 1993). Salmon with advanced cases of the bacterial kidney disease (BKD) can suffer significant mortality both in freshwater or during transition to seawater or during seawater residence (Banner et al., 1986).

Conclusion by the OIE ad hoc group: - (criterion does not apply)

EU ad hoc group: The EU ad hoc group challenges the opinion of the OIE ad hoc group that BKD fails to comply with criterion 1. EU ad hoc group agrees with the OIE ad hoc group text concerning criterion 1 but disagrees with the conclusion drawn up by the OIE ad hoc group. According to the OIE ad hoc group, "the impact of the disease on cultured populations of salmonids is clear" (see OIE-text in criteria 2). Several authors have published work underlining the effect of BKD on farmed populations (see e.g. OIE Aquatic Manual, 2003, fourth edition). Losses as high as 80 % in stocks of Pacific salmon and 40 % in stocks of Atlantic salmon have been reported (Evenden et al. 1993). Moreover, it is estimated e.g. that, in British Columbia coastal waters, 20-60 % of farmed salmon may succumb to BKD prior to commercial harvest (Albright et al, 1988).

BKD can cause significant production losses in Atlantic salmon also in Europe. Losses may occur in freshwater and in broodstock units but the biggest losses seem to occur in marine cages late in the production cycle. The latter observation is particularly significant as these are large fish with heavy investment in labour and feed costs. There is evidence that a light infection is significant as salmon entering saltwater continue to develop BKD with later mortality (Bullock and Herman, 1980). The following examples illustrate the scale of this potential loss:

- In Scotland BKD occurs rarely, due to the strict control programme, but again losses are generally associated with the later stages of production in fish from 1-2 Kg in weight. Industry are currently reporting stock losses to be roughly 2% per month on infected sites with sub-optimal marketing due to early harvest at affected sites. Exceptionally losses of up to 40% have been recorded.
- Previous Scottish experience (Bruno, 1986) has shown that losses in Atlantic salmon pre-smolts from BKD have also been severe with one case documented with 20% losses over a 6 month period. At transfer to seawater 69% of the fish where found to be infected with the causative agent of BKD and 56% showed evidence of gross pathology resulting in a further 15% loss in the stock (Bruno, 1986).
- Faeroe Islands losses up to 15-20% of production on individual farms have been reported, with up to 60-70% of farms affected. In addition to direct losses from mortality reduced growth and susceptibility to other diseases is also reported

Appendix XXII (contd)Appendix A (contd)**Appendix I**

It is also apparent that losses can occur in rainbow trout culture especially in marine cage rearing sites:

- In the UK there are historical reports of losses in cage sites up to 10% of production in the late 1980's. The mortalities were in all sizes of fish up to market size. Bruno (1986) reported that losses at four trout farms were 15-20% per annum and in extreme cases mortalities reached 5% per day over short periods.
- According to experiences in Finland in 2001 (Finnish National Veterinary and Food Research Institute, unpublished data), BKD was diagnosed in 0-1 year old rainbow trout soon after their transfer from fresh water farm to seawater farms. The source of infection was the infected brood fish farm. The diseased fish had also severe peritonitis partly due to vaccination. It seemed that the stress caused by vaccination and transport to sea triggered the diseases and also the secondary effects of ip. vaccination. Acute mortality was estimated to reach 10 %. However, mortality continued over a long period time and losses due to reduced growth in infected fish was also observed.
- In Poland BKD has shown to cause considerable mortality at fresh water farms; up to 60% in 1989-1992 and 30 % at two farms in 2000.

When occurring, BKD is difficult to control as the use of antibacterials is not sufficiently effective although prolonged treatment may stop the progression of the disease to some extent. There are some promising results on the effect of live vaccines. However, it is not known now whether vaccination will be a relevant control system of BKD in future.

Thus, prevention is the only valid method of control which means that health control, surveillance and certification as well as movement restrictions on live fish, eggs and gametes have to be in force (for imports as well as in trade). If BKD cannot be controlled by preventive measures, it may give large socio-economic impacts on the aquaculture industry.

Conclusion by the EU *ad hoc* group: + (criterion applies)

2. Affects wild fish populations

OIE ad hoc group: *The impact of the disease on cultured populations of salmonids is clear but the potential effects on wild salmonids is much less clear. The presence of the bacterium in populations with no contact with hatchery-reared salmonids, indicates a potential concern for the health of wild populations of fish (Souter et al., 1987) but studies to demonstrate such population impacts are not available. All salmonids, recently to include whitefish, are known hosts for the bacterium which may be present throughout the natural geographic distribution of wild and cultured salmonid fishes.*

Conclusion by the OIE *ad hoc* group: - (criterion does not apply)

EU *ad hoc* group: The EU *ad hoc* group challenges the opinion of the OIE *ad hoc* group that BKD fails to comply with criterion 2, as several authors have published work underlining the effect of BKD in wild populations (see e.g. OIE Aquatic Manual, 2003, fourth edition). In addition, the EU *ad hoc* group wish to point out that information on the effects of pathogens on the wild fish populations are usually missing before they actually happen. We refer to the situation concerning *Gyrodactylus salaris* and Atlantic salmon in Norway in the 1970's. EU *ad hoc* group is not suggesting as dramatic effects in the BKD free zones, but calls attention to our lack of knowledge on these kinds of effects due to limited scientific interests and the long-lasting and difficult nature of the research.

Appendix XXII (contd)Appendix A (contd)**Appendix I**

Several references provide clear evidence of affect of BKD on wild salmonid stocks. BKD has been shown to affect the physiological adjustment needed when salmonids migrate from fresh water to salt water. There are many experimental studies demonstrating losses in BKD infected chinook salmon experimentally transferred from freshwater to seawater (Elliott *et al.*, 1997) and also implicating BKD as a major cause of mortality in wild chinook and coho smolts on entry into seawater (Ellis *et al.*, 1978; Fryer and Sanders, 1981; Banner *et al.*, 1983; Banner and Rohovec, 1985; Fryer and Lannan, 1993; Elliot *et al.* 1995; Holey *et al.*, 1998; Mesa *et al.* 1999; Moles 1997; Williams *et. al* 2001). For example, Fryer and Sanders (1981) reported that losses in sea water coho smolts was considerably higher than a fresh water group with the majority of deaths occurring between 2-4 months after sea water transfer. BKD was first reported in Atlantic salmon from the River Dee in Scotland. Epizootics of BKD from Scottish rivers between 1930 and 1960 were associated with significant mortality and high prevalence of BKD infected fish in returning broodstock (Smith, 1964). Moreover, there is a report suggesting that chronic BKD could be in association with the mortality of wild freshwater fish (Arctic char and brown trout) in waters in which there has never been fish farming or stocking activity (Jónsdóttir *et al.* 1998).

Another consideration in assessing BKD against criteria 2 is whether wild salmonid stocks are “*an asset worth protecting for economic or ecological reasons*”. Within the European Community Council Directive 92/43/EEC on the conservation of natural habitats and wild fauna specifies the species and habitats worth protecting in the Community. The Directive specifies that e.g. *Coregonus oxyrhynchus* in North Sea area and *Salmo salar* in fresh water area require special protection. Furthermore, the Directive lay down that e.g. *Salmo salar* stocks in fresh water, *Thymallus thymallus* and *Coregonus* spp. stocks may need management measures. It is notable that all these species are susceptible to BKD (Smith, 1964; Kettler *et al.*, 1986; Kettler, 1987; Nagai, 2002; Rimaila-Pärnänen, 2002).

Wild salmonid populations, especially the Atlantic salmon and the sea trout, are in severe decline in many sea areas and this has principally been associated with a reduced marine survival. For example, in the Baltic Sea statistically 90 percent of all salmon (*Salmo salar*) recruitment consists of compensatory reared salmon and only 50 percent of the catch belong to this category, indicating lower post smolt survival of stocked salmon. Considering the effects of BKD on post smolt survival as described above, it is likely that an accelerated decrease in post-smolt survival will be the result if zones with broodstock farms, hatcheries and smolt farms conducting restocking programmes cannot be protected from BKD any longer. The existing broodfish farms, hatcheries and smolt farms e.g. in Sweden and Finland are based on river water and are thus influenced by the fish health status of the water catchment area. Because of prohibitive costs the water supply cannot be protected. Thus, freedom of brood fish stocks, hatcheries and smolt farms from BKD has to be considered as a prerequisite for successful restocking programmes.

Conclusion by the EU *ad hoc* group: + (criterion applies)

3. Public health concern

OIE *ad hoc* group: *There is no evidence to suggest that the bacterium possesses any capabilities to infect homiotherms. In fact, the bacterium may be quite host specific for members of the family Salmonidae.*

Conclusion by the OIE *ad hoc* group: - (criterion does not apply)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: - (criterion does not apply)

Appendix XXII (contd)Appendix A (contd)**Appendix I****4. Infectious aetiology proven**

OIE ad hoc group: *Renibacterium salmoninarum* is the proven aetiological agent of BKD and a firm association between the bacterium and disease outbreaks is established (Evelyn, 1993). What remains difficult to assess are all factors that contribute to disease as detection of the bacterium by sensitive diagnostic methods indicates a rather broad distribution of the agent in salmonid populations. A majority of these detections occur in the absence of disease.

Conclusion by the OIE ad hoc group: + (criterion applies)

EU ad hoc group: EU agrees with the OIE conclusion.

Conclusion by the EU ad hoc group: + (criterion applies)

5. Infectious agent associated but aetiology not proven

OIE ad hoc group: Not applicable.

EU ad hoc group: Not applicable.

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

OIE ad hoc group: The bacterium is capable of spreading via both horizontal and vertical modes with perhaps the greatest concern being transport over large distances with salmonid eggs originating from moderate to heavily infected female salmon (Evelyn, 1993; Fryer and Sanders, 1981). That the bacterium can be present within the egg and therefore not subject to surface disinfection was established by Evelyn (reviewed in Evelyn, 1993). Transport of live fish also represent a mode by which the agent may be spread over shorter distances.

Conclusion by the OIE ad hoc group: + (criterion applies)

EU ad hoc group: EU agrees with the OIE conclusion.

Conclusion by the EU ad hoc group: + (criterion applies)

7. Several countries/zones may be declared free

OIE ad hoc group: No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the OIE Aquatic Manual.

Conclusion by the OIE ad hoc group: (-) (criterion does not apply sufficiently)

EU ad hoc group: EU ad hoc group agree that BKD is widespread. However, there are few countries and also many zones in European countries that are free or *may be declared free*. These countries are valuable source of uninfected material which could be used as a Community-wide resource. This resource should remain fully protected in the future. According to the Commission Decision 2004/453/EY the whole territory of Ireland and in the United Kingdom the territories of Northern Ireland, the Isle of Man and Jersey are free of BKD. In addition, in other parts of Great Britain and continental parts of Finland and Sweden BKD have a limited occurrence and the eradication programmes have been approved by the Commission Decision 2004/453/EY. Norway is preparing an application for additional guarantees for BKD according to article 13 of Council Directive 91/67/EC on the grounds that the whole continental parts of the country are considered free from the disease. Also Island has conducted BKD-eradication programme since 1985 and is planning to apply for BKD-freedom in future. Thus, several countries/zones may be declared BKD-free and there are experiences of successful eradication programmes in many countries.

Conclusion by the EU ad hoc group: + (criterion applies)

Appendix I

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

OIE ad hoc groups: Suitable screening methods as well as standardized procedures exist. A series of robust tests including antigen and DNA-based systems are available for detection of the agent or its respective antigens or nucleic acids. These tests are widely available and in some cases fully commercialized.

Conclusion by the OIE ad hoc groups: + (criterion applies)

EU ad hoc group: EU agrees with the OIE conclusion.

Conclusion by the EU ad hoc group: + (criterion applies)

Table: Summary compiled by the EU ad hoc group of the evaluation of BKD related to the listing criteria

A 1	A 2	A 3	B 4	B 5	B 6	B 7	C 8	Retain on OIE list?
+	+	-	+	NA	+	+	+	Yes

Overall conclusion: BKD fulfils the OIE criteria for listing an aquatic animal disease (A1 + A2, B4+B6+B7 and C8). Thus, BKD should remain on the OIE list.

Listing was supported by the following States in the meeting in Brussels on 13th December 2004: United Kingdom, Sweden, Finland, Hungary, Luxembourg, Austria, France, Spain, Greece, The Netherlands, Germany, Denmark, Czech Republic and Norway. Additional support was received from Ireland, Poland and Island. Many experts from these countries have provided their experience and expertise particularly in relation to criteria 1, 2 and 7. None of the EU Member States have informed the *ad hoc* group to be against the listing, although some critical comments were received from German expert.

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Appendix XXII (contd)

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Appendix I

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**Evaluation of Infectious pancreatic necrosis (IPN) by the EU ad hoc group
(including the OIE ad hoc group evaluation)**

- + criterion applies
- (+) criterion applies but to limited circumstances
 - criterion does not apply
- (-) criterion does not apply sufficiently
- ? insufficient information available
- NA not applicable.

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

OIE ad hoc group: Infectious pancreatic necrosis (IPN) is a highly contagious viral disease principally of young fish of salmonid species held under intensive hatchery conditions (Wolf et al., 1960; Hill, 1982; Wolf, 1988). The disease most characteristically occurs in young fry of trout, char and salmon species. Although high mortalities can occur in first-feeding fry, susceptibility generally decreases with age, with resistance to clinical disease usually being reached at about 3 months post-hatch. The economic impact of such outbreaks in such young fish is not high and, where it is endemic, the salmonid farming industry has largely learned to live with the disease, often simply discarding affected fry batches. Control methods include the implementation of hygiene practices in salmonid husbandry, through the avoidance of the introduction of fertilised eggs originating from IPNV-carrier brood stock, and the use of a protected water supply (e.g., spring or borehole) where the ingress of fish, particularly possible virus carriers, is prevented. In outbreaks, a reduction in the population density ('thinning out') can reduce the overall mortality. However, it also causes significant losses in Atlantic salmon smolts after transfer from fresh water to seawater (Smail et al., 1989) but whether this is due to expression of infection acquired in freshwater or from a marine fish reservoir in the vicinity of the salmon cages is not clear.

Commercial vaccines are now available to ameliorate the losses in Atlantic salmon marine farms but there are mixed reports about their efficiency.

Conclusion by the OIE ad hoc group: (+) (criterion applies but to limited circumstances)

EU ad hoc group: IPN is considered the most serious viral disease in salmon production (Ariel et al., 2002). It affects, as described by the OIE ad hoc group, mainly salmonid fry and atlantic salmon (*Salmo salar*) smolt shortly after transfer from freshwater to seawater. IPN is also associated with loss of appetite and therefore production (Damsgård, 1998). Losses in fry because of IPN vary from less than 10 % to more than 90 % (OIE Aquatic Manual, 2003, fourth edition). IPN infected salmon smolts are estimated to have a mortality rate five times higher than non-infected smolts (Jarp, 1999). In spite of control and management measures the economic impact of IPN is serious. Data from Shetland for 2001 showed an average loss of 20–30 % (losses as high as 80 % were observed) in affected farms and an overall loss of 10% of the total smolt input to seawater sites (Report of the Aquaculture Health Joint Working Group on Infectious Pancreatic Necrosis in Scotland, 2003). Norway reports an average mortality during IPN outbreaks of 10% - 20% post smolts, with mortalities reaching more than 90% in some cases (Brun, 2003). IPN cause significant losses due to morbidity, mortality and product quality in the Norwegian fish farming industry. The disease is today recognized to be one of the largest fish health problems in Norwegian aquaculture (Martin Binde, personal communication). Pathogeneticity of the virus seems to increase over the years. No treatment or entirely effective vaccine is available at present (OIE Aquatic, 2003, fourth edition)

Appendix XXII (contd)Appendix A (contd)**Appendix II**

Conclusion by the EU *ad hoc* group: + (criterion applies)

2. Affects wild fish populations

OIE *ad hoc* group: *Although there have been many isolations of IPN virus from a wide range of wild fish species, there is no published scientific evidence that demonstrates such infections have any adverse effect at the population level, or even on the individual host.*

Conclusion by the OIE *ad hoc* group: - (criterion does not apply)

EU *ad hoc* group: The EU *ad hoc* group challenges the OIE *ad hoc* groups opinion that IPN fails to comply with criterion 2.

Within the European Community Council Directive 92/43/EEC on the conservation of natural habitats and wild fauna specifies the species and habitats worth protecting in the Community. The Directive specifies that e.g. *Salmo salar* in fresh water area require special protection. Furthermore, the Directive lays down that e.g. *Salmo salar* stocks in fresh water may need management measures.

While statistically 90 percent of all salmon (*Salmo salar*) recruitment in the Baltic Sea consists of compensatory reared salmon only 50 percent of the catches belong to this category, indicating lower post smolt survival of compensatory reared salmon. Considering the effects of IPN on post smolt survival as described under criterion 1, it is likely that an accelerated decrease in post-smolt survival will be the result if zones with hatcheries and smolt-farms conducting restocking programmes cannot be protected from IPN any longer. Existing broodfish farms, hatcheries and smolt farms in Sweden and Finland are based on river water and are thus influenced by the fish health status of the water catchment area. Because of prohibitive costs the water supplies cannot be protected. Mortalities of the magnitudes described under criterion 1 for Scotland and Norway could not be compensated for and therefore endanger the programmes. Thus, freedom of brood fish stocks, hatcheries and smolt farms from IPN has to be considered as a prerequisite for successful restocking programmes.

Salmon fishery in the Baltic Sea is heavily dependent on stocked salmon (*Salmo salar*).

As already mentioned about 50 percent of all salmon catch origin from restocking. The value of the commercial catches on stocked salmon in the Baltic (all Baltic Sea countries involved) can be estimated to 3,3 – 3,8 million EURO (1200 tonnes). Non-commercial catch (non-licensed fishermen and recreational fisheries) on salmon and trout can be estimated to 11-16 million EURO only in Sweden (those figures include all returns including profits in tourist industry, fishing supply etc.).

Conclusion by the EU *ad hoc* group: + (criterion applies)

3. Public health concern

OIE *ad hoc* group: *None*

Conclusion by the OIE *ad hoc* group: - (criterion does not apply)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: - (criterion does not apply)

4. Infectious aetiology proven

No doubts about the aetiology being an infectious birnavirus.

Appendix II

Conclusion by the OIE ad hoc group: + (criterion applies)

EU ad hoc group: EU agrees with the OIE conclusion.

Conclusion by the EU ad hoc group: + (criterion applies)

5. Infectious agent associated but aetiology not proven

OIE ad hoc group: Not applicable.

EU ad hoc group: Not applicable.

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

OIE ad hoc group: *The biggest risk of international spread of IPN is via live fish. However, the international trade is traditionally mostly in eyed-eggs that have been subjected to a disinfection procedure. It is widely accepted that vertical transmission of IPN is a typical characteristic of the disease in trout. The published evidence for vertical transmission of IPNV via the fertilised egg of trout species is quite comprehensive and, in the main, conclusive, but the evidence for salmon species is much less convincing.*

For Atlantic salmon in Europe, there is a potential international trade in live salmon smolts to on-growing marine cage farms, delivery being by wellboat or, more rarely, by helicopter. This would introduce the potential for transfer of the virus in carrier fish but, as stated above, it is not certain that such fish are the cause of outbreaks of IPN in salmon farms rather than the source being infected local wild marine fish.

Conclusion by the OIE ad hoc group: (+) (criterion applies but to limited circumstances)

EU ad hoc group: The EU ad hoc group agrees with the OIE ad hoc group that horizontal transmission of IPN poses the biggest risk. However vertical transmission has been reported for brook trout (Bootland *et al.*, 1991; Bullock, *et al.*, 1976) and rainbow trout (Dorson *et al.*, 1985), as well as for Arctic char (Ahne *et al.*, 1985). Vertical transmission intra-ovum is demonstrated for brook trout and rainbow trout (Dorson *et al.*, 1997). While vertical transmission has not been conclusively demonstrated in salmon, it is thought likely to occur. As international trade is traditionally mostly in eyed-eggs and disinfection procedures do not affect intra-ovum transmission, the EU ad hoc group challenges the view that criteria 6 only applies to limited circumstances.

Furthermore, while the OIE ad hoc group questions, whether infected salmon smolt rather than infected local wild marine fish is the source of outbreaks of IPN in salmon farms, the EU ad hoc group feels that infected smolt is the most likely source of infection (see criterion 1). We are not aware of any reports of feral fish transmitting IPN to farmed stocks rather than vice versa.

A study on the distribution and prevalence of IPN virus in wild fish, principally mature brown trout, in Loch Awe/Scotland after an IPN outbreak in a rainbow trout farm showed that IPN virus was not self-sustaining as a natural infection in the wild fishery in the absence of the source of virus, e.g. farmed fish (Munro *et al.*, 1976).

Conclusion by the EU ad hoc group: + (criterion applies)

Appendix XXII (contd)Appendix A (contd)**Appendix II****7. Several countries/zones may be declared free**

OIE ad hoc group: The disease already has a wide geographical distribution, occurring in most major freshwater salmonid-farming countries of North and South America, Europe and Asia. However, there have been no reports of the clinical disease from countries in Oceania and it is possible that these countries could provide the evidence to justify being declared free either on historical grounds or through targeted surveillance as described in the OIE Aquatic Manual.

It is widespread and well-established in the marine Atlantic salmon industries of the major producer countries – only Tasmania, Australia is still believed to be free.

Conclusion by the OIE ad hoc group: (-) (criterion does not apply sufficiently)

EU ad hoc group: Recently, Sweden, as well as the continental part of Finland and a zone in the United Kingdom (Isle of Man) have been declared free by Commission Decision 2004/453/EC. Oceania is free of the disease (OIE Aquatic Manual 2003, fourth edition), and according to our information even Australia and Iceland may be declared free of the disease.

According to experiences in Sweden and Finland, IPN-infected farms can under certain conditions be cleared from infection – yet thorough sanitation protocols are required. As indicated in the explanatory notes of criterion 7, it is important to protect broodstocks and remaining free zones from a widespread disease. In addition, restocking programs – as applied in countries as Sweden and Finland – aiming at the protection of species worth protecting (*as Salmo salar*) should be encouraged and not endangered.

~~Furthermore, as not all countries/zones with potential for establishing salmon farming have utilized these opportunities, it is possible that those countries/zones could provide evidence to justify being declared free either on historical grounds or through targeted surveillance as described in the OIE Aquatic Manual.~~

Conclusion by the EU ad hoc group: + (criterion applies)

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

OIE ad hoc groups: Diagnostic tests for IPN virus, as described in the OIE Aquatic Manual, are widely available.

Although the tests have not undergone formal standardization and validation, their routine nature and the fact that they have been in use for many years without dubious results make them acceptable.

Conclusion by the OIE ad hoc groups: + (criterion applies)

EU ad hoc group: EU agrees with the OIE conclusion

Conclusion by the EU ad hoc group: + (criterion applies)

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Appendix XXII (contd)

Appendix A (contd)

Appendix III

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

Finfish Team subgroup Members

Chair:

Prof Barry Hill

Centre for Environment, Fisheries
and Aquaculture Sciences
The Nothe
Weymouth DT4 8UB
UNITED KINGDOM
Tel.: + (44-1305) 20.66.26
Fax: + (44-1305) 20.66.27
E-mail: b.j.hill@cefasc.co.uk

Members:

Prof Ronald P. Hedrick

Department of Medicine and
Epidemiology, School of
Veterinary Medicine
University of California
One Shields Ave
Davis, CA 95616
Tel.: + 530-752-3411
Fax: + 530-752-0414
E-mail: rphedrick@ucdavis.edu

Dr M. Yoshimizu

Laboratory of Microbiology
Graduate School of Fisheries
Science
3-1-1 Minato-cho
Hakodate
Hokkaido 041-8611
JAPAN
Tel.: + (81.138) 40 88 10
E-mail:
yosimizu@fish.hokudai.ac.jp

Summary

The Finfish Team 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 if listed, KHVD would represent the first disease that is primarily a disease of ornamental fish. Thus a complex and currently unregulated or poorly regulated network of pathways for potential fish and pathogen movements would have to be addressed. In several member countries it is unclear whether there would be the mechanisms or the willingness to create the needed framework to deal with the required surveillance, zone establishment and issuance of health certificates.

Secondly, although it is certain that farmed (pond or cage cultured) populations of common carp are negatively impacted by KHVD, evidence for negative impacts on wild populations is just now being collected. The most recent events in Japan are suggestive that such impacts can occur. The principal host involved in the large majority of disease outbreaks however is, and will most likely continue to be, koi (fancy, colored, etc. carp).

Lastly, features of the biology of the virus remain unresolved and could severely complicate programs aimed at control and containment of KHVD. 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 Subgroup agrees that certain considerations for listing of KHVD are similar to those of currently listed diseases but others are clearly different and these make it important to carefully deliberate prior to listing of KHVD. The subgroup supports development of a format for such deliberations that consider the criteria for listing in the context of the consequences/impacts and practicality of listing KHVD. We suggest that OIE, being familiar with such exercises, coordinate this effort.

Appendix XXII (contd)Appendix A (contd)**Appendix III****Particular Comments from the Finfish team subgroup on the “Assessment/proposal”**

In the following section, the subgroup comments on particulars in the proposal by the group of international KHV 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 here forth referred to as the “Assessment”).

1. Significant production losses at a national or multinational.....

Production scale losses of koi and or common carp have been reported from Israel, Japan, Germany, Indonesia and also apparently 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. columare* or a range of ectoparasites) are often observed in fish from which KHV is identified. As an example are the events in Indonesia. Despite serious losses among cultured common carp populations in Indonesia 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 programs aimed at this goal should 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. The following information was collected from Dr. Motohiko Sano, Chief, Diagnosis and Training Center, Aquatic Animal Health Division, National Research Institute of Aquaculture, Tamaki, Watarai, Mie Japan on January 13, 2005 and refers to losses among wild common carp in Lake Biwa. “In the Lake Biwa case we found infected carp which had been transferred from Lake Kasumigaura to aquaculture farms located beside the lake in early November 2003. There are no net pens for aquaculture of carp in this lake. These facilities use under ground water which is a little warm (around 16C) even in November and therefore, some mortality occurred in the aquaculture farms in early November. Water draining from the facilities flowed directly into the lake. In late November of 2003, a little mortality was found among the wild carp population in Lake Biwa. By May to June of 2004, a large number of wild carp, over 100,000 individual fish, died with a mortality curve characteristic for KHVD. A rough estimate by the Prefectural Fisheries Experiment Station was 377 tons amounting to about 70% of the total fish stock in the lake. Few small dead fish were found in the lake but instead large fish weighing about 3 -8 kg were the principal size lost. We do not know how many juvenile fish died or not in the lake, and if known, total losses will reach over 80% of the stock in the lake”.

In other locations, the role of KHV losses among wild carp are under evaluation (e.g. UK, 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. That KHV is present in wild common carp populations in the southeastern USA has recently been reported by Dr. John Grizzle, Auburn University, Alabama (pers. comm.). 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.

Appendix XXII (contd)

Appendix A (contd)

Appendix III

Based upon the fragmentary data collected to date, the Finfish Subgroup deems KHVD does pose a 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 posed 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. pers. comm.). Lending some credence to 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.

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

The Subgroup agrees that the extensive and often unregulated movements of koi, through the ornamental fish trade (and even by individual hobbyists), provides a major network for the 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 program 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 widely spread and perhaps continuing to spread as a result of the trade in live koi. The geographic distribution of KHV is apt to significantly expand as the ornamental fish hobbyists become more informed 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 PCR tests are known, 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 measure 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 in apparent 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 Pathol* 39(3):165-168.

Appendix XXII (contd)

Appendix A (contd)

Appendix III

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, was organized by NACA in cooperation with ACIAR and AAHRI (currently checking on general availability of this report).

The entire volume of papers currently "in press" from the March meeting in Yokohama, Japan. These should be generally available soon – Contact Dr. Shigeo Hayashi, NRI, Japan.

REPORT OF THE SECOND MEETING OF THE MOLLUSC DISEASES TEAM

Paris, 27-29 July 2005

The OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases - Mollusc Team (hereinafter called the *ad hoc* Group) for the OIE *Aquatic Animal Health Code* (hereinafter called the *Aquatic Code*) held its meeting at the OIE Headquarters from 27-29 July 2005.

On behalf of the Director General of the OIE, Dr David Wilson welcomed the members of the *ad hoc* Group and thanked them for their willingness to be involved in addressing this mandate of the OIE.

The members of the OIE *ad hoc* Group are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#), and the terms of reference in [Appendix III](#).

Diseases listed [under study]

The *ad hoc* Group discussed the diseases listed as [under study] in Chapter 1.1.3. of the *Aquatic Code*, taking into account the relevant Member Countries' comments received on the Aquatic Animal Health Standards Commission's (hereinafter called the Aquatic Animals Commission) reports of October 2004 and January 2005. The *ad hoc* Group noted that those comments mainly addressed the Aquatic Animals Commission's recommendations to delist "infection with *Mikrocytos mackini*" and retain "infection with *Perkinsus olseni*".

With regard to infection with *Mikrocytos mackini*, the objection from the European Community (EC) to delisting centred on criterion 1 (criterion 1 of Article 1.1.2.1. of the *Aquatic Code* on significant production losses at national or multinational level). The recently released report from the Denman Island Disease Risk Assessment and Risk Management Workshop was produced by experts from the private and public sector (<http://www.pacshell.org/Denman.htm>), including the OIE Reference Laboratory; the *ad hoc* Group noted that this report is not in agreement with the EC comments regarding criterion 1. The *ad hoc* Group believed that the figures of product rejection given by the EC correspond to a unique event by a single grower and processor that should not be considered as representative of the normal situation. Consequently the *ad hoc* Group confirmed its previous recommendation for the removal of infection with *Mikrocytos mackini* from the OIE list of diseases. The original supporting document is attached in [Appendix IV](#) for ease of reference.

Comments were received by Australia, Italy and EC with regard to infection with *P. olseni*. The *ad hoc* Group addressed each comment individually. In reply to the Australian and EC comments, the *ad hoc* Group noted that for criterion 1, those comments didn't consider the widespread epizootics in venerid clams (*Ruditapes philippinarum*, *R. decussatus*, and *Austrovenus stutchburyi*) in Asia and Europe. With regard to criterion 7, the EC stated that this criterion doesn't apply because the parasite is largely widespread; the *ad hoc* Group agreed on the broad distribution of the disease (including a recent report from Uruguay - <http://www.int-res.com/abstracts/dao/v64/n1/p85-90/>), but considered that there are several areas free of that disease. Those areas include both coasts of North America that have susceptible species and where active surveillance has been in place for many years. In conclusion, the *ad hoc* Group maintained its original recommendation to retain *P. olseni* on the OIE list of diseases. A supporting document is attached in [Appendix V](#).

Other listed diseases

The *ad hoc* Group also addressed the Canadian comment regarding the widespread occurrence of *Bonamia ostreae* in *O. edulis*. The *ad hoc* Group considered that this did not recognise that *B. ostreae* can infect other *Ostrea* spp., not just *O. edulis*. Therefore there are oyster populations at risk world wide, and the *ad hoc* Group maintained its original recommendation to retain *B. ostreae* on the OIE list of diseases.

Appendix XXII (contd)Appendix B (contd)**Emerging diseases**

The *ad hoc* Group addressed some potentially significant diseases for addition to the OIE list of aquatic animal diseases. Regarding *Marteilioides chungmuensis*, it agreed that at present, there is not sufficient evidence that *M. chungmuensis* meets the listing criterion n. 1 (criterion 1 of Article 1.1.2.1. of the *Aquatic Code* on the significant production losses at national or multinational level). The *ad hoc* Group noted the presence of quantitative data on seasonal prevalence but not on morbidity, spawning failure or loss of marketability caused by *M. chungmuensis*. This relates directly to the criterion n. 1 in relation to “The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality”.

Recognising the economic importance of abalone farming and the emphasis in the published literature of detrimental effects of the sabellid worm (*Terebrasabella heterouncinata*), the *ad hoc* Group considered infestation caused by *T. heterouncinata*. The *ad hoc* Group recognised the production losses caused by this worm and its increasing widespread distribution, but also that it represented a large group of marine pests which also causes production losses. The *ad hoc* Group concluded that, at present, such marine pests do not meet the definition of disease as defined in the *Aquatic Code* and recommends that the Aquatic Animals Commission examine the issue of inclusion of marine pests.

The *ad hoc* Group discussed the recent findings of *Bonamia* spp. in Argentina, Australia, Chile and USA and encouraged the Microcell Working Group to provide a set of recommendation on species boundaries.

Recommended listed emerging aquatic animal disease

The abalone viral mortality syndrome (see the disease card developed by NACA/FAO/OIE for the quarterly reporting system at <http://library.enaca.org/Health/DiseaseLibrary/Abalone-Disease.pdf>; the card is attached as Appendix VI) was discussed by the *ad hoc* Group which concluded there is sufficient evidence that this disease matches listing criteria 2 and 4 (criterion 2 and 4 of Article 1.1.2.2. of the *Aquatic Code*). The *ad hoc* Group therefore recommends its listing as an emerging aquatic animal disease. The *ad hoc* Group also requests clarification from the Aquatic Animals Commission and the OIE Central Bureau on the need to develop specific material on this disease (such as *Aquatic Code* and *Manual of Diagnostic Tests for Aquatic Animals* chapters and the disease cards).

.../Appendices

Appendix XXII (contd)Appendix B (contd)Appendix I**SECOND MEETING OF THE MOLLUSC DISEASES TEAM****Paris, 27-29 July 2005****List of Participants****MEMBERS OF THE AD HOC GROUP (MOLLUSC TEAM)**

Chair:	Members:
<p>Dr Franck Berthe Department of Pathology & Microbiology Atlantic Veterinary College - UPEI 550 University Ave. Charlottetown Prince Edward Island, C1A 4P3 CANADA Tel: + (1-902) 566-0868 Fax: +(1-902) 566-0851 Email: fberthe@upe.ca</p>	<p>Dr Eugene M. Bureson Director for Research and Advisory Services, Virginia Institute of Marine Science, College of William and Mary, P.O. Box 1346, Gloucester Point, VA 23062 UNITED STATES OF AMERICA Tel.: + + (1-804) 684.7015 FAX: + (1-804) 684.70.97 E-mail: gene@vims.edu</p> <p>Dr Mike Hine Aquatic Animal Diseases National Centre for Disease Investigation MAF Operations, P.O. Box 40-742 Upper Hutt NEW ZEALAND Tel.: + (64-4) 526-5600 Fax: + (64-4) 526-5601 E-mail: hinem@maf.govt.nz</p>

OIE HEADQUARTERS

<p>Dr Bernard Vallat Director General OIE 12, Rue de Prony 75017 Paris Tel: 33-(0) 1 44 15 18 88 Fax: 33-(0) 1 42 67 09 87 E-mail: oie@oie.int</p>	<p>Dr David Wilson Head International Trade Department OIE Tel: 33-(0) 1 44 15 18 88 Fax: 33-(0) 1 42 67 09 87 E-mail: d.wilson@oie.int</p>	<p>Dr Francesco Berlingieri Deputy International Trade Department OIE Tel: 33-(0) 1 44 15 18 88 Fax: 33-(0) 1 42 67 09 87 E-mail: f.berlingieri@oie.int</p>
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Appendix XXII (contd)

Appendix B (contd)

Appendix II

SECOND MEETING OF THE MOLLUSC DISEASES TEAM

Paris, 27-29 July 2005

Adopted Agenda

1 OIE List of Aquatic Animal Diseases

- a. assess mollusc diseases currently listed as [under study] against the aquatic animal disease listing criteria taking into account the comments received

Appendix XXII (contd)

Appendix B (contd)

Appendix III

Ad hoc Group on the OIE List of Aquatic Animal Diseases

Terms of Reference

1. To assess the diseases currently listed as [under study] in the *Aquatic Animal Health Code* against the aquatic animal disease listing criteria, and recommend whether they should be added to or deleted from the list; to provide documented scientific justification for any recommendations.
2. To produce a report on these findings to the OIE Aquatic Animal Health Standards Commission **by 1 August 2005**.
3. To consider comments received and submit a report to the Commission **by 15 February 2006**.

Infection with *Mikrocytos mackini*

		Listing	Comment
A1	<p>The impact of <i>Mikrocytos mackini</i> is unclear, as the natural beds where it occurs do not appear to be routinely monitored. Mortalities (10%) were first reported among 4-year-old Japanese (<i>Crassostrea gigas</i>) and local oysters in Pender Harbour, British Columbia, in autumn 1956 (1). In 1960, further mortalities (10%) occurred in Henry Bay, Denman Island, and 33% of oysters were found to have yellowy green pustules, regarded as pathognomic of Denman Island disease. The following month (May) 40% mortalities and <55% infection were recorded, followed by an apparent epizootic (1). Prevalence of infection is likely to have been under-estimated as light infections were very difficult to detect, at that time. Epizootics have been on-going (2-5). However, since the early 1990s, losses due to mikrocytosis in enzootic areas have been insignificant (Susan Bower, Pacific Biological Station: <i>pers. comm.</i>). <i>M. mackini</i> is was thought to be confined to Denman Island and surrounding islands, but it was reported from northern Washington State, U.S.A., in 2002. Examination of the Washington beds showed that it occurred in beds of relict oysters and that its presence was therefore enzootic, and not due to recent introduction (Susan Bower: <i>pers. comm.</i>).</p> <p>Mortalities may economically impact oyster farmers, as the disease occurs in 4-year-old oysters, of marketable size, which appear otherwise to be in good condition (1, 6-7). However, this spring (2004) one grower has experienced ~10% mortality, and others have had product refused by processors due to 10-80% prevalence of oysters with pustules (Susan Bower: <i>pers. comm.</i>). Also, a digoxigenin <i>in situ</i> hybridisation technique has recently shown that the digestive tracts of spat are infected by <i>M. mackini</i>, which may account for mortalities among spat (Susan Bower: <i>pers. comm.</i>). This has yet to be proved.</p>	-	Lack of quantitative data on mortalities in the wild, and it is not possible to quantify economic losses. The scale of <i>C. gigas</i> farming in waters <12°C is unknown
or			
A2	<p><i>M. mackini</i> naturally infects, and causes mortalities in wild <i>Crassostrea gigas</i>, and it naturally infects <i>Ostrea conchaphila</i> (5). It also experimentally infects <i>Crassostrea virginica</i> and <i>Ostrea edulis</i> (5, 8-10). Although the lack of host specificity might make it seem likely that <i>M. mackini</i> will spread through oyster populations, the disease is limited by temperature. Disease occurs following 3-4 months of <10°C temperatures, and does not occur at >12°C, but infections may persist for 3 months at 15°C (7, 11). Disease develops at 8°C (1). Therefore, oysters in waters that reach >12°C are not susceptible to the disease. Conversely, wild oyster populations in waters <12°C may be susceptible. Despite this, there have not been any reports of epizootics in oyster species, other than <i>C. gigas</i>.</p>	-	Only <i>C. gigas</i> in waters <12°C are susceptible

Appendix XXII (contd)

Appendix B (contd)

Appendix IV

or			
A3	<i>M. mackini</i> is not harmful to human health	-	
and			
B4	<i>Mikrocytos mackini</i> can be readily transmitted by inoculation of <i>C. gigas</i> with purified parasites or infected oyster homogenates, and by exposure to infected oysters (9). When uninfected oysters were exposed to infected oysters, prevalence generally increased with time, from 13% at 3 months, 7% at 3.5 months, 30% at 6 months, and 49% at 6.5 months. Disease only developed when oysters were held at low temperatures (~10°C) for prolonged periods (2.5-5.0 months) (9).	+	Although infection may occur at <12°C, disease only occurs at <10°C
or			
B5	The aetiology is known (see B4).	NA	NA
and			
B6	Mikrocytosis can be managed in southern British Columbia by hatchery producing larvae and settling them away from infected areas, hanging culture techniques, and shortened production cycles. (Susan Bower: <i>pers. comm.</i>). Oysters are not exported from infected areas, but even if they were, there appears to be very little risk that the parasite would establish in most other countries. The oyster would have to be kept at <12°C for several months in the area into which they were introduced. This would negate spread to countries with temperate or sub-tropical climates. Although gut infections in spat suggest that <i>M. mackini</i> may be spread by spat, spat are not exported. However, the expert on <i>M. mackini</i> , Dr Susan Bower, believes that the parasite could be a major problem in countries with very cold climates.	+	Spread, even if exported, appears unlikely
and			
B7	Except for British Columbia, Canada, and the north western U.S.A., all other countries that culture, or have wild stocks of <i>C. gigas</i> , appear to be free of <i>M. mackini</i> . Although all these countries have potentially susceptible hosts, only those in very cold regions, where temperatures do not exceed 12°C, are at risk. With global warming, the distribution of the parasite is likely to become even more restricted.	+	Zones can be established on the basis of temperature
and			
C8	<i>Mikrocytos mackini</i> has been very difficult to detect in light infections. However, the development of imprint techniques (8), concentration (9) and purification (12) techniques, serology and PCR (13), which has been validated (14), give a robust, repeatable means of detecting the parasite.	+	
		De-list	

Appendix XXII (contd)

Appendix B (contd)

Appendix IV

Listing here:-

1	2	3	4	5	6	7	8	Retain on OIE list?
-	-	-	+	N/A	+	+	+	De-list

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Appendix XXII (contd)

Appendix B (contd)

Appendix V

Infection with *Perkinsus olseni*

No.	Parameters that support listing	Listing	Comments
A1	<i>P. olseni</i> is known to cause high mortality in clams, <i>Ruditapes philippinarum</i> and <i>R. decussatus</i> , in Korea, Japan, France, Italy, Spain and Portugal (1, 6, 9, 10). The parasite is widely distributed in a variety of hosts throughout the tropical, sub-tropical and warm temperate Pacific Ocean, although it seems to cause little mortality in the tropical Pacific. <i>P. atlanticus</i> was recently synonymized with <i>P. olseni</i> (9).	+	Very good data
or			
A2	<i>P. olseni</i> has been shown to negatively affect economically important wild abalone populations in Australia (5, 8) and economically important wild clam populations in New Zealand, Korea, Japan and Europe (1, 7, 10, 11).	+	Very good data
or			
A3	<i>P. olseni</i> is not harmful to human health.	-	Very confident
and			
B4	Koch's postulates have been satisfied for <i>P. olseni</i> . The life cycle is direct from mollusc to mollusc (6).	+	Very good data
or			
B5	The aetiology is known (see B4). The taxonomic boundaries are still not clearly established.	N/A	Very confident
and			
B6	There is a potential for international spread of <i>P. olseni</i> . In fact, it is likely that the parasite was introduced from Asia to Spain and Portugal with importations of <i>R. philippinarum</i> for aquaculture. <i>P. olseni</i> has a very wide host range, which increases the chances of spread.	+	Introduction to Europe speculative
and			
B7	<i>P. olseni</i> occurs in New Zealand, eastern Australia, throughout the tropical Pacific, Asia, and the coasts of Spain and Portugal. Although it is widespread, <i>P. olseni</i> has not been reported from the Pacific or Atlantic coasts of North America, the Pacific coast of South America or in the Gulf of Mexico, where susceptible species do exist. It has now been reported in Uruguay (13). Clams destined for importation into Mexico and eventually to the US from Korea were heavily infected with a <i>Perkinsus</i> , likely <i>P. olseni</i> (4). The importation was stopped, but this situation demonstrates the potential for spread.	+	Apparently widespread and non-host specific, but host and geographic range not well documented. There are disease free zones that should be protected.

Appendix XXII (contd)Appendix B (contd)Appendix V

and			
C8	Hosts typically are examined by culture of tissue in Ray's fluid thioglycollate medium (RFTM), but this technique is not species specific. Specific PCR primers for both the ITS and NTS region of the rRNA gene have been developed for <i>P. olseni</i> (3, 12).	+	PCR assays have not been validated against RFTM

Listing here:-

1	2	3	4	5	6	7	8	Retain on OIE list?
+	+	-	+	NA	+	+	+	Yes

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Abalone Viral Mortality - Disease Card¹

by

Shi Zhengli² and Judith Handler³

Preliminary remark. For the purposes of this disease card, abalone viral mortality encompasses crack-shell disease of *Haliotis hannai* and viral disease of *Haliotis diversicolor*, two syndromes which could be distinct diseases, pending further scientific information.

Pathogen information

1. causative agent

1.1. pathogen type

viruses

1.2. disease name and synonyms

crack-shell disease of *Haliotis hannai*, *Haliotis diversicolor* viral disease

1.3. pathogen common name and synonyms

abalone spherical viruses

1.4. taxonomic affiliation

1.4.1. pathogen scientific name (Genus species sub-species or type)

no data

1.4.2. phylum, class, family etc...

no data

1.5. description of the pathogen

Virus type 1: spherical virion, 90-140 nm in diameter, two-layer envelope (8-10 nm) with a smooth surface; nucleocapsid measured 70-100 nm in diameter; replicated in cytoplasm of haemocytes and interstitial (or connective) tissues. ^(4,5,7)

Virus type 2: spherical virion, 100 nm in diameter, enveloped, hexagonal nucleocapsid (or icosahedral shape), replicated in cytoplasm of the epithelial cells of liver (hepatopancreas), kidney and intestines, and usually present in endoplasmic reticulum; DNA virus. ^(1,3,6)

¹ Shi Zhengli and Judith Handler (2004) Abalone Viral Mortality – Disease card. Developed to support the NACA/FAO/OIE regional quarterly aquatic animal disease (QAAD) reporting system in the Asia-Pacific. NACA, Bangkok, Thailand. 5 pp.

² Dr Shi Zhengli, Wuhan Institute of Virology, Chinese Academy of Sciences, 44 Xiao Hong Shan, 430071 Wuhan, Hubei Province, People's Republic of China

³ Dr Judith Handler, Senior Veterinary Pathologist (Aquatic Animals), Fish Health Unit, Animal Health Laboratory, Department of Primary Industries, Water and Environment, Tasmania, Mt Pleasant Laboratories, PO Box 46, Kings Meadows TAS 7249

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Virus type 3: spherical virion, 135-150 nm, enveloped, with spikes on the surface, icosahedral nucleocapsid with a size of 100-110 nm in diameter; assembled in double-layered vesicles of the cytoplasm of infected liver and intestines cells (both epithelial cells and connective cells); speculated as nuclear replicated virus.⁽⁹⁾

Virus type 4: spherical virion, 90-110 nm, enveloped with a smooth surface, icosahedral nucleocapsid; assembled in double-layered vesicles of the cytoplasm of infected liver and intestines cells (both epithelial cells and connective cells); speculated as nuclear replicated virus.⁽⁹⁾

Additional information:

- The samples of virus type 2, 3 and 4 are from the same region, Dongshan Fujian province, China.
- *Vibrio alginolyticus* and *V. parahaemolyticus* may co-infect abalone which has been infected with virus and could be co-factors for *H. diversicolor* diseases.^(9,10)

1.6. authority (first scientific description, reference)

virus type 1: Wang B., Li X., Gou C. Infection of spherical viruses from *Haliotis discus hannai* Ino. *Virologica Sinica*, 1997, 12(4): 360-363

virus type 2: Huang Y., Wu W., Yan J., Zhou W. Investigation on an exterminate disease of *Haliotis diversicolor aquatilis*, *Fujian Veterinary and Zootechnics*, 1999, 21(3): 4-5

1.7. pathogen environment (fresh, brackish, marine waters)

Marine water

2. modes of transmission

2.1. routes of transmission (horizontal, vertical, direct, indirect)

virus type 1: horizontal, per os or oral transmission

virus type 2 (3 and 4): horizontal,

2.2. life cycle

no data

2.3. associated factors (temperature salinity, etc...)

virus type 1: low temperature (less than 20 °C)

virus type 2 (3 and 4): low temperature (less than 24 °C), usually in winter (from October to November) and summer (from April to May)

2.4. additional comments

Virus type 1-like particles were found present in other mollusc species such as turban shell (*Turbo* sp), mussel (*Mytilus edulis*) and tegula (*Tegula* [*Chlorostoma*] *rusticum*).

Appendix XXII (contd)Appendix B (contd)Appendix VI

3. host range

3.1. host type

abalone

3.2. host scientific names

virus type 1: *Haliotis hannai* Inovirus type 2 (3 and 4): *Haliotis diversicolor* Reeve

3.3. other known or suspected hosts

virus type 1: *Turbo* sp., *Tegula rusticum*, *Mytilus edulis*

virus type 2: unknown

3.4. affected life stage

virus type 1: young abalone. However, viral particles are also found in adult healthy abalone.

virus type 2: all developmental stages of abalone.

3.5. additional comments

Different names are used for the host species, such as *Haliotis diversicolor*, *Haliotis diversicolor aquatilis*, *Haliotis diversicolor supertexta* and *Haliotis diversicolor diversicolor*. It is suggested that these different names should be unified to be *Haliotis diversicolor* Reeve.

4. geographic distribution

4.1. region

virus type 1: North and Northeast of China (Dalian, Liaoning province along Bohai coast line)

virus type 2: South of China (Fujian, Hainan and Guangdong province in the southern sea of China)

4.2. country

China

4.3. additional comments

In Bohai and Huanghai coast line of China, the cultured abalone specie is *Haliotis hannai* Ino, while in southern sea coast line, the cultured abalone specie is *Haliotis diversicolor* Reeve

Appendix XXII (contd)Appendix B (contd)Appendix VI**Disease information**

1. clinical signs and case description

1.1. host tissues and infected organs

type 1: viral particles present in cytoplasm of haemocytes and interstitial (or connective) tissues.

type 2 (3 and 4): viral particles usually present in cytoplasm of epithelial and connective cells of liver and intestines. Apparently, viral particles may also be found in infected cell nuclei.

1.2. gross observations and macroscopic lesions

type 1 (associated with virus type 1): low activity, lost appetite, unsusceptible to light, thin shell, edge turndown, decreased growth rate, 50% mortality in 40-89 d by oral infection.

type 2 (associated with virus type 3 and 4): secretion of mucus, low activity, lost appetite, contracted feet and mantle, black and hardened feet, dead abalone presents swollen liver and intestines and adheres to the bottom of the pond, high mortality (100% in 3-9 d).

1.3. microscopic lesions and tissue abnormality

type 1: Observation based on H & E staining sections of mantle, feet, gill, liver (hepatopancreas), stomach and intestines, the common pathological changes are: necrosis and disorder of connective tissues of all organs; necrosis of haemocytes and epithelial cells; disorder and detachment of epithelial cells of feet, mantle, liver and gills.

type 2 (3 and 4): based on microscopic observation: disorder and hypertrophy of epithelial cells of liver, detachment and vacuolization of epithelium and connective tissues. Based on ultrathin section observation, the infected cells show pathological change such as swollen membrane and mitochondria, denatured nucleoplasm, vacuolisation of cells and abound of endoplasmic reticulum in the cells.

1.4 OIE status

Currently not listed by the OIE

2. social and economic significance

No data but significant economic importance is suspected through the different reports which are currently available.

3. zoonotic importance

no data

4. diagnostic methods

Three levels of examination procedures are used: screening methods for surveillance, presumptive diagnostic methods when abnormal mortalities occur, and confirmatory methods if available when a pathogen is encountered during screening or mortality outbreaks.

Appendix XXII (contd)Appendix B (contd)Appendix VI

4.1. screening methods

4.1.1. level I

type 1 (associated with virus type 1): low activity, lost appetite, unsusceptible to light, thin shell, edge turndown, decreased growth rate.

type 2 (associated with virus type 2): secretion of mucus, low activity, lost appetite, contracted feet and mantle, black and hardened feet, dead abalone presents swollen liver and intestines and adheres to the bottom of fishpond, high mortality (100% in 3-9 d).

4.1.2. level II: None

4.1.3. level III: None

4.2. presumptive methods

4.2.1. level I: see section 4.1.1.

4.2.2. level II

type 1: Observation based on H & E staining sections of mantle, feet, gill, liver (hepatopancreas), stomach and intestines, the common pathological changes are: necrosis and disorder of connective tissues of all organs; necrosis of haemocytes and epithelial cells; disorder and detachment of epithelial cells of feet, mantle, liver and gills.

type 2 (3 and 4): based on microscopic observation: disorder and hypertrophy of epithelial cells of liver, detachment and vacuolization of epithelium and connective tissues. Based on ultrathin section observation, the infected cells show pathological changes such as swollen membrane and mitochondria, denatured nucleoplasm, vacuolisation of cells and abound of endoplasmic reticulum in the cells.

4.2.3. level III: None

4.3. confirmatory methods

4.3.1. level I: None

4.3.2. level II: None

4.3.3. level III

Transmission Electron Microscopy. See description in sections above.

5. control methods

No known methods of prevention or control. Infected abalone should not be transported into areas known to be free of the disease.

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Appendix XXII (contd)Appendix B (contd)Appendix VI

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**REPORT OF THE MEETING OF THE OIE AD HOC GROUP
ON FISH DISEASE CHAPTERS OF THE OIE AQUATIC ANIMAL HEALTH CODE**

Paris, 20-22 July 2005

The OIE *ad hoc* Group on fish disease chapters of the OIE *Aquatic Animal Health Code* (*Aquatic Code*) held its first meeting at the OIE Headquarters from 20-22 July 2005.

On behalf of the Director General of the OIE, Dr Francesco Berlingieri welcomed the members of the *ad hoc* Group and thanked them for their willingness to be involved in addressing this mandate of the OIE.

The members of the OIE *ad hoc* Group are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#), and the terms of reference in [Appendix III](#).

The Chair indicated that the terms of reference provided by the Aquatic Animals Commission should form the scope of the *ad hoc* Group's work.

Internationally traded commodities for which no disease specific measures are required

The *ad hoc* Group recognised the paucity of scientific literature on the survival of fish pathogens in internationally traded commodities. On the other hand, it agreed that the proposals should be supported, as far as possible, by scientific evidence or reasoning in the report to ensure transparency the Aquatic Animals Commission and for Member Countries. During its discussions, the *ad hoc* Group consulted various documents for scientific data on individual pathogens, and a non-exhaustive list is provided in [Appendix IV](#).

After discussion of the basic principles, the *ad hoc* Group concluded that the likelihood of the introduction of listed pathogens as a result of international trade in a commodity should be negligible in order for the commodity to be listed in Article 3 of a disease chapter. Unrestricted trade in the commodities listed in Article 3 of each proposed chapter should be allowed regardless of the health status of the exporting country, zone or compartment for that disease.

The *ad hoc* Group agreed that the commodities could be grouped into three categories:

- commodities from susceptible species destined for any use,
- commodities from susceptible species destined only for human consumption, and
- commodities from non susceptible species destined for any use.

Appendix XXIII (contd)

For commodities from susceptible species destined for any use, the *ad hoc* Group considered that the processing (commercial canning or tanning) would inactivate the pathogens. For specified commodities from susceptible species destined for human consumption, the *ad hoc* Group considered that the likelihood of exposure of a pathogen to susceptible hosts and its establishment in them would be too low for concern, provided that the commodities were not diverted to other uses. A footnote to this effect is provided in each chapter. The *ad hoc* Group considered that live fish of non-susceptible species may act as mechanical vectors for the pathogens, whereas products from these species were considered to present a negligible risk.

The *ad hoc* Group requested the Aquatic Animals Commission to consider if it would be useful to add to the User's Guide in the *Aquatic Code* a point (consistent with the *Terrestrial Code*) highlighting the need for Member Countries to perform a risk analysis to address trade in commodities not covered by the current *Aquatic Code*.

In assessing the commodities for Article X.X.X.3, the *ad hoc* Group found some inconsistencies between other articles of the Chapters; to address these inconsistencies, amendments are proposed in Article X.X.X.9 and a new article is proposed as Article X.X.X.9 bis. Additional text on risk mitigation measures for dead fish is proposed for Article XXX 11 (as shown) for each disease.

The *ad hoc* Group consulted recent scientific information in addressing the sanitary aspects of trade in fishmeal. It noted the conclusions reached in the European Commission's 'Report of the Scientific Committee on Animal Health and Animal Welfare (2003) - The use of fish by-products in aquaculture', in particular the following:

"It is likely that the time/temperature treatments normally applied in the production of fishmeal would result in sufficient inactivation to reduce to negligible the risk of disease from the majority of conventional fish pathogens, based on available data. However, there are major knowledge gaps in the scientific literature concerning inactivation parameters for many fish pathogens."

The *ad hoc* Group concurred with this conclusion and felt unable to make any specific recommendation on trade in fishmeal, but noted that studies are underway with regard to inactivation of pathogens in the processing of fish by-products. Because of the importance of international trade in fishmeal the *ad hoc* Group recommended that the Aquatic Animals Commission place it [under study] and take into account the results of such studies as they emerge.

Update of the chapters for the other OIE listed fish diseases

The *ad hoc* Group used the proposed amended Chapter 2.1.1. (EHN) (Appendix V) as a model to update the chapters for the other OIE listed fish diseases: infectious haematopoietic necrosis (IHN) (Appendix VI), spring viraemia of carp (SVC) (Appendix VII), viral haemorrhagic septicaemia (VHS) (Appendix VIII), infectious salmon anaemia (ISA) (Appendix IX), epizootic ulcerative syndrome (EUS) (Appendix X), gyrodactylosis (Appendix XI) and red sea bream iridoviral disease (RSIVD) (Appendix XII). The *ad hoc* Group took into account epidemiological differences between EHN and the other listed diseases but, other than for gyrodactylosis, the *ad hoc* Group did not consider the epidemiological differences would significantly alter risk. In the case of gyrodactylosis, the *ad hoc* Group considered that additional alternative risk management measures could be specified in Articles 2.1.14.9, 2.1.14.9bis and 2.1.14.11. In updating the chapters for the other listed diseases the *ad hoc* Group encountered some inconsistencies and highlighted the following points for consideration by the Aquatic Animals Commission:

- it is not clear whether the targeted surveillance referred to in paragraph 4 of Articles X.X.X.4 and X.X.X.5 is to be applied to the infected zone or to the buffer zone, or to both;
- for consistency with Article X.X.X.5, it may be helpful to provide details in Article X.X.X.8 (the importation of live animals for aquaculture from a country, zone or compartment not declared free) on when the aquatic animals should be considered suitable for release from quarantine;

- as the current Aquatic Code chapter for viral haemorrhagic septicaemia (VHS) does not distinguish the virulence/importance of different genotypes; the Aquatic Animals Commission may wish to consider if there is enough scientific justification for differentiating between VHSV genotypes for international trade purposes;

In formulating Article X.X.X.2 on susceptible species, the *ad hoc* Group used, among other data, the new draft chapters for the OIE Aquatic Manual. The *ad hoc* Group submitted its draft work on the susceptible species to the relevant authors and requested their assistance in finalising the list of susceptible species. During the course of the meeting, the answers received on VHS, gyrodactylosis and ISA were considered and some amendments were made to the list. Any further answers will be forwarded by the OIE Central Bureau to the Aquatic Animals Commission.

The *ad hoc* Group considered that it made as much progress as possible with the information available. It suggests that the Aquatic Animals Commission requests detailed comments on the proposed texts from OIE Member Countries supported, to the extent possible, by scientific data and references.

.../Appendices

**MEETING OF THE OIE AD HOC GROUP ON FISH DISEASE CHAPTERS
OF THE OIE AQUATIC ANIMAL HEALTH CODE**

Paris, 20-22 July 2005

List of Participants

MEMBERS OF THE AD HOC GROUP

Chair:

Prof. Barry Hill

Centre for Environment, Fisheries
and Aquaculture Sciences
The Nothe
Weymouth DT4 8UB
UNITED KINGDOM
Tel.: + (44-1305) 20.66.26
FAX: + (44-1305) 20.66.27
E-mail: b.j.hill@cefasc.co.uk

Members:

Dr Peter Beers

Principal Veterinary Officer
Office of the Chief Veterinary
Officer
Department of Agriculture,
Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601
AUSTRALIA
Fax +61 2 6272 3372
email peter.beers@daff.gov.au

Members:

Dr. CJ Rodgers

Centre d'Aquicultura
L'Institut de Recerca i Tecnologia
Agroalimentàries (CA-IRTA)
c/Poble Nou, s/n.,
P.O. Box 200
43450 San Carlos de la Rapita
Tarragona
Spain
Tel: +(34) 977 744660
Fax: +(34) 977 744660
E-mail: crodgers@terra.es

OIE HEADQUARTERS

Dr Bernard Vallat

Director General
OIE
12, rue de Prony
75017 Paris
Tel: 33-(0) 1 44 15 18 88
Fax: 33-(0) 1 42 67 09 87
E-mail: ois@ois.int

Dr David Wilson

Head
International Trade Department Tel:
33-(0) 1 44 15 18 88
Fax: 33-(0) 1 42 67 09 87
E-mail: d.wilson@ois.int

Dr Francesco Berlingieri

Deputy
International Trade Department Tel:
33-(0) 1 44 15 18 88
Fax: 33-(0) 1 42 67 09 87
E-mail: f.berlingieri@ois.int

**MEETING OF THE OIE *AD HOC* GROUP ON FISH DISEASE CHAPTERS
OF THE OIE *AQUATIC ANIMAL HEALTH CODE***

Paris, 20-22 July 2005

Adopted Agenda

Aquatic Animal Health Code

- a. identify safe commodities for the Article 2.1.1.3. (EHN)
- b. draft new chapters for the other OIE listed fish diseases

Ad hoc Group on fish disease chapters
of the OIE *Aquatic Animal Health Code*

Terms of Reference

1. With respect to Article 2.1.1.3. (EHN) of the *Aquatic Animal Health Code*, to identify measures applicable to commonly traded commodities to ensure their safety and to provide documented scientific justification for any recommendations.
2. Using Chapter 2.1.1. (EHN) in the *Aquatic Animal Health Code* as a model, to draft new chapters for the other OIE listed fish diseases and to provide documented scientific justification for any recommendations.
3. To submit a report to the OIE Aquatic Animal Health Standards Commission **by 1 August 2005**.
4. To consider comments received and submit a report to the Commission **by 15 February 2006**.

List of documents consulted by the *ad hoc* Group

- World Organisation for Animal Health (OIE) (2005) Aquatic Animal Health Code, Eighth Edition, Paris, 568pp..
- World Organisation for Animal Health (OIE) (2005) Diagnostic Manual for Aquatic Animal Diseases, Fourth Edition, Paris, 374pp..
- OIE web site (<http://www.oie.int>)
- OIE Collaborating Centre for Information on Aquatic Animal Diseases web site (<http://www.collabcen.net/>)
- Proceedings of the OIE International Conference on Risk Analysis in Aquatic Animal Health, 2000
- Australian import risk analysis on non-viable salmonids and non-salmonid marine finfish, 1999
- “An assessment of the risk of spreading the fish parasite *Gyrodactylus salaris* to uninfected territories in the European Union with the movement of live Atlantic salmon (*Salmo salar*) from coastal waters”, (Peeler et al., 2005). [In press, Aquaculture].

CHAPTER 2.1.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

Article 2.1.1.1.

For the purposes of this *Aquatic Code*, epizootic haematopoietic necrosis (EHN) means infection with ~~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*) and rainbow trout (*Oncorhynchus mykiss*).

Suspect cases of natural infection with EHNV 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 2.1.1.3.

Commodities

1. When authorising import or transit of the following ~~commodities (under study)~~, *Competent Authorities* should not require any EHN related conditions, regardless of the EHN status of the *exporting country, zone or compartment*:
 - a) For the species in Article 2.1.1.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following products destined for human consumption⁴ from species in Article 2.1.1.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;

⁴ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

Appendix XXIII (contd)Appendix V (contd)

- iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For other species than those in Article 2.1.1.2., all aquatic animal products.
2. When authorising import or transit of the ~~following commodities,~~ of a species listed in Article 2.1.1.2., ~~other than those listed in paragraph 1 of Article 2.1.1.3.,~~ *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 any other commodity of a species not listed in Article 2.1.1.2. 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 EHN, 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 2.1.1.4.

EHN free country

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

If a country shares a *zone or compartment water-catchment* with one or more other countries, it can only declare itself an EHN free country if all the areas covered by the shared water 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 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 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:

Appendix XXIII (contd)Appendix V (contd)

- a) *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 last 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 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 points 1), 2), 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 *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 declare itself free from EHN when *basic biosecurity conditions* have been 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 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 met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

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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) *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 last 2 years without detection of EHN.

OR

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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of EHN.

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.

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Article 2.1.1.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.1.2., other than *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. 1 given in Part 6. of this *Aquatic Code*.

Article 2.1.1.8.

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

When importing, for *aquaculture*, *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:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of EHN.

Article 2.1.1.9.

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

When importing, for processing ~~and/or~~ for human consumption, *aquatic animals* of the species listed in Article 2.1.1.2., other than any ~~those~~ live *commodities* listed in paragraph 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 require ~~assess the risk and apply risk mitigation measures such as:~~

1. the consignment is delivered directly to and held in *quarantine* facilities for ~~a short period before slaughter and processing~~ to one of the products listed in paragraph 1 of Article 2.1.1.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of EHN.

Appendix XXIII (contd)Appendix V (contd)Article 2.1.1.9.bis**Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from EHN**

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, aquatic animals of the species listed in Article 2.1.1.2., other than any live commodities listed in paragraph 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 require:

1. the consignment is delivered directly to and held in quarantine facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of EHN.

Article 2.1.1.10.**Importation of products from a country, zone or compartment 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 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 the Model Certificate in Appendix 6.2.1..

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.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in facilities for processing to one of the products listed in paragraph 1 of Article 2.1.1.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of EHN.

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CHAPTER 2.1.2.

INFECTIOUS HAEMATOPOIETIC NECROSIS

Article 2.1.2.1.

For the purposes of this *Aquatic Code*, epizootic haematopoietic necrosis (IHN) means infection with IHN virus (IHNV) of the genus *Novirhabdovirus* of the family Rhabdoviridae.

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

Article 2.1.2.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for IHN are: rainbow or steelhead trout (*Oncorhynchus mykiss*), the Pacific salmon species [chinook (*O. tshawytscha*), sockeye (*O. nerka*), chum (*O. keta*), masou (*O. masou*), pink (*O. rhodurus*) and coho (*O. kisutch*)], and Atlantic salmon (*Salmo salar*).

Suspect cases of natural infection with IHNV 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 2.1.2.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any IHN related conditions, regardless of the IHN status of the *exporting country*, *zone* or *compartment*:
 - a) For the species in Article 2.1.2.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following products destined for human consumption⁵ from species in Article 2.1.2.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;

⁵ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

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- iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.2.2., all *aquatic animal products*.
2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.2.2., other than those listed in paragraph 1 of Article 2.1.2.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.2.7. to 2.1.2.11. of this Chapter, relevant to the IHN status of the *exporting country*, *zone* or *compartment*.
 3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.2.2. from an *exporting country*, *zone* or *compartment* not declared free of IHN, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of IHNV, 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 2.1.2.4.

IHN free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an IHN free country if all the areas covered by the shared water are declared IHN free countries or zones (see Article 2.1.2.5.).

1. A country where none of the species listed in Article 2.1.2.2. is present may declare itself free from IHN when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.2.2. 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 IHN when *basic biosecurity conditions* have been 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 IHN when:
 - a) *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 last 2 years without detection of IHNV.

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OR

4. A country that had declared itself free from IHN but in which the disease is detected may not declare itself free from IHN 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of IHNV.

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 2.1.2.5.

Article 2.1.2.5.

IHN free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from IHN 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.2.2. is present may declare itself free from IHN when *basic biosecurity conditions* have been 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 2.1.2.2. 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 IHN when *basic biosecurity conditions* have been 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 IHN when:
 - a) *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 last 2 years without detection of IHNV.

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OR

4. A *zone* previously declared free from IHN but in which the disease is detected may not be declared free from IHN 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of IHN.

Article 2.1.2.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from IHN following the provisions of points 1) or 2) of Articles 2.1.2.4. or 2.1.2.5., respectively, may maintain its status as IHN free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from IHN following the provisions of point 3) of Articles 2.1.2.4. or 2.1.2.5., respectively, may discontinue *targeted surveillance* and maintain its status as IHN free provided that conditions that are conducive to clinical expression of IHN, 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 IHN, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.2.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.2.2., other than *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* declared free from IHN, 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 2.1.2.4. or 2.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IHN.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

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Article 2.1.2.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.2.2., other than those *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of IHNV.

Article 2.1.2.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.2.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of IHNV.

Article 2.1.2.9.bis

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from IHN

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of IHNV.

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Article 2.1.2.10.

Importation of products from a country, zone or compartment declared free from IHN

When importing *aquatic animal products* of the species listed in Article 2.1.2.2., other than those *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* free from IHN, 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 2.1.2.4. or 2.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IHN.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.2.11.

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

When importing *aquatic animal products* of the species listed in Article 2.1.2.2., other than those *commodities* listed in point 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 2.1.2.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of IHN.

CHAPTER 2.1.4.

SPRING VIRAEMIA OF CARP

Article 2.1.4.1.

For the purposes of this *Aquatic Code*, spring viraemia of carp (SVC) means infection with the viral species SVC virus (SVCV) tentatively placed in the genus *Vesiculovirus* of the family Rhabdoviridae.

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

Article 2.1.4.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for SVC are: common carp (*Cyprinus carpio carpio*) and koi carp (*Cyprinus carpio koi*), crucian carp (*Carassius carassius*), sheatfish, (also known as European catfish or wels) (*Silurus glanis*), silver carp (*Hypophthalmichthys molitrix*), bighead carp (*Aristichthys nobilis*), grass carp (white amur) (*Ctenopharyngodon idella*), goldfish (*Carassius auratus*), orfe (*Leuciscus idus*), and tench (*Tinca tinca*).

Suspect cases of natural infection with SVCV 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 2.1.4.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any SVC related conditions, regardless of the SVC status of the *exporting country*, *zone* or *compartment*:
 - a) For the species in Article 2.1.4.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following products destined for human consumption⁶ from species in Article 2.1.4.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);

⁶ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

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- iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
- c) For species other than those in Article 2.1.4.2., all *aquatic animal products*.
2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.4.2., other than those listed in paragraph 1 of Article 2.1.4.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.4.7. to 2.1.4.11. of this Chapter, relevant to the SVC status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.4.2. from an *exporting country*, *zone* or *compartment* not declared free of SVC, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of SVCV, 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 2.1.4.4.

SVC free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an SVC free country if all the areas covered by the shared water are declared SVC free countries or zones (see Article 2.1.4.5.).

1. A country where none of the species listed in Article 2.1.4.2. is present may declare itself free from SVC when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.4.2. 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 SVC when *basic biosecurity conditions* have been 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 SVC when:

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- a) *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 last 2 years without detection of SVCV.

OR

4. A country that had declared itself free from SVC but in which the disease is detected may not declare itself free from SVC 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of SVCV.

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 2.1.4.5.

Article 2.1.4.5.

SVC free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from SVC 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.4.2. is present may declare itself free from SVC when *basic biosecurity conditions* have been 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 2.1.4.2. 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 SVC when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

Appendix XXIII (contd)Appendix VII (contd)

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 SVC when:

- a) *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 last 2 years without detection of SVCV.

OR

4. A *zone* previously declared free from SVC but in which the disease is detected may not be declared free from SVC 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of SVCV.

Article 2.1.4.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from SVC following the provisions of points 1) or 2) of Articles 2.1.4.4. or 2.1.4.5., respectively, may maintain its status as SVC free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from SVC following the provisions of point 3) of Articles 2.1.4.4. or 2.1.4.5., respectively, may discontinue *targeted surveillance* and maintain its status as SVC free provided that conditions that are conducive to clinical expression of SVC, 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 SVC, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Appendix XXIII (contd)Appendix VII (contd)

Article 2.1.4.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.4.2., other than *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* declared free from SVC, 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 2.1.4.4. or 2.1.4.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from SVC.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.4.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.4.2., other than those *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

Article 2.1.4.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.4.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.4.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

Appendix XXIII (contd)Appendix VII (contd)

Article 2.1.4.9.bis

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from SVC

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.4.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

Article 2.1.4.10.

Importation of products from a country, zone or compartment declared free from SVC

When importing *aquatic animal products* of the species listed in Article 2.1.4.2., other than those *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* free from SVC, 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 2.1.4.4. or 2.1.4.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from SVC.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.4.11.

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

When importing *aquatic animal products* of the species listed in Article 2.1.4.2., other than those *commodities* listed in point 1) of Article 2.1.4.3., from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 2.1.4.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

CHAPTER 2.1.5.

VIRAL HAEMORRHAGIC SEPTICAEMIA

Article 2.1.5.1.

For the purposes of this *Aquatic Code*, viral haemorrhagic septicaemia (VHS) means infection with VHS virus (VHSV, synonym: Egtved virus) of the genus *Novirhabdovirus* of the family Rhabdoviridae.

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

Article 2.1.5.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for VHS are:

Atlantic salmon (*Salmo salar*), Atlantic cod (*Gadus morhua*), Atlantic herring (*Clupea harengus*), black cod (*Anaplopoma fimbria*), blue whiting (*Micromesistius poutassou*), brook trout (*Salvelinus fontinalis*), brown trout (*Salmo trutta*), chinook salmon (*Oncorhynchus tshawytscha*), coho salmon (*O. kisutch*), common dab (*Limanda limanda*), English sole (*Parophrys vetulus*), flounder (*Platichthys flesus*), golden trout (*Salmo aguabonita*), grayling (*Thymallus thymallus*), Greenland halibut (*Reinhardtius hippoglossoides*), haddock (*Melanogrammus aeglefinus*), Japanese flounder (*Paralichthys olivaceus*), lake trout (*Salvelinus namaycush*), lesser argentine (*Argentina sphyraena*), Norway pout (*Trisopterus esmarkii*), Pacific cod (*Gadus macrocephalus*), Pacific hake (*Merluccius productus*), Pacific herring (*Clupea harengus pallasii*), Pacific mackerel (*Scomber japonicus*), Pacific sandlance (*Ammodytes hexapterus*), pike (*Esox lucius*), pilchard (*Sardinops sagax*), plaice (*Pleuronectes platessa*), poor cod (*Trisopterus minutus*), rainbow trout (*Oncorhynchus mykiss*), rockling (*Rhinonemus cimbrius*), sea bass (*Dicentrarchus labrax*), shiner perch (*Cymatogaster aggregata*), smelt (*Thaleichthys pacificus*), sprat (*Sprattus sprattus*), surf smelt (*Hypomesus pretiosus pretiosus*), threespine stickleback (*Gasterosteus aculeatus*), turbot (*Scophthalmus maximus*), sand goby (*Pomatoschistus minutus*), walleye pollock (*Theragra chalcogramma*), whitefish (*Coregonus* sp.) and whiting (*Merlangius merlangus*).

Suspect cases of natural infection with VHSV 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 2.1.5.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any VHS related conditions, regardless of the VHS status of the *exporting country*, *zone* or *compartment*:
 - a) For the species in Article 2.1.5.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;

Appendix XXIII (contd)Appendix VIII (contd)

- b) The following products destined for human consumption⁷ from species in Article 2.1.5.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
- i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
- c) For species other than those in Article 2.1.5.2., all *aquatic animal products*.
2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.5.2., other than those listed in paragraph 1 of Article 2.1.5.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.5.7. to 2.1.5.11. of this Chapter, relevant to the VHS status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.5.2. from an *exporting country, zone or compartment* not declared free of VHS, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of VHSV, 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 2.1.5.4.

VHS free country

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

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself an VHS free country if all the areas covered by the shared water are declared VHS free countries or zones (see Article 2.1.5.5.).

1. A country where none of the species listed in Article 2.1.5.2. is present may declare itself free from VHS when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.5.2. 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 VHS when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

⁷ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

Appendix XXIII (contd)Appendix VIII (contd)

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 VHS when:
 - a) *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 last 2 years without detection of VHSV.

OR

4. A country that had declared itself free from VHS but in which the disease is detected may not declare itself free from VHS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of VHSV.

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 2.1.5.5.

Article 2.1.5.5.

VHS free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from VHS 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.5.2. is present may declare itself free from VHS when *basic biosecurity conditions* have been 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 2.1.5.2. 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 VHS when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

Appendix XXIII (contd)Appendix VIII (contd)

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 VHS when:
 - a) *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 last 2 years without detection of VHSV.

OR

4. A *zone* previously declared free from VHS but in which the disease is detected may not be declared free from VHS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of VHSV.

Article 2.1.5.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from VHS following the provisions of points 1) or 2) of Articles 2.1.5.4. or 2.1.5.5., respectively, may maintain its status as VHS free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from VHS following the provisions of point 3) of Articles 2.1.5.4. or 2.1.5.5., respectively, may discontinue *targeted surveillance* and maintain its status as VHS free provided that conditions that are conducive to clinical expression of VHS, 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 VHS, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Appendix XXIII (contd)Appendix VIII (contd)

Article 2.1.5.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.5.2., other than *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* declared free from VHS, 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 2.1.5.4. or 2.1.5.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from VHS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.5.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.5.2., other than those *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

Article 2.1.5.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.5.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.5.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

Appendix XXIII (contd)Appendix VIII (contd)

Article 2.1.5.9.bis

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from VHS

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.5.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

Article 2.1.5.10.

Importation of products from a country, zone or compartment declared free from VHS

When importing *aquatic animal products* of the species listed in Article 2.1.5.2., other than those *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* free from VHS, 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 2.1.5.4. or 2.1.5.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from VHS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.5.11.

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

When importing *aquatic animal products* of the species listed in Article 2.1.5.2., other than those *commodities* listed in point 1) of Article 2.1.5.3., from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 2.1.5.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of VHSV

CHAPTER 2.1.9.

INFECTIOUS SALMON ANAEMIA

Article 2.1.9.1.

For the purposes of this *Aquatic Code*, infectious salmon anaemia (ISA) means infection with ISA virus (ISAV) of the genus *Isavirus* of the family Orthomyxoviridae.

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

Article 2.1.9.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for ISA are: Atlantic salmon (*Salmo salar*), brown and sea trout (*S. trutta*), pollock (*Pollachius virens*) and cod (*Gadus morhua*).

Suspect cases of natural infection with ISAV 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 2.1.9.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any ISA related conditions, regardless of the ISA status of the *exporting country*, *zone* or *compartment*:
 - a) For the species in Article 2.1.9.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following products destined for human consumption⁸ from species in Article 2.1.9.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;

⁸ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

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- iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
 - c) For species other than those in Article 2.1.9.2., all *aquatic animal products*.
2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.9.2., other than those listed in paragraph 1 of Article 2.1.9.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.9.7. to 2.1.9.11. of this Chapter, relevant to the ISA status of the *exporting country, zone or compartment*.
 3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.9.2. from an *exporting country, zone or compartment* not declared free of ISA, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of ISAV, 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 2.1.9.4.

ISA free country

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

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself an ISA free country if all the areas covered by the shared water are declared ISA free countries or zones (see Article 2.1.9.5.).

1. A country where none of the species listed in Article 2.1.9.2. is present may declare itself free from ISA when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.9.2. 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 ISA when *basic biosecurity conditions* have been 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 ISA when:
 - a) *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 last 2 years without detection of ISAV.

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OR

4. A country that had declared itself free from ISA but in which the disease is detected may not declare itself free from ISA 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of ISAV.

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 2.1.9.5.

Article 2.1.9.5.

ISA free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from ISA 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.9.2. is present may declare itself free from ISA when *basic biosecurity conditions* have been 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 2.1.9.2. 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 ISA when *basic biosecurity conditions* have been 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 ISA when:
 - a) *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 last 2 years without detection of ISAV.

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OR

4. A *zone* previously declared free from ISA but in which the disease is detected may not be declared free from ISA 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of ISAV.

Article 2.1.9.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from ISA following the provisions of points 1) or 2) of Articles 2.1.9.4. or 2.1.9.5., respectively, may maintain its status as ISA free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from ISA following the provisions of point 3) of Articles 2.1.9.4. or 2.1.9.5., respectively, may discontinue *targeted surveillance* and maintain its status as ISA free provided that conditions that are conducive to clinical expression of ISA, 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 ISA, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.9.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.9.2., other than *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* declared free from ISA, 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 2.1.9.4. or 2.1.9.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from ISA.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

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Article 2.1.9.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.9.2., other than those *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

Article 2.1.9.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.9.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.9.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

Article 2.1.9.9.bis

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from ISA

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.9.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

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Article 2.1.9.10.

Importation of products from a country, zone or compartment declared free of products from a country, zone or compartment declared free from ISA

When importing *aquatic animal products* of the species listed in Article 2.1.9.2., other than those *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* free from ISA, 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 2.1.9.4. or 2.1.9.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from ISA.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.9.11.

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

When importing *aquatic animal products* of the species listed in Article 2.1.9.2., other than those *commodities* listed in point 1) of Article 2.1.9.3., from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures. In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 2.1.9.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of ISA.

CHAPTER 2.1.10.

EPIZOOTIC ULCERATIVE SYNDROME

Article 2.1.10.1.

For the purposes of this *Aquatic Code*, epizootic ulcerative syndrome (EUS) means infection with the Oomycete fungus *Aphanomyces invadans*.

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

Article 2.1.10.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for EUS are: Seabream, yellowfin (*Acantopagrus australis*); Perch, climbing (*Anabas testudineus*); Eels (Anguillidae); Catfishes, bagrid (Bagridae); Perch, silver (*Bidyanus bidyanus*); Menhaden, Atlantic (*Brevoortia tyrannus*); Jacks (*Caranx* spp.); Catla (*Catla catla*); Snakehead, striped (*Channa striatus*); Cichlids (Cichlidae); Mrigal (*Cirrhinus mrigala*); Catfishes, torpedo-shaped (*Clarius* spp.); Cyprinids (Cyprinidae); Grouper, brown-spotted and greasy (*Epinephelus tawina*); Flying fishes, Halfbeaks (Exocoetidae); Goby, tank (*Glossogobius giuris*); Gobies (Gobiidae); Roho (*Labeo rohita*); Rhinofishes (*Labeo* spp.); Barramundi and Perch, giant sea (*Lates calcarifer*); Mullet, striped (*Mugil cephalus*); Mulletts [Mugilidae (*Mugil* spp.; *Liza* spp.)]; Ayu (*Plecoglossus altivelis*); Barb, pool (*Puntius sophore*); Grunter, barcoo (*Scortum barcoo*); Whiting, sand (*Sillago ciliata*); Catfishes, wells (Siluridae); Gourami, snakeskin (*Trichogaster pectoralis*).

Suspect cases of natural infection with *A. invadans* 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 2.1.10.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any EUS related conditions, regardless of the EUS status of the *exporting country*, *zone* or *compartment*:
 - a) For the species in Article 2.1.10.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;

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- b) The following products destined for human consumption⁹ from species in Article 2.1.10.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
- i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
- c) For species other than those in Article 2.1.10.2., all *aquatic animal products*.
2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.10.2., other than those listed in paragraph 1 of Article 2.1.10.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.10.7. to 2.1.10.11. of this Chapter, relevant to the EUS status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.10.2. from an *exporting country*, *zone* or *compartment* not declared free of EUS, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *A. invadans*, 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 2.1.10.4.

EUS free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an EUS free country if all the areas covered by the shared water are declared EUS free countries or zones (see Article 2.1.10.5.).

1. A country where none of the species listed in Article 2.1.10.2. is present may declare itself free from EUS when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

⁹ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

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2. A country where the species listed in Article 2.1.10.2. 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 EUS when *basic biosecurity conditions* have been 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 EUS when:
- a) *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 last 2 years without detection of *A. invadans*.

OR

4. A country that had declared itself free from EUS but in which the disease is detected may not declare itself free from EUS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of *A. invadans*.

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 2.1.10.5.

Article 2.1.10.5.

EUS free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from EUS 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.10.2. is present may declare itself free from EUS when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

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OR

2. A *zone* or *compartment* where the species listed in Article 2.1.10.2. 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 EUS when *basic biosecurity conditions* have been 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 EUS when:
- a) *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 last 2 years without detection of *A. invadans*.

OR

4. A *zone* previously declared free from EUS but in which the disease is detected may not be declared free from EUS 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of *A. invadans*.

Article 2.1.10.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from EUS following the provisions of points 1) or 2) of Articles 2.1.10.4. or 2.1.10.5., respectively, may maintain its status as EUS free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from EUS following the provisions of point 3) of Articles 2.1.10.4. or 2.1.10.5., respectively, may discontinue *targeted surveillance* and maintain its status as EUS free provided that conditions that are conducive to clinical expression of EUS, as described in Chapter X.X.X. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

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

Article 2.1.10.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.10.2., other than *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* declared free from EUS, 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 2.1.10.4. or 2.1.10.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from EUS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.10.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.10.2., other than those *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *A. invadans*.

Article 2.1.10.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.10.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.10.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.10.3. or other products authorised by the competent authority; and

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2. all effluent and waste material are treated in a manner that ensures inactivation of *A. invadans*.

Article 2.1.10.9.bis

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from EUS

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.10.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.10.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *A. invadans*.

Article 2.1.10.10.

Importation of products from a country, zone or compartment declared free from EUS

When importing *aquatic animal products* of the species listed in Article 2.1.10.2., other than those *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* free from EUS, 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 2.1.10.4. or 2.1.10.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from EUS.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.10.11.

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

When importing *aquatic animal products* of the species listed in Article 2.1.10.2., other than those *commodities* listed in point 1) of Article 2.1.10.3., from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 2.1.10.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of *A. invadans*

CHAPTER 2.1.14.

GYRODACTYLOSIS
(*Gyrodactylus salaris*)

Article 2.1.14.1.

For the purposes of this *Aquatic Code*, Gyrodactylosis means *infection* with the viviparous freshwater ectoparasite *Gyrodactylus salaris* (Platyhelminthes; Monogenea).

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

Article 2.1.14.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for Gyrodactylosis (in declining order of susceptibility) are: Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), Arctic char (*Salvelinus alpinus*), North American brook trout (*Salvelinus fontinalis*), grayling (*Thymallus thymallus*), North American lake trout (*Salvelinus namaycush*) and brown trout (*Salmo trutta*).

Suspect cases of natural infection with *G. salaris* 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 2.1.14.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any Gyrodactylosis related conditions, regardless of the Gyrodactylosis status of the *exporting country, zone or compartment*:
 - a) For the species in Article 2.1.14.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following products destined for human consumption¹⁰ from species in Article 2.1.14.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);

¹⁰ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

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- iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;
 - iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
- c) For species other than those in Article 2.1.14.2., all *aquatic animal products*.
2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.14.2., other than those listed in paragraph 1 of Article 2.1.14.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.14.7. to 2.1.14.11. of this Chapter, relevant to the Gyrodactylosis status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.14.2. from an *exporting country*, *zone* or *compartment* not declared free of Gyrodactylosis, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *G. salaris*, 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 2.1.14.4.

Gyrodactylosis free country

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

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself an Gyrodactylosis free country if all the areas covered by the shared water are declared Gyrodactylosis free countries or zones (see Article 2.1.14.5.).

1. A country where none of the species listed in Article 2.1.14.2. is present may declare itself free from Gyrodactylosis when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.14.2. 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 Gyrodactylosis when *basic biosecurity conditions* have been 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 Gyrodactylosis when:

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

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- 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 years without detection of *G. salaris*.

OR

4. A country that had declared itself free from Gyrodactylosis but in which the disease is detected may not declare itself free from Gyrodactylosis again until the following conditions have been met:
- on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - 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 years without detection of *G. salaris*.

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 2.1.14.5.

Article 2.1.14.5.

Gyrodactylosis free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from Gyrodactylosis 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 points 1), 2), 3) or 4) below.

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

- A *zone* or *compartment* where none of the species listed in Article 2.1.14.2. is present may declare itself free from Gyrodactylosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

- A *zone* or *compartment* where the species listed in Article 2.1.14.2. 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 Gyrodactylosis when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

- 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 Gyrodactylosis when:
 - basic biosecurity conditions* have been met continuously for at least the past 2 years; and
 - 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 years without detection of *G. salaris*.

Appendix XXIII (contd)Appendix XI (contd)

OR

4. A *zone* previously declared free from Gyrodactylosis but in which the disease is detected may not be declared free from Gyrodactylosis 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of *G. salaris*.

Article 2.1.14.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from Gyrodactylosis following the provisions of points 1) or 2) of Articles 2.1.14.4. or 2.1.14.5., respectively, may maintain its status as Gyrodactylosis free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from Gyrodactylosis following the provisions of point 3) of Articles 2.1.14.4. or 2.1.14.5., respectively, may discontinue *targeted surveillance* and maintain its status as Gyrodactylosis free provided that conditions that are conducive to clinical expression of Gyrodactylosis, 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 Gyrodactylosis, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.14.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.14.2., other than *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* declared free from Gyrodactylosis, 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 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from Gyrodactylosis.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Appendix XXIII (contd)Appendix XI (contd)

Article 2.1.14.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.14.2., other than those *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*.

Article 2.1.14.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.14.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should require:

1. a certificate from the *Competent Authority* of the exporting country stating that the fish have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days.

OR

2. a) the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.14.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*.

Article 2.1.14.9.bis

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from Gyrodactylosis

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.14.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should require:

Appendix XXIII (contd)Appendix XI (contd)

1. a certificate from the *Competent Authority* of the exporting country stating that the fish have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days.

OR

2. a) the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.14.3. or other products authorised by the competent authority; and
 - b) all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*.

Article 2.1.14.10.

Importation of products from a country, zone or compartment declared free from Gyrodactylosis

When importing *aquatic animal products* of the species listed in Article 2.1.14.2., other than those *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* free from Gyrodactylosis, 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 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from Gyrodactylosis.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1..

Article 2.1.14.11.

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

When importing *aquatic animal products* of the species listed in Article 2.1.14.2., other than those *commodities* listed in point 1) of Article 2.1.14.3., from a country, *zone* or *compartment* not declared free from Gyrodactylosis, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 2.1.14.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of *G. salaris*;

Appendix XXIII (contd)

Appendix XI (contd)

OR

- c) the *Competent Authority* of the *importing country* should require a certificate from the *Competent Authority* of the *exporting country* attesting that the product was derived from fish which had been held, immediately prior to processing, in water with a salinity of at least 25 parts per thousand for a continuous period of 14 days.
-

CHAPTER 2.1.15.

RED SEA BREAM IRIDOVIRAL DISEASE

Article 2.1.15.1.

For the purposes of this *Aquatic Code*, red sea bream iridoviral disease (RSIVD) means infection with red sea bream iridovirus (RSIV) of the family Iridoviridae.

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

Article 2.1.15.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for RSIVD are: red sea bream (*Pagrus major*), yellowtail (*Seriola quinqueradiata*), amberjack (*Seriola dumerili*), sea bass (*Lateolabrax* sp., *Lates calcarifer*), Albacore (*Thunnus thynnus*), Japanese parrotfish (*Oplegnathus fasciatus*), striped jack (*Caranx delicatissimus*), mandarin fish (*Siniperca chuatsi*), red drum (*Sciaenops ocellatus*), mullet (*Mugil cephalus*) and groupers (*Epinephelus* spp.).

Suspect cases of natural infection with RSIV 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 2.1.15.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any RSIVD related conditions, regardless of the RSIVD status of the *exporting country, zone or compartment*:
 - a) For the species in Article 2.1.2.2. for any purpose:
 - i) Commercially sterile canned fish;
 - ii) Leather made from fish skin;
 - b) The following products destined for human consumption¹¹ from species in Article 2.1.2.2 which have been prepared in such a way to minimise the risk of diversion for alternative uses:
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals, fish oil);
 - iii) Eviscerated fish (chilled or frozen) packaged for direct retail trade;

¹¹ A Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any other purpose than for human consumption.

Appendix XXIII (contd)Appendix XII (contd)

- iv) Fillets or cutlets (chilled or frozen);
 - v) Dried eviscerated fish (including air dried, flame dried, sun dried);
- c) For species other than those in Article 2.1.2.2., all *aquatic animal products*.
2. When authorising import or transit of the *commodities*, of a species listed in Article 2.1.2.2., other than those listed in paragraph 1 of Article 2.1.2.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.2.7. to 2.1.2.11. of this Chapter, relevant to the RSIVD status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any live *commodity* of a species not listed in Article 2.1.2.2. from an *exporting country, zone or compartment* not declared free of RSIVD, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of RSIV, 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 2.1.15.4.

RSIVD free country

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

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself an RSIVD free country if all the areas covered by the shared water are declared RSIVD free countries or zones (see Article 2.1.15.5.).

1. A country where none of the species listed in Article 2.1.15.2. is present may declare itself free from RSIVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 2.1.15.2. 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 RSIVD when *basic biosecurity conditions* have been 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 RSIVD when:
- a) *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 last 2 years without detection of RSIV.

OR

4. A country that had declared itself free from RSIVD but in which the disease is detected may not declare itself free from RSIVD 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of RSIV.

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 2.1.15.5.

Article 2.1.15.5.

RSIVD free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from RSIVD 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 points 1), 2), 3) or 4) below.

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

1. A *zone* or *compartment* where none of the species listed in Article 2.1.15.2. is present may declare itself free from RSIVD when *basic biosecurity conditions* have been 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 2.1.15.2. 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 RSIVD when *basic biosecurity conditions* have been 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 RSIVD when:
 - a) *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 last 2 years without detection of RSIV.

Appendix XXIII (contd)Appendix XII (contd)

OR

4. A *zone* previously declared free from RSIVD but in which the disease is detected may not be declared free from RSIVD 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 years without detection of RSIV.

Article 2.1.15.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from RSIVD following the provisions of points 1) or 2) of Articles 2.1.15.4. or 2.1.15.5., respectively, may maintain its status as RSIVD free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from RSIVD following the provisions of point 3) of Articles 2.1.15.4. or 2.1.15.5., respectively, may discontinue *targeted surveillance* and maintain its status as RSIVD free provided that conditions that are conducive to clinical expression of RSIVD, 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 RSIVD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 2.1.15.7.

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

When importing live *aquatic animals* of the species listed in Article 2.1.15.2., other than *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* declared free from RSIVD, 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 2.1.15.4. or 2.1.15.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from RSIVD.

The certificate shall be in accordance with the Model Certificate in Appendix 6.1.1..

Article 2.1.15.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 2.1.15.2., other than those *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* and their first generation progeny are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of RSIV.

Article 2.1.2.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products listed in paragraph 1 of Article 2.1.2.3. or other products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of RSIV.

Article 2.1.2.9.bis

Importation of live animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use from a country, zone or compartment not declared free from RSIVD

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, *aquatic animals* of the species listed in Article 2.1.2.2., other than any live *commodities* listed in paragraph 1) of Article 2.1.2.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the competent authority; and
2. all effluent and waste material are treated in a manner that ensures inactivation of RSIV.

Appendix XXIII (contd)Appendix XII (contd)

Article 2.1.15.10.

Importation of products from a country, zone or compartment declared free from RSIVD

When importing *aquatic animal products* of the species listed in Article 2.1.15.2., other than those *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* free from RSIVD, 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 2.1.15.4. or 2.1.15.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from RSIVD.

The certificate shall be in accordance with the Model Certificate in Appendix 6.2.1.

Article 2.1.15.11.

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

When importing *aquatic animal products* of the species listed in Article 2.1.15.2., other than those *commodities* listed in point 1) of Article 2.1.15.3., from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead fish, whether eviscerated or uneviscerated, such risk mitigation measures may include:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 2.1.15.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of RSIV



REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE CHAPTERS FOR MOLLUSC DISEASES FOR THE OIE AQUATIC ANIMAL HEALTH CODE

Paris, 27-29 July 2005

The OIE *ad hoc* Group on chapters for mollusc diseases of the OIE *Aquatic Animal Health Code (Aquatic Code)* held its meeting at the OIE Headquarters from 27-29 July 2005.

On behalf of the Director General of the OIE, Dr David Wilson welcomed the members of the *ad hoc* Group and thanked them for their willingness to be involved in addressing this mandate of the OIE.

The members of the OIE *ad hoc* Group are listed in [Appendix I](#). The Agenda adopted is given in [Appendix II](#), and the terms of reference in [Appendix III](#).

The Chair indicated that the terms of reference provided by the Aquatic Animals Commission should form the scope of the *ad hoc* group's work. The *ad hoc* Group noted the report of the *ad hoc* Group on fish disease chapters of the OIE *Aquatic Animal Health Code* and endorsed its approach and recommendations. The *ad hoc* Group based its work on this approach.

Internationally traded commodities for which no disease specific measures are required

The *ad hoc* Group acknowledged that the statements made by the *ad hoc* Group on fish disease chapters of the OIE *Aquatic Animal Health Code* also apply to molluscs. The scientific considerations underpinning the *ad hoc* Group recommendations may be found in the Proceedings of the OIE International Conference on Risk Analysis in Aquatic Animal Health (2000).

The *ad hoc* Group developed a summary table of internationally traded commodities for which no disease specific measures are required ([Appendix IV](#)). In defining the commodities from non susceptible species destined for any use, the *ad hoc* Group agreed that there are some species that have been demonstrated to be refractory to infection and there are many other species that have not been challenged for susceptibility. Therefore the column "Any *commodities* from these known non susceptible species destined for any use" in [Appendix IV](#) contains a positive list of known non susceptible species. Any species not listed in [Appendix IV](#) should be considered of undetermined susceptibility.

Commodities from susceptible species destined for human consumption, which have been prepared in such a way as to minimise the likelihood of diversion for alternative uses, are considered suitable for international trade regardless of the health status of the exporting country for a particular disease if they are not diverted from their normal use. The *ad hoc* Group stressed that, in case of diversion of the commodity, the risk posed by the commodity would no longer be negligible. In certain instances, for example with regard to *Perkinsus marinus* and *P. olsenii*, conventional use of certain commodities may pose a risk even without diversion (such as the water containing larvae or shucked shell containing remnant tissue). In such cases, the commodities were not regarded as safe for international trade even without diversion.

Appendix XXIV (contd)**Update of the chapters for the other OIE listed mollusc diseases**

The *ad hoc* Group reviewed the changes proposed to Chapter 2.1.1. by the *ad hoc* Group on fish disease chapters of the OIE *Aquatic Code* and, where applicable, revised Chapter 3.1.5. accordingly. The proposed Chapter 3.1.5. is attached as Appendix V.

Using Chapter 3.1.5. as a template, the *ad hoc* Group developed specific Chapters on: infection with *Bonamia exitiosa* (Appendix VI), infection with *Bonamia ostreae* (Appendix VII), infection with *Haplosporidium nelsoni* (Appendix VIII), infection with *Mikrocytos mackini* (Appendix IX), infection with *Perkinsus olseni* (Appendix X), infection with *Perkinsus marinus* (Appendix XI) and infection with *Xenohaliotis californiensis* (Appendix XII).

The *ad hoc* Group recommended to the Aquatic Animals Commission that chapters on infection with *H. nelsoni* and infection with *M. mackini* be included in the next edition of the Aquatic Code, despite the removal of these diseases from the OIE list of diseases. This recommendation is based on the need to provide trade guidance to OIE Member Countries. For the diseases that have been removed from the OIE list of diseases primarily based on the absence of international trade (infection with *Mikrocytos roughleyi* and infection with *Marteilia sydneyi*), the *ad hoc* Group recommended the removal of the corresponding chapter in the Aquatic Code. The *ad hoc* Group also recommended the removal of the Chapter on infection with *Haplosporidium costale* because of its removal from the OIE list of diseases based on the negligible impact of this disease.

The *ad hoc* Group recommended that for those diseases that have a chapter in the *Aquatic Code*, an updated corresponding chapter in the *Manual of Diagnostic Tests for Aquatic Animals* (*Aquatic Manual*) be retained; the reverse should also apply.

The *ad hoc* Group also recommended to the Aquatic Animals Commission that be included the date of the last significant update for chapters in the *Aquatic Manual* and in the *Aquatic Code*.

.../Appendices

**MEETING OF THE OIE AD HOC GROUP ON CHAPTERS FOR MOLLUSC DISEASES
FOR THE OIE AQUATIC ANIMAL HEALTH CODE**

Paris, 27-29 July 2005

List of Participants

MEMBERS OF THE AD HOC GROUP

Chair:

Dr Franck Berthe

Department of Pathology & Microbiology
Atlantic Veterinary College - UPEI
550 University Ave.
Charlottetown
Prince Edward Island, C1A 4P3
CANADA
Tel: + (1-902) 566-0868
Fax: +(1-902) 566-0851
Email: fberthe@upe.ca

Members:

Dr Eugene M. Bureson

Director for Research and
Advisory Services, Virginia Institute of Marine
Science, College of William and Mary, P.O. Box
1346, Gloucester Point, VA 23062
UNITED STATES OF AMERICA
Tel.: + (1-804) 684.7015
FAX: + (1-804) 684.70.97
E-mail: gene@vims.edu

Dr Mike Hine

Aquatic Animal Diseases
National Centre for Disease Investigation
MAF Operations, P.O. Box 40-742
Upper Hutt
NEW ZEALAND
Tel.: + (64-4) 526-5600
Fax: + (64-4) 526-5601
E-mail: hinem@maf.govt.nz

OIE HEADQUARTERS

Dr Bernard Vallat

Director General
OIE
12, Rue de Prony
75017 Paris
Tel: 33-(0) 1 44 15 18 88
Fax: 33-(0) 1 42 67 09 87
E-mail: oie@oie.int

Dr David Wilson

Head
International Trade Department
OIE
Tel: 33-(0) 1 44 15 18 88
Fax: 33-(0) 1 42 67 09 87
E-mail: d.wilson@oie.int

Dr Francesco Berlingieri

Deputy
International Trade Department
OIE
Tel: 33-(0) 1 44 15 18 88
Fax: 33-(0) 1 42 67 09 87
E-mail: f.berlingieri@oie.int

**MEETING OF THE OIE AD HOC GROUP ON CHAPTERS FOR MOLLUSC DISEASES
FOR THE OIE AQUATIC ANIMAL HEALTH CODE**

Paris, 27-29 July 2005

Adopted Agenda

Aquatic Animal Health Code

- c. identify safe commodities for the Article 3.1.5.3. (*Marteilia refringens*)
- d. draft new chapters for the other OIE listed mollusc diseases

***Ad hoc* Group on chapters for mollusc diseases
for the OIE *Aquatic Animal Health Code***

Terms of Reference

1. With respect to Article 3.1.5.3. (*Marteilia refringens*) of the *Aquatic Animal Health Code*, to identify measures applicable to commonly traded commodities to ensure their safety and to provide documented scientific justification for any recommendations.
 2. Using Chapter 3.1.5. (*Marteilia refringens*) in the *Aquatic Animal Health Code* as a model, to draft new chapters for the other OIE listed mollusc diseases and to provide documented scientific justification for any recommendations.
 3. To submit a report to the OIE Aquatic Animal Health Standards Commission **by 1 August 2005**.
 4. To consider comments received and submit a report to the Commission **by 15 February 2006**.
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SUMMARY TABLE OF THE INTERNATIONALLY TRADED COMMODITIES FOR WHICH NO DISEASE SPECIFIC MEASURES ARE REQUIRED				
Agent	Susceptible species *	Commodities from susceptible species destined for any use	Commodities from susceptible species destined only for human consumption	Any commodities from these known non susceptible species destined for any use **
<i>Bonamia ostreae</i>	<i>Ostrea</i> spp., <i>Crassostrea ariakensis</i>	Canned or cooked products, <i>Gametes</i> , <i>eggs</i> and larvae	Half-shell, chemically preserved products, non commercially sterile heat treated products, off the shell	<i>Crassostrea gigas</i> , <i>C. virginica</i> , <i>Mytilus edulis</i> , <i>M. galloprovincialis</i> , <i>Ruditapes decussatus</i> , <i>R. philippinarum</i>
<i>Bonamia exitiosa</i>	<i>Ostrea</i> spp.	Canned or cooked products, <i>Gametes</i> , <i>eggs</i> and larvae	Half-shell, chemically preserved products, non commercially sterile heat treated products, off the shell	<i>Crassostrea gigas</i> , <i>C. virginica</i> , <i>Saccostrea glomerata</i> ,
<i>Marteilia refringens</i>	<i>Ostrea</i> spp., <i>Mytilus edulis</i> , <i>M. galloprovincialis</i>	Canned or cooked products, <i>Gametes</i> , <i>eggs</i> and larvae	Half-shell, chemically preserved products, non commercially sterile heat treated products, off the shell	<i>Crassostrea gigas</i>
<i>Perkinsus marinus</i>	<i>Crassostrea virginica</i> , <i>C. gigas</i> , <i>C. ariakensis</i> , <i>Mya arenaria</i> , <i>Macoma balthica</i> , <i>Mercenaria mercenaria</i>	Canned or cooked products	Chemically preserved products, non commercially sterile heat treated products	
<i>Xenobalotus californiensis</i>	<i>H. cracherodii</i> , <i>H. sorenseni</i> , <i>H. rufescens</i> , <i>H. corrugata</i> , <i>H. fulgens</i> , <i>H. wallalensis</i> , <i>H. discus-hannai</i>	Canned or cooked products, shells, <i>Gametes</i>	Chemically preserved products, non commercially sterile heat treated products, off the shell eviscerated	
<i>Perkinsus olseni</i>	Bivalves and Abalone	Canned or cooked products, shells	Chemically preserved products, non commercially sterile heat treated products,	
<i>Mikrocytos mackini</i>	<i>Crassostrea gigas</i> , <i>C. virginica</i> , <i>Ostrea edulis</i> , <i>O. conchaphila</i>	Canned or cooked products, <i>Gametes</i> , <i>eggs</i> and larvae,	Chemically preserved products, non commercially sterile heat treated products, off the shell	
<i>Haplosporidium nelsoni</i>	<i>Crassostrea gigas</i> , <i>C. virginica</i>	Canned or cooked products, <i>Gametes</i> , <i>eggs</i> and larvae,	Half-shell, chemically preserved products, non commercially sterile heat treated products, off the shell	<i>Crassostrea ariakensis</i>

Appendix XXIV (contd)Appendix IV

- * World Organisation for Animal Health (OIE) (2005) Aquatic Animal Health Code, Eighth Edition, Paris, 568pp..
World Organisation for Animal Health (OIE) (2005) Diagnostic Manual for Aquatic Animal Diseases, Fourth Edition, Paris, 374pp..
OIE web site (<http://www.oie.int>)
OIE Collaborating Centre for Information on Aquatic Animal Diseases web site (<http://www.collabcen.net/>)
Synopsis of Infectious Diseases and Parasites of Commercially Exploited Shellfish web site (<http://www.pac.dfo-mpo.gc.ca/sci/shelldis/>)

- ** National surveillance data from EU, New Zealand, USA.
Culloty et al. 1999. Susceptibility of a number of bivalve species to the protozoan parasite *Bonamia ostreae* and their ability to act as vectors for this parasite. Diseases of Aquatic Organisms. 37(1): 73-80.
Calvo et al. 2001. A comparative field study of *Crassostrea ariakensis* and *Crassostrea virginica* in relation to salinity in Virginia. Journal of Shellfish Research 20(1):221-229.

CHAPTER 3.1.5.

INFECTION WITH MARTEILIA REFRINGENS

Article 3.1.5.1.

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 3.1.5.2.

Susceptible species

For the purposes of this *Aquatic Code*, known susceptible species for infection with *Marteilia refringens* are: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean oyster (*O. puelchana*) and Chilean flat oyster (*O. chilensis*), blue mussel (*Mytilus edulis*) and ~~m~~ Mediterranean mussel (*M. galloprovincialis*).

To date all species of the genera *Ostrea* and *Mytilus* exposed to *Marteilia refringens* have been susceptible to infection. Therefore all species of these genera should be regarded as potentially susceptible.

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 3.1.5.3.

Commodities

1. When authorising import or transit of the following *commodities* (~~under study~~), *Competent Authorities* should not require any *Marteilia refringens* related conditions, regardless of the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*:
 - a) From the species listed in Article 3.1.5.2. for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) Gametes, eggs and larvae;
 - b) The following products destined for human consumption from the species listed in Article 3.1.5.2. which have been prepared in such a way as to minimise the risk for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);

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- c) For *Crassostrea gigas*, all products.
2. When authorising import or transit of the ~~following commodities~~ of a species listed in Article 3.1.5.2., other than commodities listed in point 1 of Article 3.1.5.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.5.7. to 3.1.5.11. 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 any other commodity from bivalve species not listed in Article 3.1.5.2. (especially *Ostrea* and *Mytilus* spp.)~~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 3.1.5.4.

***Marteilia refringens* free country**

A country may declare itself free from *Marteilia refringens* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a ~~water catchment or coastal~~ zone or compartment 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 are declared *Marteilia refringens* free zones (see Article 3.1.5.5.).

1. A country where ~~none of the species of genera *Ostrea* and *Mytilus* listed in Article 3.1.5.2.~~ is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years[†].

OR

2. A country where the species listed in Article 3.1.5.2. are present but there has never been any observed occurrence of the ~~disease~~ 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 3.1.5. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been 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~~ 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) *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 years² without detection of *Marteilia refringens*.

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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:
- on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - 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 3.1.5.5.

Article 3.1.5.5.

***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 points 1), 2), 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*.

- In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where ~~none of the species of genera *Ostrea* and *Mytilus* listed in Article 3.1.5.2.~~ is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years².

OR

- In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where the species listed in Article 3.1.5.2. are present but there has never been any observed occurrence of the ~~disease~~ *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 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.

OR

- 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:

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- a) ~~basic biosecurity~~ 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 years² 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3.1.5.6.

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 3.1.5.4. or 3.1.5.5., 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 3.1.5.4. or 3.1.5.5., 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.

However, for declared free *zones* or *compartments* 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 3.1.5.7.

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 3.1.5.2., other than *commodities* listed in point 1) of Article 3.1.5.3., 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 3.1.5.4. or 3.1.5.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

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The certificate shall be in accordance with the Model Certificate No. 3 in Appendix 6.3.1. given in Part 6. of this Aquatic Code.

Article 3.1.5.8.

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

When importing for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.5.2., other than those *commodities* listed in point 1) of Article 3.1.5.3., 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:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Marteilia refringens*.

Article 3.1.5.9.

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 3.1.5.2., other than any ~~those~~ live *commodities* listed in point 1) of Article 3.1.5.3., from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should require ~~assess the risk and apply risk mitigation measures such as:~~

1. the consignment is delivered directly to and held in *quarantine* facilities ~~for a short period before~~ until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Marteilia refringens*.

Article 3.1.5.10.

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

When importing *aquatic animal products* of the species listed in Article 3.1.5.2., other than *commodities* listed in point 1) of Article 3.1.5.3., 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 3.1.5.4. or 3.1.5.5. (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 the Model Certificate No. [X] in Appendix 6.3.2.. given in Part 6. of this Aquatic Code.

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Article 3.1.5.11.

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 3.1.5.2., other than those *commodities* listed in point 1) of Article 3.1.5.3., 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.

- ~~1- 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.~~
- ~~2- 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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CHAPTER 3.1.2.

INFECTION WITH *BONAMIA EXITIOSA*

Article 3.1.2.1.

For the purposes of this *Aquatic Code*, infection with *Bonamia exitiosa* means infection only with *Bonamia exitiosa*.

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

Article 3.1.2.2.

Susceptible species

For the purposes of this *Aquatic Code*, known *susceptible species* for infection with *Bonamia exitiosa* are: Australian mud oyster (*Ostrea angasi*), and Chilean flat oyster (*O. chilensis*).

Bonamia isolates closely related to *Bonamia exitiosa* have been reported from *O. puelchana* and *Crassostrea ariakensis*. All *Ostrea* spp. should be regarded as potentially susceptible.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Bonamia exitiosa* 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 3.1.2.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Bonamia exitiosa* related conditions, regardless of the *Bonamia exitiosa* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.2.2. for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) *Gametes, eggs and larvae*;
 - b) The following products destined for human consumption from the species listed in Article 3.1.2.2. which have been prepared in such a way as to minimise the risk for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);
 - c) For *Crassostrea gigas*, *C. virginica* and *Saccostrea glomerata* all products.

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2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.2.2., other than *commodities* listed in point 1 of Article 3.1.2.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.2.7. to 3.1.2.11. of this Chapter, relevant to the *Bonamia exitiosa* status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any other commodity from bivalve species not listed in Article 3.1.2.2. (especially *Ostrea* spp.) from an *exporting country, zone or compartment* not declared free of *Bonamia exitiosa*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Bonamia exitiosa*, 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 3.1.2.4.

***Bonamia exitiosa* free country**

A country may declare itself free from *Bonamia exitiosa* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself a *Bonamia exitiosa* free country if all the areas covered by the shared water are declared *Bonamia exitiosa* free zones (see Article 3.1.2.5.).

1. A country where no species of the genus *Ostrea* is present may declare itself free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 3.1.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 3.1.2. of the *Aquatic Manual*, may declare itself free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Bonamia exitiosa* 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 *Bonamia exitiosa* when:
 - a) *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 *Bonamia exitiosa*.

OR

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

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- a) on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
- b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia exitiosa*.

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 3.1.2.5.

Article 3.1.2.5.

***Bonamia exitiosa* free zone or free compartment**

A *zone* or *compartment* free from *Bonamia exitiosa* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia exitiosa* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia exitiosa* 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 *Bonamia exitiosa*, a *zone* or *compartment* where no species of the genus *Ostrea* is present may declare itself free from *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia exitiosa*, a *zone* or *compartment* where the species listed in Article 3.1.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – 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 *Bonamia exitiosa* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia exitiosa* is not known to be established in wild populations.

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 *Bonamia exitiosa* when:
 - a) *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 *Bonamia exitiosa*.

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OR

4. A *zone* previously declared free from *Bonamia exitiosa* but in which the disease is detected may not be declared free from *Bonamia exitiosa* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia exitiosa*.

Article 3.1.2.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of points 1) or 2) of Articles 3.1.2.4. or 3.1.2.5., respectively, may maintain its status as *Bonamia exitiosa* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of point 3) of Articles 3.1.2.4. or 3.1.2.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Bonamia exitiosa* free provided that conditions that are conducive to clinical expression of infection with *Bonamia exitiosa*, 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 infection with *Bonamia exitiosa*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.2.7.

Importation of live animals from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing live *aquatic animals* of the species listed in Article 3.1.2.2., other than *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* declared free from *Bonamia exitiosa*, 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 3.1.2.4. or 3.1.2.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

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Article 3.1.2.8.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.2.2., other than those *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia exitiosa*.

Article 3.1.2.9.

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

When importing, for processing and/or human consumption, *aquatic animals* of the species listed in Article 3.1.2.2., other than any live *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia exitiosa*.

Article 3.1.2.10.

Importation of products from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of the species listed in Article 3.1.2.2., other than *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* free from *Bonamia exitiosa*, 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 3.1.2.4. or 3.1.2.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Appendix XXIV (contd)

Appendix VI (contd)

Article 3.1.2.11.

Importation of products from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of the species listed in Article 3.1.2.2., other than those *commodities* listed in point 1) of Article 3.1.2.3., from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 3.1.1.

INFECTION WITH *BONAMIA OSTREAE*

Article 3.1.1.1.

For the purposes of this *Aquatic Code*, infection with *Bonamia ostreae* means infection only with *Bonamia ostreae*.

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

Article 3.1.1.2.

Susceptible species

For the purposes of this *Aquatic Code*, known *susceptible species* for infection with *Bonamia ostreae* are: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean flat oyster (*O. puelchana*), Chilean flat oyster (*O. chilensis*), Asiatic oyster (*O. denselammellosa*) and Suminoe oyster (*Crassostrea ariakensis*).

To date all species of the genus *Ostrea* (except *O. conchaphila*) exposed to *Bonamia ostreae* have been susceptible to *infection*. Therefore all species of this genus should be regarded as potentially susceptible.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Bonamia ostreae* 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 3.1.1.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Bonamia ostreae* related conditions, regardless of the *Bonamia ostreae* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.1.2. for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) *Gametes, eggs* and larvae;
 - b) The following products destined for human consumption from the species listed in Article 3.1.1.2. which have been prepared in such a way as to minimise the risk for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);

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- c) For *Crassostrea gigas*, *C. virginica*, *Ruditapes decussatus*, *R. philippinarum*, *Mytilus galloprovincialis* and *M. edulis* all products.
2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.1.2., other than *commodities* listed in point 1 of Article 3.1.1.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.1.7. to 3.1.1.11. of this Chapter, relevant to the *Bonamia ostreae* status of the *exporting country*, *zone* or *compartment*.
 3. When considering the import or transit of any other commodity from bivalve species not listed in Article 3.1.1.2. (especially *Ostrea* spp.) from an *exporting country*, *zone* or *compartment* not declared free of *Bonamia ostreae*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Bonamia ostreae*, 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 3.1.1.4.

***Bonamia ostreae* free country**

A country may declare itself free from *Bonamia ostreae* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Bonamia ostreae* free country if all the areas covered by the shared water are declared *Bonamia ostreae* free zones (see Article 3.1.1.5.).

1. A country where no species of the genus *Ostrea* is present may declare itself free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 3.1.1.2. 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 3.1.1. of the *Aquatic Manual*, may declare itself free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Bonamia ostreae* 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 *Bonamia ostreae* when:
 - a) *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 *Bonamia ostreae*.

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OR

4. A country that had declared itself free from *Bonamia ostreae* but in which the disease is detected may not declare itself free from *Bonamia ostreae* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia ostreae*.

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 3.1.1.5.

Article 3.1.1.5.

***Bonamia ostreae* free zone or free compartment**

A *zone* or *compartment* free from *Bonamia ostreae* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia ostreae* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia ostreae* 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 *Bonamia ostreae*, a *zone* or *compartment* where no species of the genus *Ostrea* is present may declare itself free from *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia ostreae*, a *zone* or *compartment* where the species listed in Article 3.1.1.2. 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 *Bonamia ostreae* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia ostreae* is not known to be established in wild populations.

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 *Bonamia ostreae* when:

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- a) *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 *Bonamia ostreae*.

OR

4. A *zone* previously declared free from *Bonamia ostreae* but in which the disease is detected may not be declared free from *Bonamia ostreae* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Bonamia ostreae*.

Article 3.1.1.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of points 1) or 2) of Articles 3.1.1.4. or 3.1.1.5., respectively, may maintain its status as *Bonamia ostreae* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of point 3) of Articles 3.1.1.4. or 3.1.1.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Bonamia ostreae* free provided that conditions that are conducive to clinical expression of infection with *Bonamia ostreae*, 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 infection with *Bonamia ostreae*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.1.7.

Importation of live animals from a country, zone or compartment declared free from *Bonamia ostreae*

When importing live *aquatic animals* of the species listed in Article 3.1.1.2., other than *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* declared free from *Bonamia ostreae*, 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 3.1.1.4. or 3.1.1.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

Appendix XXIV (contd)Appendix VII (contd)

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.1.8.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.1.2., other than those *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia ostreae*.

Article 3.1.1.9.

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

When importing, for processing and/or human consumption, *aquatic animals* of the species listed in Article 3.1.1.2., other than any live *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Bonamia ostreae*.

Article 3.1.1.10.

Importation of products from a country, zone or compartment declared free from *Bonamia ostreae*

When importing *aquatic animal products* of the species listed in Article 3.1.1.2., other than *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* free from *Bonamia ostreae*, 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 3.1.1.4. or 3.1.1.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

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Article 3.1.1.11.

Importation of products from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing *aquatic animal products* of the species listed in Article 3.1.1.2., other than those *commodities* listed in point 1) of Article 3.1.1.3., from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 3.1.4.

INFECTION WITH *HAPLOSPORIDIUM NELSONI*

Article 3.1.4.1.

For the purposes of this *Aquatic Code*, infection with *Haplosporidium nelsoni* means infection only with *Haplosporidium nelsoni*.

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

Article 3.1.4.2.

Susceptible species

For the purposes of this *Aquatic Code*, known *susceptible species* for infection with *Haplosporidium nelsoni* are: Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*).

Clinical manifestations and disease are mainly observed in *C. virginica*.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Haplosporidium nelsoni* 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 3.1.4.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Haplosporidium nelsoni* related conditions, regardless of the *Haplosporidium nelsoni* status of the *exporting country*, *zone* or *compartment*:
 - a) From the species listed in Article 3.1.4.2. for any purpose:
 - i) Commercially-sterile canned or cooked products;
 - ii) *Gametes*, *eggs* and *larvae*;
 - b) The following products destined for human consumption from the species listed in Article 3.1.4.2. which have been prepared in such a way as to minimise the risk for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
 - iv) Half-shell (chilled);
 - c) For *Crassostrea ariakensis*, all products.

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2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.4.2., other than *commodities* listed in point 1 of Article 3.1.4.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.4.7. to 3.1.4.11. of this Chapter, relevant to the *Haplosporidium nelsoni* status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any other commodity from bivalve species not listed in Article 3.1.4.2. from an *exporting country, zone or compartment* not declared free of *Haplosporidium nelsoni*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Haplosporidium nelsoni*, 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 3.1.4.4.

***Haplosporidium nelsoni* free country**

A country may declare itself free from *Haplosporidium nelsoni* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself a *Haplosporidium nelsoni* free country if all the areas covered by the shared water are declared *Haplosporidium nelsoni* free zones (see Article 3.1.4.5.).

1. A country where no species listed in Article 3.1.4.2. are present may declare itself free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 3.1.4.2. 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 3.1.4. of the *Aquatic Manual*, may declare itself free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Haplosporidium nelsoni* 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 *Haplosporidium nelsoni* when:
 - a) *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 *Haplosporidium nelsoni*.

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OR

4. A country that had declared itself free from *Haplosporidium nelsoni* but in which the disease is detected may not declare itself free from *Haplosporidium nelsoni* again until the following conditions have been met:
- on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - 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 *Haplosporidium nelsoni*.

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 3.1.4.5.

Article 3.1.4.5.

***Haplosporidium nelsoni* free zone or free compartment**

A *zone* or *compartment* free from *Haplosporidium nelsoni* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Haplosporidium nelsoni* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

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

- In a country of unknown status for *Haplosporidium nelsoni*, a *zone* or *compartment* where none of the species listed in Article 3.1.4.2. is present may declare itself free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

- In a country of unknown status for *Haplosporidium nelsoni*, a *zone* or *compartment* where the species listed in Article 3.1.4.2. 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 *Haplosporidium nelsoni* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Haplosporidium nelsoni* is not known to be established in wild populations.

OR

- 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 *Haplosporidium nelsoni* when:

Appendix XXIV (contd)Appendix VIII (contd)

- a) *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 *Haplosporidium nelsoni*.

OR

4. A *zone* previously declared free from *Haplosporidium nelsoni* but in which the disease is detected may not be declared free from *Haplosporidium nelsoni* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Haplosporidium nelsoni*.

Article 3.1.4.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of points 1) or 2) of Articles 3.1.4.4. or 3.1.4.5., respectively, may maintain its status as *Haplosporidium nelsoni* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of point 3) of Articles 3.1.4.4. or 3.1.4.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Haplosporidium nelsoni* free provided that conditions that are conducive to clinical expression of infection with *Haplosporidium nelsoni*, 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 infection with *Haplosporidium nelsoni*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.4.7.

Importation of live animals from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing live *aquatic animals* of the species listed in Article 3.1.4.2., other than *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*, 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 3.1.4.4. or 3.1.4.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

Appendix XXIV (contd)Appendix VIII (contd)

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.4.8.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.4.2., other than those *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

Article 3.1.4.9.

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

When importing, for processing and/or human consumption, *aquatic animals* of the species listed in Article 3.1.4.2., other than any live *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

Article 3.1.4.10.

Importation of products from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing *aquatic animal products* of the species listed in Article 3.1.4.2., other than *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* free from *Haplosporidium nelsoni*, 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 3.1.4.4. or 3.1.4.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Appendix XXIV (contd)

Appendix VIII (contd)

Article 3.1.4.11.

Importation of products from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing *aquatic animal products* of the species listed in Article 3.1.4.2., other than those *commodities* listed in point 1) of Article 3.1.4.3., from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

CHAPTER 3.1.7.

INFECTION WITH *MIKROCYTOS MACKINI*

Article 3.1.7.1.

For the purposes of this *Aquatic Code*, infection with *Mikrocytos mackini* means infection only with *Mikrocytos mackini*.

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

Article 3.1.7.2.

Susceptible species

For the purposes of this *Aquatic Code*, known *susceptible species* for infection with *Mikrocytos mackini* are: European flat oyster (*Ostrea edulis*), Olympia oyster (*O. conchaphila*), Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*).

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Mikrocytos mackini* 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 3.1.7.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Mikrocytos mackini* related conditions, regardless of the *Mikrocytos mackini* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.7.2. for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) *Gametes, eggs and larvae*;
 - b) The following products destined for human consumption from the species listed in Article 3.1.7.2. which have been prepared in such a way as to minimise the risk for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell (chilled or frozen) packaged for direct retail trade;
2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.7.2., other than *commodities* listed in point 1 of Article 3.1.7.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.7.7. to 3.1.7.11. of this Chapter, relevant to the *Mikrocytos mackini* status of the *exporting country, zone or compartment*.

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3. When considering the import or transit of any other commodity from bivalve species not listed in Article 3.1.7.2. (especially ostreids) from an *exporting country*, *zone* or *compartment* not declared free of *Mikrocytos mackini*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Mikrocytos mackini*, 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 3.1.7.4.

***Mikrocytos mackini* free country**

A country may declare itself free from *Mikrocytos mackini* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Mikrocytos mackini* free country if all the areas covered by the shared water are declared *Mikrocytos mackini* free zones (see Article 3.1.7.5.).

1. A country where no species listed in Article 3.1.7.2. are present may declare itself free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 3.1.7.2. 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 3.1.7. of the *Aquatic Manual*, may declare itself free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Mikrocytos mackini* 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 *Mikrocytos mackini* when:

- a) *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 *Mikrocytos mackini*.

OR

4. A country that had declared itself free from *Mikrocytos mackini* but in which the disease is detected may not declare itself free from *Mikrocytos mackini* 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

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- b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Mikrocytos mackini*.

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 3.1.7.5.

Article 3.1.7.5.

***Mikrocytos mackini* free zone or free compartment**

A *zone* or *compartment* free from *Mikrocytos mackini* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Mikrocytos mackini* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Mikrocytos mackini* 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 *Mikrocytos mackini*, a *zone* or *compartment* where none of the species listed in Article 3.1.7.2. is present may declare itself free from *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where the species listed in Article 3.1.7.2. 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 *Mikrocytos mackini* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

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 *Mikrocytos mackini* when:
 - a) *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 *Mikrocytos mackini*.

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OR

4. A *zone* previously declared free from *Mikrocytos mackini* but in which the disease is detected may not be declared free from *Mikrocytos mackini* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Mikrocytos mackini*.

Article 3.1.7.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of points 1) or 2) of Articles 3.1.7.4. or 3.1.7.5., respectively, may maintain its status as *Mikrocytos mackini* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of point 3) of Articles 3.1.7.4. or 3.1.7.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Mikrocytos mackini* free provided that conditions that are conducive to clinical expression of infection with *Mikrocytos mackini*, 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 infection with *Mikrocytos mackini*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.7.7.

Importation of live animals from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing live *aquatic animals* of the species listed in Article 3.1.7.2., other than *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, 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 3.1.7.4. or 3.1.7.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Appendix XXIV (contd)Appendix IX (contd)

Article 3.1.7.8.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.7.2., other than those *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Mikrocytos mackini*.

Article 3.1.7.9.

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

When importing, for processing and/or human consumption, *aquatic animals* of the species listed in Article 3.1.7.2., other than any live *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Mikrocytos mackini*.

Article 3.1.7.10.

Importation of products from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of the species listed in Article 3.1.7.2., other than *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* free from *Mikrocytos mackini*, 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 3.1.7.4. or 3.1.7.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Appendix XXIV (contd)Appendix IX (contd)

Article 3.1.7.11.

Importation of products from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of the species listed in Article 3.1.7.2., other than those *commodities* listed in point 1) of Article 3.1.7.3., from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

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CHAPTER 3.1.9.

INFECTION WITH *PERKINSUS OLSENI*

Article 3.1.9.1.

For the purposes of this *Aquatic Code*, infection with *Perkinsus olseni* means infection only with *Perkinsus olseni*.

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

Article 3.1.9.2.

Susceptible species

For the purposes of this *Aquatic Code*, known *susceptible species* for infection with *Perkinsus olseni* are: primarily venerid clams (*Austrovenus stutchburyi*, *Venerupis pullastra* *V. aurea*, *Ruditapes decussatus*, *R. philippinarum*), abalone (*Haliotis rubra*, *H. laevigata*, *H. cyclobates*, *H. scalaris*) and other species (*Anadara trapezia*, *Barbatia novaezelandiae*, *Macomona liliana*, *Paphies australis*, *Crassostrea gigas*, *Crassostrea ariakensis*).

Any species of bivalves and gastropods should be regarded as potentially susceptible. Clinical manifestations and disease are mainly observed in the families Veneridae, Haliotidae and Arcidae.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Perkinsus olseni* 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 3.1.9.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Perkinsus olseni* related conditions, regardless of the *Perkinsus olseni* status of the *exporting*

country, zone or compartment:

- a) From the species listed in Article 3.1.9.2. for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - b) The following products destined for human consumption from the species listed in Article 3.1.9.2. which have been prepared in such a way as to minimise the risk for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals).
2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.9.2., other than *commodities* listed in point 1 of Article 3.1.9.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.9.7. to 3.1.9.11. of this Chapter, relevant to the *Perkinsus olseni* status of the *exporting country, zone or compartment*.
3. When considering the import or transit of any other commodity from bivalve species not listed in Article 3.1.9.2. from an *exporting country, zone or compartment* not declared free of *Perkinsus olseni*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Perkinsus olseni*, 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 3.1.9.4.

***Perkinsus olseni* free country**

A country may declare itself free from *Perkinsus olseni* if it meets the conditions in points 1), 2) or 3) below.

If a country shares a *zone or compartment* with one or more other countries, it can only declare itself a *Perkinsus olseni* free country if all the areas covered by the shared water are declared *Perkinsus olseni* free zones (see Article 3.1.9.5.).

1. A country where the species listed in Article 3.1.9.2. 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 3.1.9. of the *Aquatic Manual*, may declare itself free from *Perkinsus olseni* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years and infection with *Perkinsus olseni* is not known to be established in wild populations.

OR

2. 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 *Perkinsus olseni* when:
 - a) *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 past 3 years without detection of *Perkinsus olseni*.

OR

3. A country that had declared itself free from *Perkinsus olseni* but in which the disease is detected may

not declare itself free from *Perkinsus olseni* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3 years without detection of *Perkinsus olseni*.

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 3.1.9.5.

Article 3.1.9.5.

***Perkinsus olseni* free zone or free compartment**

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Perkinsus olseni* 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 *Perkinsus olseni*, a *zone* or *compartment* where the species listed in Article 3.1.9.2. 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 *Perkinsus olseni* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years and infection with *Perkinsus olseni* is not known to be established in wild populations.

OR

2. 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 *Perkinsus olseni* when:
 - a) *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 past 3 years without detection of *Perkinsus olseni*.

OR

3. A *zone* previously declared free from *Perkinsus olseni* but in which the disease is detected may not be declared free from *Perkinsus olseni* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3 years without detection of *Perkinsus olseni*.

Article 3.1.9.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Perkinsus olseni* following the provisions of point 1) of Articles 3.1.9.4. or 3.1.9.5., respectively, may maintain its status as *Perkinsus olseni* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Perkinsus olseni* following the provisions of point 2) of Articles 3.1.9.4. or 3.1.9.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Perkinsus olseni* free provided that conditions that are conducive to clinical expression of infection with *Perkinsus olseni*, 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 infection with *Perkinsus olseni*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.9.7.

Importation of live animals from a country, zone or compartment declared free from *Perkinsus olseni*

When importing live *aquatic animals* of the species listed in Article 3.1.9.2., other than *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* declared free from *Perkinsus olseni*, 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 3.1.9.4. or 3.1.9.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus olseni*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.9.8.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Perkinsus olseni*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.9.2., other than those *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* not declared free from *Perkinsus olseni*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus olseni*.

Article 3.1.9.9.

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

When importing, for processing and/or human consumption, *aquatic animals* of the species listed in Article 3.1.9.2., other than any live *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* not declared free from *Perkinsus olseni*, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus olseni*.

Article 3.1.9.10.

Importation of products from a country, zone or compartment declared free from *Perkinsus olseni*

When importing *aquatic animal products* of the species listed in Article 3.1.9.2., other than *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* free from *Perkinsus olseni*, 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 3.1.9.4. or 3.1.9.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus olseni*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.9.11.

Importation of products from a country, zone or compartment not declared free from *Perkinsus olseni*

When importing *aquatic animal products* of the species listed in Article 3.1.9.2., other than those *commodities* listed in point 1) of Article 3.1.9.3., from a country, *zone* or *compartment* not declared free from *Perkinsus olseni*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures such as:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 3.1.9.3. or other products authorised by the competent authority; and
- b) all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus olseni*.

CHAPTER 3.1.8.

INFECTION WITH *PERKINSUS MARINUS*

Article 3.1.8.1.

For the purposes of this *Aquatic Code*, infection with *Perkinsus marinus* means infection only with *Perkinsus marinus*.

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

Article 3.1.8.2.

Susceptible species

For the purposes of this *Aquatic Code*, known *susceptible species* for infection with *Perkinsus marinus* are: Eastern oyster (*Crassostrea virginica*), Pacific oyster (*C. gigas*), Suminoe oyster (*C. ariakensis*), soft shell clam (*Mya arenaria*), Baltic clam (*Macoma balthica*) and hard clam (*Mercenaria mercenaria*).

Clinical manifestations and disease are mainly observed in *C. virginica*.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Perkinsus marinus* 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 3.1.8.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Perkinsus marinus* related conditions, regardless of the *Perkinsus marinus* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.8.2. for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - b) The following products destined for human consumption from the species listed in Article 3.1.8.2. which have been prepared in such a way as to minimise the risk of diversion for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially-sterile heat treated products (e.g. ready prepared meals).
2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.8.2., other than commodities listed in point 1) of Article 3.1.8.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.8.7. to 3.1.8.11. of this Chapter, relevant to the *Perkinsus marinus* status of the *exporting country, zone or compartment*.

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3. When considering the import or transit of any other *commodity* from bivalve species not listed in Article 3.1.8.2. from an *exporting country*, *zone* or *compartment* not declared free of *Perkinsus marinus*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Perkinsus marinus*, 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 3.1.8.4.

***Perkinsus marinus* free country**

A country may declare itself free from *Perkinsus marinus* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Perkinsus marinus* free country if all the areas covered by the shared water are declared *Perkinsus marinus* free zones (see Article 3.1.8.5.).

1. A country where no species listed in Article 3.1.8.2. are present may declare itself free from *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years.

OR

2. A country where the species listed in Article 3.1.8.2. 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 3.1.8. of the *Aquatic Manual*, may declare itself free from *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years and infection with *Perkinsus marinus* 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 *Perkinsus marinus* when:
 - a) *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 past 3 years without detection of *Perkinsus marinus*.

OR

4. A country that had declared itself free from *Perkinsus marinus* but in which the disease is detected may not declare itself free from *Perkinsus marinus* 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

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- b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3 years without detection of *Perkinsus marinus*.

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 4) of Article 3.1.8.5.

Article 3.1.8.5.

***Perkinsus marinus* free zone or free compartment**

A *zone* or *compartment* free from *Perkinsus marinus* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Perkinsus marinus* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

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

1. A country where no species listed in Article 3.1.8.2. are present may declare itself free from *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the country for at least the past 3 years.

OR

2. In a country of unknown status for *Perkinsus marinus*, a *zone* or *compartment* where the species listed in Article 3.1.8.2. 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 *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 3 years and infection with *Perkinsus marinus* is not known to be established in wild populations.

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 *Perkinsus marinus* when:
 - a) *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 past 3 years without detection of *Perkinsus marinus*.

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OR

4. A *zone* previously declared free from *Perkinsus marinus* but in which the disease is detected may not be declared free from *Perkinsus marinus* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 3 years without detection of *Perkinsus marinus*.

Article 3.1.8.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Perkinsus marinus* following the provisions of points 1) or 2) of Articles 3.1.8.4. or 3.1.8.5., respectively, may maintain its status as *Perkinsus marinus* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Perkinsus marinus* following the provisions of point 3) of Articles 3.1.8.4. or 3.1.8.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Perkinsus marinus* free provided that conditions that are conducive to clinical expression of infection with *Perkinsus marinus*, 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 infection with *Perkinsus marinus*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.8.7.

Importation of live animals from a country, zone or compartment declared free from *Perkinsus marinus*

When importing live *aquatic animals* of the species listed in Article 3.1.8.2., other than *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* declared free from *Perkinsus marinus*, 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 3.1.8.4. or 3.1.8.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus marinus*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

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Article 3.1.8.8.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Perkinsus marinus*

When importing for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.8.2., other than those *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* not declared free from *Perkinsus marinus*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus marinus*.

Article 3.1.8.9.

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

When importing, for processing and/or human consumption, *aquatic animals* of the species listed in Article 3.1.8.2., other than any live *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* not declared free from *Perkinsus marinus*, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus marinus*.

Article 3.1.8.10.

Importation of products from a country, zone or compartment free from *Perkinsus marinus*

When importing *aquatic animal products* of the species listed in Article 3.1.8.2., other than *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* free from *Perkinsus marinus*, 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 3.1.8.4. or 3.1.8.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus marinus*.

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Appendix XXIV (contd)Appendix XI (contd)

Article 3.1.8.11.

Importation of products from a country, zone or compartment not declared free from *Perkinsus marinus*

When importing *aquatic animal products* of the species listed in Article 3.1.8.2., other than those *commodities* listed in point 1) of Article 3.1.8.3., from a country, *zone* or *compartment* not declared free from *Perkinsus marinus*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures such as:

- a) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products listed in paragraph 1 of Article 3.1.8.3. or other products authorised by the competent authority; and
 - b) all effluent and waste material are treated in a manner that ensures inactivation of *Perkinsus marinus*.
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CHAPTER 3.1.11.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Article 3.1.11.1.

For the purposes of this *Aquatic Code*, infection with *Xenobaliothis californiensis* means infection only with *Xenobaliothis californiensis*.

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

Article 3.1.11.2.

Susceptible species

For the purposes of this *Aquatic Code*, known *susceptible species* for infection with *Xenobaliothis californiensis* are: black abalone (*Haliotis cracherodii*), white abalone (*H. sorenseni*), red abalone (*H. rufescens*), pink abalone (*H. corrugata*), green abalone (*H. fulgens*), flat abalone (*H. wallalensis*) and Japanese abalone (*H. discus-hannai*).

All *Haliotis* spp. should be regarded as potentially susceptible.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Xenobaliothis californiensis* 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 3.1.11.3.

Commodities

1. When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Xenobaliothis californiensis* related conditions, regardless of the *Xenobaliothis californiensis* status of the *exporting country, zone or compartment*:
 - a) From the species listed in Article 3.1.11.2. for any purpose:
 - i) Commercially-sterile canned or other heat treated products;
 - ii) *Gametes*;
 - iii) Shells.
 - b) The following products destined for human consumption from the species listed in Article 3.1.11.2. which have been prepared in such a way as to minimise the risk for alternative uses (a Member Country may wish to consider the need to introduce internal measures to prevent the commodity being used for any purpose other than for human consumption):
 - i) Chemically preserved products (e.g. smoked, salted, pickled, marinated, etc ...);
 - ii) Non commercially sterile heat treated products (e.g. ready prepared meals);
 - iii) Off the shell, eviscerated abalone (chilled or frozen) packaged for direct retail trade;

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2. When authorising import or transit of the *commodities* of a species listed in Article 3.1.11.2., other than *commodities* listed in point 1 of Article 3.1.11.3., *Competent Authorities* should require the conditions prescribed in Articles 3.1.11.7. to 3.1.11.11. of this Chapter, relevant to the *Xenobalotus californiensis* status of the *exporting country*, *zone* or *compartment*.
3. When considering the import or transit of any other commodity from bivalve species not listed in Article 3.1.11.2. (especially *Haliotis* spp.) from an *exporting country*, *zone* or *compartment* not declared free of *Xenobalotus californiensis*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Xenobalotus californiensis*, 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 3.1.11.4.

***Xenobalotus californiensis* free country**

A country may declare itself free from *Xenobalotus californiensis* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment* with one or more other countries, it can only declare itself a *Xenobalotus californiensis* free country if all the areas covered by the shared water are declared *Xenobalotus californiensis* free zones (see Article 3.1.11.5.).

1. A country where no species of the genus *Haliotis* is present may declare itself free from *Xenobalotus californiensis* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the species listed in Article 3.1.11.2. 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 3.1.11. of the *Aquatic Manual*, may declare itself free from *Xenobalotus californiensis* when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years and infection with *Xenobalotus californiensis* 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 *Xenobalotus californiensis* when:
 - a) *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 *Xenobalotus californiensis*.

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OR

4. A country that had declared itself free from *Xenobalotus californiensis* but in which the disease is detected may not declare itself free from *Xenobalotus californiensis* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Xenobalotus californiensis*.

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 3.1.11.5.

Article 3.1.11.5.

***Xenobalotus californiensis* free zone or free compartment**

A *zone* or *compartment* free from *Xenobalotus californiensis* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Xenobalotus californiensis* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1), 2), 3) or 4) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Xenobalotus californiensis* 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 *Xenobalotus californiensis*, a *zone* or *compartment* where no species of the genus *Haliotis* is present may declare itself free from *Xenobalotus californiensis* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Xenobalotus californiensis*, a *zone* or *compartment* where the species listed in Article 3.1.11.2. 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 *Xenobalotus californiensis* when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years and infection with *Xenobalotus californiensis* is not known to be established in wild populations.

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 *Xenobalotus californiensis* when:

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- a) *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 *Xenobalotus californiensis*.

OR

4. A *zone* previously declared free from *Xenobalotus californiensis* but in which the disease is detected may not be declared free from *Xenobalotus californiensis* 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) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, 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 *Xenobalotus californiensis*.

Article 3.1.11.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from *Xenobalotus californiensis* following the provisions of points 1) or 2) of Articles 3.1.11.4. or 3.1.11.5., respectively, may maintain its status as *Xenobalotus californiensis* free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from *Xenobalotus californiensis* following the provisions of point 3) of Articles 3.1.11.4. or 3.1.11.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Xenobalotus californiensis* free provided that conditions that are conducive to clinical expression of infection with *Xenobalotus californiensis*, 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 infection with *Xenobalotus californiensis*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Article 3.1.11.7.

Importation of live animals from a country, zone or compartment declared free from *Xenobalotus californiensis*

When importing live *aquatic animals* of the species listed in Article 3.1.11.2., other than *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* declared free from *Xenobalotus californiensis*, 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 3.1.11.4. or 3.1.11.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Xenobalotus californiensis*.

Appendix XXIV (contd)Appendix XII (contd)

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.1..

Article 3.1.11.8.

Importation of live animals for aquaculture from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing, for *aquaculture*, *aquatic animals* of the species listed in Article 3.1.11.2., other than those *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the risk and apply risk mitigation measures such as:

1. the consignment is delivered directly into and held in *quarantine* facilities; and
2. the imported *aquatic animals* are continuously isolated from the local environment; and
3. all effluent and waste material are treated in a manner that ensures inactivation of *Xenohaliotis californiensis*.

Article 3.1.11.9.

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

When importing, for processing and/or human consumption, *aquatic animals* of the species listed in Article 3.1.11.2., other than any live *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should require:

1. the consignment is delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material are treated in a manner that ensures inactivation of *Xenohaliotis californiensis*.

Article 3.1.11.10.

Importation of products from a country, zone or compartment declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of the species listed in Article 3.1.11.2., other than *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* free from *Xenohaliotis californiensis*, 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 3.1.11.4. or 3.1.11.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*.

Appendix XXIV (contd)

Appendix XII (contd)

The certificate shall be in accordance with the Model Certificate in Appendix 6.3.2..

Article 3.1.11.11.

Importation of products from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of the species listed in Article 3.1.11.2., other than those *commodities* listed in point 1) of Article 3.1.11.3., from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

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