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Subject: Meeting of the Aquatic Animal Health 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 Aquatic Animal Health Standards Commission.

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

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

Dr. Arthur Besch

*Directeur  
Administration des Services Vétérinaires  
Luxembourg*

Jaana Husu-Kallio

*Deputy Director General*

Enclosures: 2

Copy:

CVOs all Member States

CVOs Andorra, Bulgaria, Iceland, Norway, Romania and Switzerland

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

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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. Furthermore, 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. Such approach should be aligned with the terrestrial Code.

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 asks the OIE AAC not to include *any* new species as susceptible to any disease in the Code without the advice of the relevant 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, 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.

### **Report on the 73rd OIE General Session**

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

#### **2.1. 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.

## 2.2. 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](#).

## 2.3. 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.

#### **2.4. 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).

#### **2.5. 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.

#### **2.6. 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.

#### **2.7. 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.

#### **2.8. 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 5<sup>th</sup> edition of the *Aquatic Manual***

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**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 74<sup>th</sup> 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 24<sup>th</sup> 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 23<sup>rd</sup> 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.

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.../Appendices

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

**Paris, 1-5 August 2005**

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**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 73<sup>rd</sup> 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 5<sup>th</sup> 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**

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## 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)*.

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## 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  |
|------------------------|----------------|--|--|
| <b>A. Consequences</b> |                |  |  |
| 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.   |  |
| <b>And</b>             |                |  |  |
| <b>B. Spread</b>       |                |  |  |
| 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. |
| <b>And<br/>C. Diagnosis</b> |                |  |  |
| 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**

| <b>A. For listed diseases</b>     |  |
|-----------------------------------|--|
| 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>B. For non-listed diseases</b> |  |
| 1.                                | Emerging disease/pathogenic agent if there are findings that are of epidemiological significance to other countries.   |

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

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Appendix V

## CHAPTER 1.1.3.

## DISEASES LISTED BY THE OIE

**Community 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~~<sup>†</sup>
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- ~~Bacterial kidney disease (*Renibacterium salmoninarum*)~~<sup>†</sup>
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease
- Koi herpesvirus disease<sup>2</sup>

## 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*~~<sup>‡</sup>
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*<sup>‡</sup>
- 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 hepatopancreatitis<sup>2</sup>
- Infectious myonecrosis<sup>2</sup>.

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<sup>1</sup> ~~Delisting of this disease is under study.~~

<sup>2</sup> Listing of this disease is under study.

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— 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 1<sup>st</sup> paragraph are known susceptible species.**

**Furthermore, in the 2<sup>nd</sup> 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 years<sup>1</sup>.

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 years<sup>2</sup> 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~~ any 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 years<sup>2</sup>.

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 years<sup>2</sup> 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, 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.~~

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 — text deleted



## CHAPTER 3.1.2.

INFECTION WITH *BONAMIA EXITIOSA*

## 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 1<sup>st</sup> paragraph are known susceptible species.**

**Furthermore, in the 2<sup>nd</sup> 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, 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.

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## 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 1<sup>st</sup> paragraph are known susceptible species.**

**Furthermore, in the 2<sup>nd</sup> 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, 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, 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, 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 1<sup>st</sup> paragraph are known susceptible species.**

**Furthermore, in the 2<sup>nd</sup> 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, 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, 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 1<sup>st</sup> paragraph are known susceptible species.**

**Furthermore, in the 2<sup>nd</sup> 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.

|                           |
|---------------------------|
| <b>Community comment:</b> |
|---------------------------|

**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, 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**

**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.

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 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.

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. 4 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, 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 EHNV.

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 EHNV

**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 ~~these~~ 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 EHN.

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 2<sup>nd</sup> 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.

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— 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, 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 2<sup>nd</sup> 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 epidemiological importance. However, in such cases, the consignment should be accompanied with an 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:
- 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.

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, 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 2<sup>nd</sup> 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.

## VIRAL HAEMORRHAGIC SEPTICAEMIA

**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*.**

**The Community does not agree to the inclusion of Sea bass (*Dicentrarchus labrax*) as susceptible to VHS. To the Community's knowledge, this inclusion is based solely on a report not validated by the OIE Reference laboratory for VHS, in accordance with the rules of the OIE.**

**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.

#### 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, nor known to be infected” the Community could agree to this Article.**

**However, it 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 2<sup>nd</sup> 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, 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 2<sup>nd</sup> 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.; *Liza* 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 (*Rohetea* 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, 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 2.1.10.3., 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 2<sup>nd</sup> 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](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, 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**

**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.

#### **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.**

### 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, 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 2<sup>nd</sup> 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.