COMMISSION OF THE EUROPEAN COMMUNITIES



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COMMISSION STAFF WORKING DOCUMENT

Draft position of the Community on the report of the meeting of the OIE [World Organisation for Animal Health] Aquatic Animals Health Standards Commission [Paris March 2006] to be submitted for consideration at the General Session in May 2006

For information only

This Commission Staff Working Document, includes only those Annexes to the report from the March meeting of the OIE AAC, that the OIE intends to present for adoption during the General Session in May 2006.

The other Annexes to the report from the March meeting of the OIE AAC, to which the OIE have asked for comments by 10 September 2006 will be covered by a separate Commission Staff Working Document that will be distributed for Member States comments at a later stage.

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

Paris, 13-17 March 2006

The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 13 to 17 March 2006. The meeting was chaired by Dr Eva-Maria Bernoth, President of the Commission, and Dr Ricardo Enriquez, Secretary General, acted as Rapporteur. Participants are listed at <u>Appendix I</u>. The Agenda adopted is given at <u>Appendix II</u>.

Dr Wilson, Deputy Director General of the OIE, welcomed the members and informed the Aquatic Animals Commission that, based on the standard development biannual cycle, both the August 2005 and this March 2006 reports would be distributed to OIE Delegates during the 74th General Session. He clarified that the list of diseases present in Chapter 1.1.3. of the OIE *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) related to the reporting obligations of Member Countries and that the disease chapters served to assist Member Countries to develop their import regulations. The Aquatic Animals Commission agreed that there may be chapters in the OIE *Codes* and *Manuals* for diseases that are no longer listed but which would provide useful advice to Member Countries.

The Aquatic Animals Commission recognised the contribution of the following Member Countries in providing comments: Australia, Canada, Chile, Colombia, El Salvador, the European Community (EC), Japan, New Zealand, Norway, Panama, Paraguay, Thailand and the United States of America (USA).

The Aquatic Animals Commission examined various Aquatic Code texts from its August 2005 report in the light of Member Countries' comments. The outcome of the Aquatic Animals Commission's work is presented as appendices to the August 2005 report and to this report. Additions made during the August 2005 meeting are shown as double underlined text, with deleted text in strikeout, and those made at this meeting (March 2006) in a similar fashion but with a coloured background to distinguish the two groups of proposals.

The following texts in the table are proposed for adoption. The texts are included in the August 2005 report of the Aquatic Animals Commission; texts modified at the March 2006 meeting are presented in appendices in **Part A** of this report. Both reports will be in the Delegates' folders for the 74th General Session.

Issue	Appendix number in the August 2005 report	Appendix number in the March 2006 report
Definitions (Ch. 1.1.1.)	Appendix III	Appendix III
Disease listing and notification criteria (Ch. 1.1.2.)	Appendix IV	Appendix IV
Diseases listed by the OIE (Ch. 1.1.3.)	Appendix V	Appendix V
Infection with Marteilia refringens (Ch. 3.1.5.)	Appendix VI	Appendix VI
Infection with Bonamia exitiosa (Ch. 3.1.2.)	Appendix VII	Appendix VII
Infection with Bonamia ostreae (Ch. 3.1.1.)	Appendix VIII	Appendix VIII
Infection with Haplosporidium nelsoni (Ch. 3.1.4.)	Appendix IX	Appendix IX
Infection with Mikrocytos mackini (Ch. 3.1.7.)	Appendix X	Appendix X
Infection with Perkinsus olseni (Ch. 3.1.9.)	Appendix XI	Appendix XI
Infection with Perkinsus marinus (Ch. 3.1.8.)	Appendix XII	Appendix XII
Infection with <i>Xenohaliotis californiensis</i> (Ch. 3.1.11.)	Appendix XIII	Appendix XIII
Epizootic haematopoietic necrosis (Ch. 2.1.1.)	Appendix XIV	Appendix XIV
Infectious haematopoietic necrosis (Ch. 2.1.2.)	Appendix XV	Appendix XV
Spring viraemia of carp (Ch. 2.1.4.)	Appendix XVI	Appendix XVI
Viral haemorrhagic septicaemia (Ch. 2.1.5.)	Appendix XVII	Appendix XVII
Infectious salmon anaemia (Ch. 2.1.9.)	Appendix XVIII	Appendix XVIII
Epizootic ulcerative syndrome (Ch. 2.1.10.)	Appendix XIX	Appendix XIX
Blank appendix		Appendix XX
Red sea bream iridoviral disease (Ch. 2.1.15.)	Appendix XXI	Appendix XXI

The following texts are presented in **Part B** of this report for Member Countries' comment:

White spot disease (Chapter 4.1.2.) at Appendix XXII;

Taura syndrome (Chapter 4.1.1.) at Appendix XXIII;

Yellowhead disease (Chapter 4.1.3.) at Appendix XXIV;

Tetrahedral baculovirosis (Chapter 4.1.4.) at Appendix XXV;

Spherical baculovirosis (Chapter 4.1.5.) at Appendix XXVI;

Infectious hypodermal and haematopoietic necrosis (Chapter 4.1.6.) at Appendix XXVII;

Crayfish plague (Chapter 4.1.7.) at Appendix XXVIII;

Infectious myonecrosis (Chapter 4.1.9.) at Appendix XXIX;

Necrotising hepatopancreatitis (Chapter 4.1.10.) at Appendix XXX;

Animal Welfare Definitions (to be added to Chapter 1.1.1.) at Appendix XXXI;

Introduction to OIE guidelines for the welfare of aquatic animals at Appendix XXXII;

Guidelines for the transport of fish by boat at Appendix XXXIII;

Guidelines for the land transport of fish at Appendix XXXIV;

Guidelines for the slaughter of farmed fish for human consumption at Appendix XXXV;

Guidelines for the humane killing of fish for disease control purposes at Appendix XXXVI.

Member Countries are invited to submit their comments to the OIE on Part B of this report <u>prior to 10th September 2006</u>. The comments should be sent <u>preferably by electronic mail</u> to the following address: <u>trade.dept@oie.int.</u>

The following documents are presented in **Part C** of this report for Member Countries' information:

Report of the meeting of the teams comprising the OIE *ad hoc* Group on the List of Aquatic Animal Diseases at Appendix XXXVII;

Report of the meeting of the OIE *ad hoc* Group on the Chapters for Crustacean Diseases for the OIE *Aquatic Animal Health Code* at Appendix XXXVIII;

Report of the meeting of the OIE ad hoc Group on Aquatic Animal Transport at Appendix XXXIX;

Report of the meeting of the OIE *ad hoc* Group on the Slaughter and Killing of Aquatic Animals at Appendix XL;

Aquatic Animals Commission's work plan at Appendix XLI

PART A:

1. Proposed chapters for the Aquatic Animal Health Code

Community Speaking Position

The European Community appreciates the efforts done by the OIE AAC with respect to amendments of the Code. In general, the Community can support the proposals for updates of the Code. The Community also welcomes the explanation by the OIE AAC on their assessment of the comments received in points 1.1-1.6. This ensures greater transparency.

However, the Community would ask the OIE AAC to re-consider its position to request animal health certificates for non-viable molluscs or mollusc products, as well as eviscerated fish products. Taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems unjustifiable.

Furthermore, the Community would also ask the OIE AAC to further assess the justification from the Community that for certain diseases, the trade in disinfected eggs should be considered as an alternative to requiring disease freedom, as these diseases are not transmitted vertically.

1.1. General comments

Member Countries' comments addressed under this agenda item were those of a generic nature, the more specific ones being deferred to the relevant agenda items.

In response to a comment from Canada, the Aquatic Animals Commission agreed on the need to update the model health certificates through the involvement of experts familiar with their usage. Acknowledging the parallel work underway on the revision of the terrestrial certificates, the Aquatic Animals Commission decided to postpone any specific aquatic initiative until it examines the revised terrestrial certificates (see also item 3.2. below).

The EC suggested that the OIE provide guidance to Member Countries wishing to ask for animal health guarantees for diseases not listed by the OIE. The Aquatic Animals Commission considered this concept worthwhile exploring and invited the EC to provide further details on its proposal.

The EC expressed concern that new susceptible species were added to the OIE list of susceptible species without consulting the OIE Reference Laboratories. The Aquatic Animals Commission advised that it is OIE policy to submit these reports to OIE Reference Laboratories at the same time as the distribution to OIE Delegates. Furthermore, these reports are made publicly available on the OIE website.

The EC queried whether the standards in the *Aquatic Code* applied to ornamental aquatic animals, which were seen, in the EC's view, to pose a lower risk compared to farmed aquatic animals. The Aquatic Animals Commission advised that the beginning of each *Aquatic Code* chapter clearly stated that chapter's scope which – depending on the disease – may include ornamental species. If an ornamental aquatic animal was listed as a susceptible species, then it was covered by the *Aquatic Code*. The Aquatic Animals Commission recognised that, in many regions of the world, ornamental aquatic animals were farmed and traded internationally in the same way as other live aquatic animals.

1.2. Definitions (chapter 1.1.1.)

Community Position

The Community supports the proposal for this Chapter in Appendix III.

The Aquatic Animals Commission appreciated the comments from Chile on the need for definitions on "case" and "epidemiological unit" and for providing constructive proposals for these. The Aquatic Animals Commission will consider these proposals at its next meeting.

Chile, the EC and the US commented on the proposed definitions for: Competent Authority, Veterinary Administration and Veterinary statutory body. The Aquatic Animals Commission advised that these proposed definitions were introduced as a step towards further harmonisation of the Terrestrial and Aquatic Codes. While the Terrestrial Animal Health Code (hereafter referred to as the Terrestrial Code) definitions were being reassessed, the proposed definitions for the Aquatic Code will be proposed to the OIE International Committee to advance further harmonisation.

The definitions proposed to the OIE International Committee for adoption at the 74th General Session in May 2006 are attached in Part A of this report, as <u>Appendix III</u>.

1.3. Disease listing and notification criteria (chapter 1.1.2.)

Community Position

The Community supports the proposal for this Chapter in Appendix IV.

The Disease listing and notification criteria were revised by the Aquatic Animals Commission addressing Member Countries' comments. The "notification criteria" were removed from this chapter because they are already contained in Chapter 1.2.1. The revised Chapter is submitted to the OIE International Committee for adoption at the May 2006 General Session (part A of this report, Appendix IV).

1.4. Revision of the list of diseases (chapter 1.1.3.)

Community Position

The Community supports the proposal for this Chapter in Appendix V.

Some Member Countries expressed concerns about the proposed deletion of BKD, IPN and infection with *Mikrocytos mackini*. These concerns appeared to be based on trade rather than reporting issues. The Aquatic Animals Commission would like to draw Member Countries' attention to the fact that while the list of diseases related to the reporting obligations of Member Countries, the disease-specific chapters in the *Aquatic Code* serve to assist Member Countries to develop their import regulations. The Aquatic Animals Commission maintained its previous decision to propose the deletion of BKD, IPN and infection with *Mikrocytos mackini* from the OIE list of diseases.

The Aquatic Animals Commission was concerned that some Member Countries appeared to have misunderstood the use of the listing criteria for an emerging aquatic animal disease (e.g. abalone viral mortality). The Aquatic Animals Commission clarified that there is only one list of diseases (Chapter 1.1.3.), but two pathways for a disease to become listed: to meet the main criteria in Article 1.1.2.1., or to meet of criteria for listing an emerging aquatic animal disease in Article 1.1.2.2. The Aquatic Animals Commission recognised the need to review the status of diseases listed using the criteria for listing an emerging aquatic animal disease after an appropriate time period. This was added to its work plan.

The Aquatic Animals Commission maintained its previous decision to propose the addition of abalone viral mortality to the OIE list of diseases. The Aquatic Animals Commission wished to thank Chile for its constructive comments on the infections described in abalone and referred these to the *ad hoc* Group on the List of Aquatic Animal Diseases with the request to update the disease information card for abalone viral mortality. If the OIE International Committee adopts the addition of abalone viral mortality to the OIE list of diseases, the disease card will be published on the OIE website to assist Member Countries with reporting.

The Aquatic Animals Commission addressed the comments received from the US, Canada and Panama on *Marteilioides chungmuensis*. The Aquatic Animals Commission maintained its position that this parasite does not meet the listing criteria, especially because of a lack of quantitative data on disease impact as opposed to mere prevalence of the pathogen. This was consistent with the recommendations presented in Appendix B of the report of the *ad hoc* Group on the List of Aquatic Animal Diseases (Paris, 20-22 July 2005). However, the Aquatic Animals Commission invited Member Countries to provide new and detailed epidemiological information on this disease.

In considering the comment from Australia, the Aquatic Animals Commission stressed that the assessment for infection with *Perkinsus olseni* took into account the broad range of hosts and not only abalone.

Prof. Hill, the Chair of the finfish team of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases for the OIE *Aquatic Code*, reported on the electronic discussion of the team. He recalled that, in its second report, the finfish team of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases had concluded that most of the listing criteria were met for koi herpes virus disease (KHVD), but that an open scientific forum would be useful to clarify issues on those criteria that appeared to be less clearly met. He explained that at its meeting in August 2005, the Aquatic Animals Commission agreed with this approach and asked the finfish team to re-assess KHVD against the disease listing criteria taking into account information and opinion presented and debated at suitable international scientific fora. Prof. Hill reported how these issues were subsequently debated at two international conferences and the outcome of the reassessment was presented to the Aquatic Animals Commission in the final report of the finfish team. The report of the *ad hoc* Group is appended for Member Countries information, in Part C of this report, at Appendix XXXVII.

The Aquatic Animals Commission accepted the conclusion and recommendation of the finfish team

and maintained its previous view that KHVD should be listed by the OIE.

The Aquatic Animals Commission noted the US comment that *Oncorhynchus masou* virus disease (OMVD) should not have been delisted. The Aquatic Animals Commission recalled that the OIE International Committee in May 2005 adopted the recommendation to delist this disease. The Aquatic Animals Commission considered that the information provided by the US was insufficient to warrant re-consideration but invited the US to provide a full assessment against the listing criteria (Chapter 1.1.2.) to support its case for listing.

Thailand suggested that tetrahedral baculovirosis and spherical baculovirosis be delisted because of the easy control of both diseases by washing eggs and larvae. The Aquatic Animals Commission agreed to refer these comments to the crustacean team of the *ad hoc* Group on the List of Aquatic Animal Diseases.

The list of diseases proposed to the OIE International Committee for adoption at May 2006 General Session is attached in Part A of this report, at <u>Appendix V</u>.

1.5. Revised chapters for fish and mollusc diseases

Community Position

The Community supports the proposal for these Chapters in Appendixes VI-XXI, with minor comments as presented in the relevant Appendixes.

The Aquatic Animals Commission clarified that the choice of a period of 25 years for the declaration of historical freedom was taken as the default based on the recommendations of the OIE *Terrestrial Code*; the same basis applied for the time period specified for targeted surveillance and the application of basic biosecurity conditions. The Aquatic Animals Commission reiterated that time periods for specific diseases would be modified in line with the information provided by the *ad hoc* Group on Surveillance. However, if Member Countries have relevant information, they are encouraged to submit it to the Aquatic Animals Commission. In the meantime, for mollusc disease chapters, the choice of 10 years to justify historical freedom is based on the relatively short lifecycle of the mollusc hosts and pathogens.

The EC queried the reason why the absence of susceptible species was not provided as an option for the declaration of freedom for VHS, as for the other fish diseases. The Aquatic Animals Commission recalled its previous decision (see August 2005 report):

"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."

The Aquatic Animals Commission specified that this would not apply to VHS.

New Zealand questioned the method used to select the susceptible species for each disease chapter. The Aquatic Animals Commission discussed this issue with the OIE Central Bureau and compared the approach to that used in the *Terrestrial Code*. As a further move towards harmonisation of the two Codes, the Aquatic Animals Commission decided to clarify in the *Aquatic Code* chapters which susceptible species are addressed by each chapter (e.g. those relevant for international trade). The Aquatic Animals Commission stressed that the full reference list of susceptible species for surveillance and notification purposes was present in each of the disease chapters of the Manual of Diagnostic Tests for Aquatic Animals (*Aquatic Manual*).

Addressing a comment from Norway and the EC on the list of commodities that could be traded with negligible risk (Article 3 of disease chapters), the Aquatic Animals Commission clarified that the listing of commodities under Article 3 needed to be supported by scientific data (other than for the generally agreed inactivation procedures) because the absence of evidence of risk alone does not justify a listing of a commodity as "safe".

The EC and Norway suggested to list eviscerated fish as a safe commodity even if not packaged for direct retail trade. The Aquatic Animals Commission was of the view that the listing of commodities

under point 1b) of Article 3 also needed to be supported by scientific data. In this case, bulk consignments of eviscerated fish, not necessarily intended for direct consumption, would need to be demonstrated as safe even if they are intended for further processing.

Member Countries that have scientific evidence supporting the listing of commodities as safe are strongly encouraged to make that evidence available to the Aquatic Animals Commission. The identification of safe commodities in the disease chapters of the *Aquatic Code* is a new concept and at this stage only commodities that are safe without any doubt have been listed; for future editions of the *Aquatic Code*, the application of this concept will evolve and take into account scientific evidence demonstrating a negligible level of risk for other commodities.

Australia suggested that guidelines be developed for translocation of species known not to be susceptible to a given disease; these guidelines would facilitate trade in such species because they could replace the requirements for risk analysis. While the Aquatic Animals Commission recognised the usefulness of guidelines for safe translocation, it believed that the methods contained in such guidelines would need to be validated for a large variety of field situations.

Australia recommended that the scientific rationale for using different time periods in Articles 4 and 5 of all fish and mollusc disease chapters be provided to Member Countries. The Aquatic Animals Commission advised that these differences were justified by different host and pathogen lifecycles and disease seasonality. Details were provided by the Aquatic Animals Commission in its January 2005 report, in the relevant draft disease chapters.

The EC questioned the requirement of 2 years for targeted surveillance for new aquaculture establishments and for those wishing to restore their free status. The Aquatic Animals Commission recognised that the current text was better suited to zones and proposes that suggestions by the EC could be best addressed by a new text specific for compartments; the Aquatic Animals Commission placed this item on its work plan. Such a new text would also address Norway's comments on regaining freedom for previously free compartments.

The EC, in Article 8, proposed that "not declared free" should not include "known to be infected" because this might mean that animals from infected areas could be moved into a declared disease free area. The Aquatic Animals Commission pointed out that as per the general approach in the *Terrestrial Code*, the *Aquatic Code* recognised only two status, i.e. "declared free" and "not declared free". The Aquatic Animals Commission also draws Member Countries' attention to the User's guide of the *Aquatic Code*:

"The recommendations in the Aquatic Code make reference only to the aquatic animal health situation in the exporting country, and assume that either the disease is not present in the importing country or is the subject of a control or eradication programme. Therefore, when determining its import measures, an importing country should do so in a way that is consistent with the principle of national treatment and the other provisions of the WTO SPS Agreement."

In the first paragraph of Article 9, the EC suggested to use the word "may" instead of the word "should". The Aquatic Animals Commission disagreed because the recommendation is based on expert advice; Member Countries are free to apply more or less stringent measures than those prescribed in the *Aquatic Code* as long as they justify it with risk analysis.

Canada, the EC and the US questioned the list of susceptible species listed in Article 2.1.5.2. The Aquatic Animals Commission acknowledged the growing complexity concerning the host range for VHS virus and is awaiting the issue of strain differentiation for this virus to be resolved (see also item 6.4. below). The currently proposed list of susceptible species is taken from Article 2.1.5.1. of the *Aquatic Code*.

Canada, the EC, the US and Norway queried the list of susceptible species listed in Article 2.1.9.2. The Aquatic Animals Commission acknowledged their view and accordingly amended the scope of that Chapter.

The Aquatic Animals Commission acknowledged the comments received from Member Countries on the proposed chapter on *Gyrodactylus salaris* and decided to forward them to the *ad hoc* Group on Fish Disease Chapters of the OIE *Aquatic Code* for consideration and submission of a revised draft chapter for the October 2006 meeting of the Aquatic Animals Commission. Therefore, the Aquatic

Animals Commission is not proposing an update of this chapter at the 2006 General Session.

Australia and Canada sought clarification on whether intermediate hosts for mollusc diseases had been considered, where applicable, as a means of transferring OIE listed diseases through international trade. The Aquatic Animals Commission (and the *ad hoc* Groups) had indeed given this some consideration but reached the conclusion that there was not enough scientific data to support such provisions at that time. In the case of infection with *Marteilia refringens*, although one species of copepod had been identified as an intermediate host, it was not known whether other species of copepod could be involved in the lifecycle of the parasite.

Australia also queried the discrepancies in the commodities listed under 1a) and 1b) of Article 3 and requested that the *ad hoc* Group provide the scientific basis for the decisions on these points. The Aquatic Animals Commission drew Member Countries' attention to the July 2005 report of the *ad hoc* Group on the Chapters for Mollusc Diseases for the OIE *Aquatic Code*, which provided this justification. The report had been appended to the report of the August 2005 Aquatic Animals Commission's report.

Australia queried whether the risks associated with any accompanying transport water had been considered when the inclusion of gametes, eggs and larvae in Article 3 had been proposed. The Aquatic Animals Commission will refer the question to the *ad hoc* groups for fish, molluscs and crustaceans for expert opinion.

Several Member Countries made a number of comments of a highly technical nature and sometime of diametrically opposed views on commodities. The Aquatic Animals Commission decided to refer these comments to the *ad hoc* Group on the Chapters for Mollusc Diseases for the OIE *Aquatic Code* which will provide a detailed response in their next report.

Canada queried whether pathogen-specific inactivation protocols or standards would be forthcoming in the *Aquatic Code* or *Aquatic Manual*. The Aquatic Animals Commission agreed on the necessity for such information. Such information will be provided as it becomes available.

The fish and mollusc disease chapters proposed to the OIE International Committee for adoption at the 74th General Session in May 2006 are in part A of this report, from <u>Appendix VI</u> to <u>Appendix XXI</u>.

1.6. Date of last update for Code Chapters

The Aquatic Animals Commission reviewed a table showing the date of the latest significant update for each disease chapter in the *Aquatic Code*. It agreed that it was useful for giving Member Countries an indication on the evolution of *Aquatic Code* chapters and requested the OIE Secretariat to introduce such a table in the *Aquatic Code* as soon as possible.

PART B

2. New standards for the Aquatic Animal Health Code

2.1. Revised chapters for crustacean diseases

Prof. Lightner, the Chair of the *ad hoc* Group on the Chapters for Crustacean Diseases for the OIE *Aquatic Code*, reported on the October 2005 meeting of the *ad hoc* Group. The updated chapters on currently listed diseases were drafted in the format of the approved chapter on white spot disease. Two new chapters on diseases proposed for listing at the 74th General Session of the OIE International Committee in May 2006 were also drafted. The report of the *ad hoc* Group is appended for Member Countries' information, in Part C of this report, at Appendix XXXVIII.

The Aquatic Animals Commission revised the updated and new chapters in line with the modifications made to the fish and mollusc chapters.

These revised chapters are attached for Member Countries' comments, in Part B of this report, from Appendix XXII to Appendix XXXI.

2.2. Crustacean diseases recommended for listing

Prof. Lightner, the Chair of the crustacean team of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases for the OIE *Aquatic Code*, reported on the October 2005 meeting of the team. Three significant crustacean diseases (white tail disease, infection with hepatopancreatic parvovirus and infection with Mourilyan virus) were assessed against the criteria in Articles 1.1.2.1. and 1.1.2.2. and were found to meet the latter i.e. the criteria for listing as an emerging aquatic animal disease. The *ad hoc* Group recommended their inclusion on the list of aquatic animal diseases.

The *ad hoc* Group updated its previous assessment of the two diseases currently listed as [under study] (necrotising hepatopancreatitis and infectious myonecrosis) in Chapter 1.1.3. of the *Aquatic Code*. The *ad hoc* Group concluded that these two diseases met the listing criteria and therefore recommended the removal of the footnote denoting [under study].

The report of the *ad hoc* Group is appended for Member Countries' information, in Part C of this report, at Appendix XXXVII.

The Aquatic Animals Commission supported the *ad hoc* Group's recommendations and requested Member Countries' comments.

2.3. New draft chapter on handling and disposal of carcasses and wastes of aquatic animals

Prof. Håstein, who is a member of Working Group on Animal Welfare, joined the meeting.

The Aquatic Animals Commission noted the proposed Appendix 3.6.5. entitled "General guidelines for the disposal of dead animals" for the *Terrestrial Code* and compared it with draft guidelines on handling and disposal of carcasses and wastes of aquatic animals which had been prepared by Prof. Håstein.

The Aquatic Animals Commission decided to await the adoption of the equivalent Appendix for the *Terrestrial Code* before submitting a revised draft for the *Aquatic Code* for Member Countries' comments.

2.4. New draft chapters on aquatic animal welfare

Dr Pinto, Deputy Head of the International Trade Department, participated in this agenda item.

Prof. Håstein briefed the Aquatic Animals Commission on the outcomes of the meetings of the two *ad hoc* Groups on aquatic animal welfare, particularly on the principles for the welfare of aquatic animals and the proposed guidelines for the slaughter of farmed fish for human consumption, guidelines for the humane killing of fish for disease control purposes, guidelines for transport by land , and guidelines for transport by sea. The reports of the two *ad hoc* Groups are appended for Member Countries' information, in Part C of this report, at <u>Appendix XXXIX</u> and <u>Appendix XL</u>.

As a result of recommendations made by the OIE Working Group on Animal Welfare during its meeting in September 2005, the principles for aquatic animal welfare were harmonised to the extent possible with the corresponding text contained in the *Terrestrial Code*.

The Aquatic Animals Commission acknowledged and supported the quality of the work of the *ad hoc* Groups chaired by Prof. Håstein.

The Aquatic Animals Commission discussed the scope of the new draft chapters and clarified that, while the general principles apply to all aquatic animals, these specific guidelines for transport, killing and slaughter currently cover only fish. It is intended to develop guidelines on crustacean welfare at a later stage.

The Aquatic Animals Commission modified some of the text; the guidelines on principles and the four proposed chapters are attached for Member Countries' comments, in Part B of this report, from Appendix XXXI to Appendix XXXVI.

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

Dr Erlacher-Vindel, Deputy Head of the Scientific and Technical Department, informed the Aquatic Animals Commission on the forthcoming FAO/WHO/OIE expert consultation on Antimicrobial Usage in Aquaculture and Resistance which will take place in Seoul (Republic of Korea) from 13 to 17 June 2006.

Copies of the documents related to the call for experts and the request for information were provided to the Members of the Aquatic Animals Commission and can be found on the OIE website (calendar June 2006:Joint FAO/WHO/OIE Expert Consultation on Antimicrobial Use in Aquaculture and Antimicrobial Resistance: http://www.oie.int/eng/manifestations/en_manifs.htm).

Some scientists and other experts were already contacted by mail. The Members of the Aquatic Animals Commission were invited to provide names of additional relevant experts to Dr Erlacher-Vindel before 24th March 2006. The final selection of 20 to 25 experts will be made by FAO/WHO and OIE at the beginning of April 2006.

The Aquatic Animals Commission addressed the existing standards present in the *Terrestrial Code* and agreed to wait for the outcomes of the Expert Consultation before deciding on the need to include similar chapters in the *Aquatic Code*.

2.6. New work on aquatic animal feed

The Aquatic Animals Commission prepared terms of reference and suggested members for the OIE ad hoc Group on Aquatic Animal Feed and requested the Director General to convene a meeting of the ad hoc Group as soon as possible.

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

The Aquatic Animals Commission prepared terms of reference and suggested members for the OIE *ad hoc* Group on Amphibian Diseases and requested the Director General to convene a meeting of the *ad hoc* Group as soon as possible.

3. Joint meeting with the President of the Terrestrial Animal Health Standards Commission

3.1. Continuing work on harmonisation of horizontal chapters in the *Aquatic* and *Terrestrial Codes* - Zoning and compartmentalisation (Chapter 1.4.4)

Dr Thiermann, the President of the Terrestrial Code Commission, joined the meeting. He illustrated the work conducted by the Terrestrial Code Commission on compartmentalisation by proposing an updated chapter to the 2006 OIE General Session. He also explained the work underway in OIE on the development of a document providing examples on the practical application of the concept of compartmentalisation to avian influenza.

The Aquatic Animals Commission agreed to wait for the outcomes of the 2006 OIE General Session before updating the chapter on zoning in the *Aquatic Code*.

3.2. Revision of model health certificates

Dr Thiermann also briefed the Aquatic Animals Commission on the future work in the Terrestrial Code Commission for updating model certificates for the *Terrestrial Code*. The Aquatic Animals Commission agreed on the need to review the outcomes of this work prior taking the decision of revising its own model certificates.

4. Joint meeting with the Animal Health Information Department

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

Dr Ben Jebara informed the Aquatic Animals Commission that the World Animal Health Information System (WAHIS) would be launched soon. The Delegates and national focal points will be provided with password-protected access. Immediate notification and six-monthly reports can now be entered on-line into WAHIS. The new system will increasingly search for discrepancies in information submitted by Member Countries. This will include comparison with the news media and the scientific literature.

Dr Ben Jebara noted that it has already proven useful to have a slightly different data entry form for aquatics compared to that for terrestrial animals but suggested that minor modifications could further improve the aquatic form.

The new data output system, World Animal Health Information Database (WAHID), will for a period of time run concurrently with the old HandiStatus system.

5. Joint meeting with the Publications Department

5.1 OIE Scientific and Technical Review: issue on aquatic animal health

The Aquatic Animals Commission was joined by Dr Raymond Dugas and Ms Annie Souyri, respectively Head and Deputy Head of the Publications Department. The Commission discussed and agreed the draft table of contents and proposed authors for the issue of the OIE *Scientific and Technical Review* on Changing Trends in Managing Aquatic Animal Disease Emergencies. This issue will now be published in April 2008.

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

For this agenda item, the meeting was joined by Dr Bruckner, Head of the OIE Scientific and Technical Department, and Ms Suarez.

6.1. Regional Commission Conferences

The Commission noted the schedule for the upcoming Regional Commission Conferences and agreed the following representation of the Commission to give follow-up presentations on developments in aquatic animal health:

Regional Commission for Europe (September 2006): Prof. Hill, Vice President of the Aquatic Animals Commission.

Regional Commission for the Americas (November 2006): Dr Ricardo Enriquez, Secretary General of the Aquatic Animals Commission.

6.2. Regional meeting: ad hoc Group for the Americas on Aquatic Animals

Dr Enriquez reported on the above-mentioned meeting in which he had presented the activities of the Aquatic Animals Commission. His presentation included explanations on the disease-listing criteria, the new definitions, the importance of national focal points for disease-reporting purposes, and the importance of safe commodities in the new disease chapters in the *Aquatic Code*. He also informed the participants on the OIE Global Conference on Aquatic Animal Health.

The Aquatic Animals Commission noted the report drafted by Dr Luis Barcos on that meeting and was impressed with the progress made to date and the *ad hoc* group's activities, e.g. the creation of permanent secretariat and technical working groups. Funds had also been received to ensure translation of the *Aquatic Manual* into Spanish.

6.3. International Symposium on Veterinary Epidemiology and Economics, August 2006

On behalf of the Aquatic Animals Commission, Dr Enriquez had submitted a proposal on OIE definitions in aquatic animal epidemiology for the next ISVEE meeting. A response has not yet been received. Therefore, it remains unclear what, if any, activity the Aquatic Animals Commission will have at this Conference.

6.4. First International Conference of OIE Reference Laboratories and Collaborating Centres, December 2006

In considering the content of this conference, the Aquatic Animals Commission agreed that it would beuseful to hold a special workshop for the OIE Reference Laboratories for aquatic animal diseases at which the issue of pathogenic agent strain differentiation could be addressed. The Aquatic Animals Commission recognised that this is a crucial issue as illustrated by the many Member Country comments that were recently received on this topic. The Aquatic Animals Commission is working on a position paper to provide guidelines on listing and notification of diseases by strain/genotype, with multiple examples in finfish, mollusc and crustacean diseases where differences in virulence have been documented for different strains/genotypes of the pathogenic agents of listed diseases.

The Conference will provide the opportunity to strengthen relations between the Aquatic Animals Commission and the network of OIE Reference Laboratories.

6.5. Global Conference on Aquatic Animal Health, October 2006

A meeting of the Scientific Committee was held in parallel with the Aquatic Animals Commission's meeting. The Scientific Committee finalised the draft programme for the Global Conference for the approval of the Steering Committee.

7. Manual of Diagnostic Tests for Aquatic Animals

7.1. Review of Member Countries' and Reviewers' comments on the introductory and disease chapters for the 5th edition of the *Aquatic Manual*

Comments had been received from reviewers and from the following Member Countries: Australia, Canada, the EC, Japan, New Zealand, South Africa, Switzerland and the US. The Commission addressed some of the technical comments but referred the highly specificones to the OIE designated experts who update the chapters. The experts will be asked to address these comments before the *Aquatic Manual* is proposed for adoption during the OIE General Session in May 2006.

Some Member Countries pointed out non-technical issues, such as a lack of consistency in the contents of sections 4, 5 and 6 within and among the chapters. The Commission agreed with most of these concerns and will address them for the next update.

Several Member Countries referred to discrepencies between the susceptible species listed in the *Aquatic Manual* chapters and those listed in the *Aquatic Code* chapters. The reason for this is because the purpose of the *Aquatic Code* is to provide guidelines for species involved in international trade while the *Aquatic Manual* provides technical guidelines for diagnostic and surveillance purposes in a wider range of species.

A number of comments had been received on aquatic animal health surveillance (see item 7.2. below). These will be addressed by the *ad hoc* group on Surveillance.

The Aquatic Animals Commission expressed concern about the increasing volume of issues relating to the *Aquatic Manual* and agreed that such issues should in first instance be addressed by a special *ad hoc* group (of fish, mollusc and crustacean disease experts) with an editorial focus. The Aquatic Animals Commission agreed that greater coordination of the three chapters, General Information on Diseases of Fish, Molluscs and Crustaceans, respectively, is also needed, because these chapters lay the foundations for the subsequent disease-specific chapters; improved consistency between these chapters would aid readability and assist in minimising confusion for readers. The proposed ad hoc group could be asked to revise chapters 1.1, 1.2 and 1.3. accordingly.

7.2. Guidelines for aquatic animal health surveillance

The Aquatic Animals Commission prepared terms of reference and suggested members for the OIE *ad hoc* Group on Aquatic Animal Health Surveillance, and requested the Director General to convene a meeting of the *ad hoc* Group as soon as possible.

7.3. Shortcomings/obsolete OIE tests

The Commission has been made aware of a publication that argues that the OIE method described in one of the chapters in the *Aquatic Manual* gives false positive results and, in the opinion of the authors, is in need of urgent revision. On reading the paper, the Commission noted that the false positives reported were the result of an improperly run assay in the authors' laboratory. This issue highlights the importance of following specific instructions for assays listed in the *Aquatic Manual*.

8. OIE Reference Laboratories

8.1. Updating the list of Reference Laboratories

The Commission reviewed the application by Reference Laboratory for *Bonamia ostreae*, *B. exitiosa*, *Mikrocytos roughleyi*, *Marteilia sydneyi* and *M. refringens* for new expert designation. The Commission reviewed the application and recommends the acceptance of Dr Arzul.

8.2. Review of annual reports

The Commission was pleased to note that all 27 laboratories had submitted their annual reports. There was a wide variation in the amount and detail of information provided. The Commission proposes to add a review of the purpose and content of the annual reports of OIE Reference Laboratories to the agenda of the First OIE Conference for Reference Laboratories and Collaborating Centres (see item 6. 4 above).

9. Any other business

9.1. Update of the Commission's web pages

The meeting was joined by Dr Chaisemartin who provided an update on the plan for the revision of the OIE website and invited suggestions from the Aquatic Animals Commission on what improvements can be made, including any on the Aquatic Animals Commission's specific pages.

Prof. Hill drew the Aquatic Animals Commission's attention to the fact that the International Database on Aquatic Animal Diseases now displays the current list of aquatic animal diseases consistent with how it is displayed in the 2005 edition of the *Aquatic Code*. Prof. Hill pointed out that information on diseases removed from the list in the *Aquatic Code* is now maintained under a separate category of "previously listed diseases".

9.2. Review of the Aquatic Animals Commission's work plan for 2006-2007

The Aquatic Animals Commission expressed their concern about the substantial increased work load, both in terms of volume as well as demand arising from several new initiatives, for example, the increasing complexity of *Aquatic Manual* text (see item 7.1. above). The Aquatic Animals Commission is of the opinion that this can be mitigated through the establishment of one or more groups to assist in reviewing and revising future editions of the *Aquatic Manual*. The Aquatic Animals Commission requests the Director General to consider this matter.

The Commission reviewed its work plan for 2006-2007. The work plan is appended in Part C of this report, at <u>Appendix XLI</u> for Member Countries' information.

9.3. Date of the next meeting

The Aquatic Animals Commission proposed to meet on 2-6 October 2006.

.../Appendices



Appendix I

MEETING OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 1-5 August 2005

Adopted Agenda

- 1. Proposed chapters for the Aquatic Animal Health Code
 - 1.1 General comments
 - 1.2 Definitions (chapter 1.1.1.)
 - 1.3 Disease listing and notification criteria (chapter 1.1.2.)
 - 1.4 Revision of the list of diseases (chapter 1.1.3.)
 - 1.5 Revised chapters for fish and mollusc diseases
 - 1.6 Date of last update for Code Chapters
- 2. New standards for the Aquatic Animal Health Code
 - 2.1 Revised chapters for crustacean diseases
 - 2.2 Crustacean diseases recommended for listing
 - 2.3 New draft chapter on handling and disposal of carcasses and wastes of aquatic animals
 - 2.4 New draft chapters on aquatic animal welfare
 - 2.5 New work on antimicrobial resistance in the field of aquatic animals
 - 2.6 New work on aquatic animal feed
 - 2.7 Including diseases of amphibians in the remit of the Commission
- 3. Joint meeting with the President of the Terrestrial Animal Health Standards Commission
 - 3.1 Continuing work on harmonisation of horizontal chapters in the *Aquatic* and *Terrestrial Codes* Zoning and compartmentalisation (Chapter 1.4.4)
 - 3.2 Revision of model health certificates
- 4. Joint meeting with the Animal Health Information Department
- 5. Joint meeting with the Publications Department
 - 5.1 OIE Scientific and Technical Review: issue on aquatic animal health

Appendix I (contd)

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

- 6.1 Regional Commission Conferences
- 6.2 Regional meeting: *ad hoc* Group for the Americas on Aquatic Animals
- 6.3 International Symposium on Veterinary Epidemiology and Economics, August 2006
- 6.4 First International Conference of OIE Reference Laboratories and Collaborating Centres,
 December 2006
- 6.5 Global Conference on Aquatic Animal Health, October 2006

7. Manual of Diagnostic Tests for Aquatic Animals

- 7.1 Review of Member Countries' and Reviewers' comments on the introductory and disease chapters for the 5th edition of the *Aquatic Manual*
- 7.2 Guidelines for aquatic animal health surveillance
- 7.3 Shortcomings/obsolete OIE tests

8. **OIE Reference Laboratories**

- 8.1 Updating the list of Reference Laboratories
- 8.2 Review of annual reports

9. Any other business

- 9.1 Update of the Commission's web pages
- 9.2 Review of the Aquatic Animals Commission's work plan for 2006-2007
- 9.3 Date of the next meeting

Appendix II

MEETING OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13-17 March 2006

List of participants

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Appendix II (contd)

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CHAPTER 1.1.1.

DEFINITIONS

Community Position

The Community supports these 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 <u>buffer zone</u> 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 Mannal*.

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 <u>self-declaration of freedom from disease</u> with respect to the <u>disease(s)</u> freedom from the <u>disease</u> under consideration, according to the relevant chapter(s) in the <u>Aquatic Code</u>.

Free country

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

Free zone

means a zone that fulfils the requirements for <u>self-declaration of freedom from disease</u> with respect to the <u>disease(s)</u> freedom from the <u>diseases</u> under consideration according to the relevant chapter(s) in the <u>Aquatic Code</u>.

Infection

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

Susceptible species

means a species of aquatic animal in which <u>infection</u> by a disease agent can multiply or otherwise develop has been demonstrated by natural cases or by experimental <u>infection</u> exposure to the <u>disease agent</u> that

mimics the natural pathways for infection. Each disease chapter in the *Aquatic Manual* contains a list of currently known *susceptible species*.

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, molluses 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 <u>Veterinary Service</u>, under the authority of the <u>Veterinary Administration</u>, 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

means 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 Combetent Authority(ies).

same health status. The zones must be clearly documente such as GPS co-ordinates) by the <i>Competent Authority(ies)</i> .			
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Appendix IV

CHAPTER 1.1.2.

DISEASE LISTING **and notification** Criteria

Community position

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. <u>Such proposals should be accompanied by a case definition for the disease under consideration.</u>

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes	
	A. Consequences			
1.		The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in <i>susceptible* species</i> , and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.	
2.	Or	The disease has been shown to or scientific evidence indicates that it is likely to negatively affect wild populations of <i>aquatic animal</i> that are an asset worth protecting for economic or ecological reasons.	populations that are commercially harvested (wild	
3.	Or	The agent is of public health concern.		
And				
B. Spread				
4.		Infectious aetiology of the disease is proven.		

No.	Criteria (A-C)	Parameters that support a listing	Explanatory notes
5.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
6.	And	Potential for international spread, including via live animals, their products or fomites.	International trade in aquatic animal species susceptible to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is a likely risk.
7.	And	Several countries or countries with zones may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 of the Aquatic Manual.	
		And C. Diagnosis	
8.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see OIE <i>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 <u>proposed for listing listed</u> if it meets the <u>following</u> criteria (1 or 2, and 3 or 4):: <u>Such proposals should be accompanied by a case definition for the disease under consideration.</u>

No.	Parameters that support a listing	Explanatory notes
1.	Infectious aetiology of the disease is proven.	4
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 zone, compartment or country level. "Naïve" means animals previously unexposed either to a new disease or a new form of a known disease.

Article 1.1.2.3.

Criteria for immediate notification of aquatic animal diseases

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

<	'Susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'.
·	text deleted

CHAPTER 1.1.3.

DISEASES LISTED BY THE OIE

Community position

The Community can accept amendments proposed to the disease list.

The Community agrees with the inclusion KHV and of abalone viral mortality.

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 necrosis¹
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- Bacterial kidney disease (Renibacterium salmoninarum)+
- Gyrodactylosis (Gyrodactylus salaris)
- Red sea bream iridoviral disease
- Koi herpesvirus disease²

Article 1.1.3.2.

The following diseases of molluscs are listed by the OIE:

- Infection with Bonamia ostreae
- Infection with Bonamia exitiosa
- Infection with Marteilia refringens
- Infection with Mikrocytos mackini[†]
- Infection with Perkinsus marinus
- Infection with Perkinsus olseni¹
- Infection with Xenohaliotis californiensis.
- Abalone viral mortality

Appendix V (contd)

Article 1.1.3.3.

The following diseases of crustaceans are listed by the OIE:

- Taura syndrome
- White spot disease
- Yellowhead disease
- Tetrahedral baculovirosis (Baculovirus penaei)
- Spherical baculovirosis (Penaeus monodon-type baculovirus)
- Infectious hypodermal and haematopoietic necrosis
- Crayfish plague (Aphanomyces astaci)
- Necrotising hepatopancreatitis²
- Infectious myonecrosis².

Delisting of this disease is under study.

² Listing of this disease is under study.

text deleted

CHAPTER 3.1.5.

INFECTION WITH MARTEILIA REFRINGENS

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.5.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Article 3.1.5.1.

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

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

Article 3.1.5.2.

Susceptible species Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for infection with Marteilia refringens are: European flat oyster (Ostrea edulis), Australian mud oyster (O. angasi), Argentinean oyster (O. puelchana) as well as Chilean flat oyster (O. chilensis), blue mussel (Mytilus edulis) and Mediterranean mussel (M. galloprovincialis). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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.

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

Article 3.1.5.3.

Commodities

- 1. When authorising importation 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 referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite;
 - 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* referred to 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 importation or transit of the following commodities of a species referred to in Article 3.1.5.2., other than commodities referred to 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. relevant to the Marteilia refringens status of the exporting country, zone or compartment.
 - a) aquatic animals;
 - b) aquatic animal products.
- 3. When considering the importation or transit of any other commodity from bivalve species not referred to in Article 3.1.5.2. (especially those of the genera Ostrea and Mytilus) not listed above nor in point 1)c) of Article 3.1.5.3, 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. The exporting country should be informed of the outcome of this assessment.

Article 3.1.5.4.

Marteilia refringens free country

A country may make a self-declaration of freedom from *Marteilia refringens* if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *mater catchment* or coastal zone or *compartment* with one or more other countries, it can only make a self-declaration of freedom from 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 <u>susceptible species</u> species of genera <u>Ostrea</u> and <u>Mytilus</u> listed in <u>Article 3.1.5.2.</u> is present may make a self-declaration of freedom from <u>Marteilia refringens</u> when <u>basic</u> biosecurity conditions have been met continuously in the country for at least the past 3 years⁴.

OR

2. A country where the <u>any</u> species referred to 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 make a self-declaration of freedom 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 make a self-declaration of freedom from *Marteilia refringens* when:
 - a) basic biosecurity conditions have been met continuously for at least the past 3 years; and
 - b) targeted surveillance as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual has been in place for at least the last 2 of the past 3 years² without detection of Marteilia refringens.

OR

- 4. A country that has made a self-declaration of freedom from *Marteilia refringens* but in which the disease is detected may not make a self-declaration of freedom 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 3) of Article 3.1.5.5.

Article 3.1.5.5.

Marteilia refringens free zone or free compartment

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

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

1. In a country of unknown status for *Marteilia refringens*, a zone or compartment where none of the <u>susceptible species</u> species of genera Ostrea and Mytilus listed in Article 3.1.5.2. is present may be declared free from Marteilia refringens when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 3 years².

OR

2. In a country of unknown status for Marteilia refringens, a zone or compartment where the any species

referred to 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 X.X.X. of the *Aquatic Manual*, may be declared 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 be declared free from Marteilia refringens when:
 - a) basic biosecurity conditions have been met continuously for at least the past 3 years; and
 - b) targeted surveillance as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual has been in place for at least the last 2 of the past 3 years² without detection of Marteilia refringens.

OR

- 4. A *zone* previously declared free from *Marteilia refringens* but in which the disease is detected may not be declared free from *Marteilia refringens* again until the following conditions have been met:
 - a) on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - c) targeted surveillance, as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual, has been in place for at least the last 2 of the past 3 years without detection of Marteilia refringens.

Article 3.1.5.6.

Maintenance of free status

A country, 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., as relevant, may maintain its status as Marteilia refringens free provided that basic biosecurity conditions are continuously maintained.

A country, 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., as relevant, may discontinue targeted surveillance and maintain its status as Marteilia refringens free provided that conditions that are conducive to clinical expression of infection with Marteilia refringens, as described in Chapter X.X.X. of the Aquatic Manual, exist and basic biosecurity conditions are continuously maintained.

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

Article 3.1.5.7.

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

When importing live aquatic animals of the species referred to in Article 3.1.5.2. 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 should be in accordance with the Model Certificate No. 3 in Appendix 6.3.1. given in Part 6. of the Aquatic Code.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.5.3.

Article 3.1.5.8.

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

When importing for aquaculture, aquatic animals of the species referred to in Article 3.1.5.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Marteilia refringens*.

This Article does not apply to *commodities* listed in point 1) of Article 3.1.5.3.

Article 3.1.5.9.

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 referred to in Article 3.1.5.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Marteilia refringens*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.5.3.

Article 3.1.5.10.

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

When importing aquatic animal products of the species referred to in Article 3.1.5.2. 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.

Appendix VI (contd)

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 should be in accordance with the Model Certificate No. [X] in Appendix 6.3.2. given in Part 6. of the Aguatic Code.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.5.3.

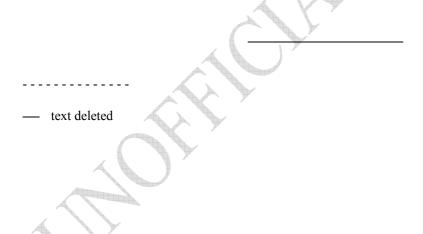
Article 3.1.5.11.

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

When importing aquatic animal products of the species referred to in Article 3.1.5.2. 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 molluses.
- 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.

This Article does not apply to commodities listed in point 1) of Article 3.1.5.3.



CHAPTER 3.1.2.

INFECTION WITH BONAMIA EXITIOSA

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.2.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Article 3.1.2.1.

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

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

Article 3.1.2.2.

Susceptible species Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for infection with Bonamia exitiosa are: Australian mud oyster (Ostrea angasi) and Chilean flat oyster (O. chilensis). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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.

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

Article 3.1.2.3.

Commodities

- 1. When authorising importation 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 referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite;
 - 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* referred to 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 importation or transit of the *commodities* of a species referred to in Article 3.1.2.2., other than *commodities* referred to 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. relevant to the *Bonamia exitiosa* status of the *exporting country*, *zone* or *compartment*.
- 3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 3.1.2.2. (especially those of the genus *Ostrea*) nor in point 1)c) of Article 3.1.2.3, 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 3.1.2.4.

Bonamia exitiosa free country

A country may make a self-declaration of freedom 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 make a self-declaration of freedom from *Bonamia exitiosa* 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 none of the *susceptible species* species of the genus *Ostrea* is present may make a self-declaration of freedom 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 referred to 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 make a self-declaration of freedom 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 make a self-declaration of freedom 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 has made a self-declaration of freedom from *Bonamia exitiosa* but in which the disease is detected may not make a self-declaration of freedom 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone, provided that they meet the conditions in point 3) of Article 3.1.2.5.

Article 3.1.2.5.

Bonamia exitiosa free zone or free compartment

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

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

1. In a country of unknown status for *Bonamia exitiosa*, a *zone* or *compartment* where none of the <u>susceptible</u> <u>species</u> species of the genus *Ostrea* is present may be declared 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 referred to 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 be declared free from Bonamia exitiosa when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 2 years and infection with Bonamia exitiosa is not known to be established in wild populations.

OR

3. A zone or compartment where the last known clinical occurrence was within the past 10 years or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the Aquatic Manual, may be declared 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, 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., as relevant, may maintain its status as Bonamia exitiosa free provided that basic biosecurity conditions are continuously maintained.

A country, 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., as relevant, 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 referred to in Article 3.1.2.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.1.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.2.3.

Article 3.1.2.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 3.1.2.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Bonamia exitiosa*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.2.3.

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 referred to in Article 3.1.2.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Bonamia exitiosa*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.2.3.

Article 3.1.2.10.

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

When importing aquatic animal products of the species referred to in Article 3.1.2.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.2.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.2.3.

Appendix VII (contd)

Article 3.1.2.11.

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

When importing aquatic animal products of the species referred to in Article 3.1.2.2. 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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This Article does not apply to <i>commodities</i> referred to in point 1) of Article 3.1.2.3.	A CONTRACT
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CHAPTER 3.1.1.

INFECTION WITH BONAMIA OSTREAE

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.1.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Article 3.1.1.1.

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

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

Article 3.1.1.2.

Susceptible species Scope

The recommendations in this Chapter apply to 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). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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.

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

Article 3.1.1.3.

Commodities

- 1. When authorising importation 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 referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite;
 - 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* referred to 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 importation or transit of the *commodities* of a species referred to in Article 3.1.1.2., other than *commodities* referred to 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. relevant to the *Bonamia ostreae* status of the exporting country, zone or compartment.
- 3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 3.1.1.2. (especially those of the genus *Ostrea*) nor in point 1)c) of Article 3.1.1.3, 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 3.1.1.4.

Bonamia ostreae free country

A country may make a self-declaration of freedom 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 make a self-declaration of freedom from *Bonamia ostreae* 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 none of the *susceptible species* species of the genus *Ostrea* is present may make a self-declaration of freedom 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 referred to 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 make a self-declaration of freedom 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 make a self-declaration of freedom 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 has made a self-declaration of freedom from *Bonamia ostreae* but in which the disease is detected may not make a self-declaration of freedom 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 3) of Article 3.1.1.5.

Article 3.1.1.5.

Bonamia ostreae free zone or free compartment

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

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

1. In a country of unknown status for *Bonamia ostreae*, a zone or compartment where none of the <u>susceptible</u> <u>species</u> species of the genus *Ostreae* is present may be declared 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 referred to 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 be declared 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 be declared 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, 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., as relevant, may maintain its status as Bonamia ostreae free provided that basic biosecurity conditions are continuously maintained.

A country, 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., as relevant, 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 referred to in Article 3.1.1.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.1.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.1.3.

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 referred to in Article 3.1.1.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Bonamia ostreae*.

This Article does not apply to commodities referred to in point 1) of Article 3.1.1.3.

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 referred to in Article 3.1.1.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Bonamia ostreae*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.1.3.

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

When importing aquatic animal products of the species referred to in Article 3.1.1.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.2.

This Article does not apply to *commodities* listed in point 1) of Article 3.1.1.3.

Appendix VIII (contd)

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 referred to in Article 3.1.1.2. 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.

This Article does not apply to <i>commodities</i> referred to in point 1) of Article 3.1.1.3.	
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CHAPTER 3.1.4.

INFECTION WITH HAPLOSPORIDIUM NELSONI

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.4.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Article 3.1.4.1.

For the purposes of the 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 Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for infection with Haplosporidium nelsoni are: Pacific oyster (Crassostrea gigas) and Eastern oyster (C. virginica). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

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

Article 3.1.4.3.

Commodities

- 1. When authorising importation 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 referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite;
 - 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* referred to 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 importation or transit of the *commodities* of a species referred to in Article 3.1.4.2., other than *commodities* referred to 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. relevant to the *Haplosporidium nelsoni* status of the *exporting country*, *zone* or *compartment*.
- 3. When considering the importation or transit of any other *commodity* from bivalve species not referred to in Article 3.1.4.2. nor in point 1)c) of Article 3.1.4.3, 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 3.1.4.4.

Haplosporidium nelsoni free country

A country may make a self-declaration of freedom 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 make a self-declaration of freedom from *Haplosporidium nelsoni* 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 none of the *susceptible species* is species listed in Article 3.1.4.2. are present may make a self-declaration of freedom 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 referred to 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 make a self-declaration of freedom 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 make a self-declaration of freedom 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 has made a self-declaration of freedom from *Haplosporidium nelsoni* but in which the disease is detected may not make a self-declaration of freedom 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone 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 <u>susceptible species</u> species listed in Article 3.1.4.2. is present may be declared 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 referred to 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 be declared 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 be declared 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, *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., as relevant, may maintain its status as *Haplosporidium nelsoni* free provided that *basic biosecurity conditions* are continuously maintained.

A country, 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., as relevant, 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 referred to in Article 3.1.4.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.1.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.4.3.

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 referred to in Article 3.1.4.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.4.3.

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 referred to in Article 3.1.4.2. 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 from the processing are treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

This Article does not apply to commodities referred to referred to in point 1) of Article 3.1.4.3.

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

When importing aquatic animal products of the species referred to in Article 3.1.4.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.2.

This Article does not apply to *commodities* listed in point 1) of Article 3.1.4.3.

Appendix IX (contd)

Article 3.1.4.11.

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

When importing aquatic animal products of the species referred to in Article 3.1.4.2. 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.

should assess the risk and apply appropriate risk mitigation measures.	
This Article does not apply to <i>commodities</i> referred to in point 1) of Article 3.1.4.3.	No.
This Article does not apply to commodities referred to in point 1) of Article 3.1.4.3. — text deleted	

CHAPTER 3.1.7.

TNFECTION WITH MIKROCYTOS MACKINI

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.7.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Article 3.1.7.1.

For the purposes of the 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 Scope

The recommendations in this Chapter apply to For the purposes of the 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). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Article 3.1.7.3.

Commodities

- 1. When authorising importation 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 referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite;
- iii) off the shell (chilled or frozen) packaged for direct retail trade.

For the *commodities* referred to 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 importation or transit of the *commodities* of a species referred to in Article 3.1.7.2., other than *commodities* referred to 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. relevant to the *Mikrocytos mackini* status of the *exporting country*, *zone* or *compartment*.
- 3. When considering the importation or transit of any other *commodity* from bivalve species not referred to 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 3.1.7.4.

Mikrocytos mackini free country

A country may make a self-declaration of freedom 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 make a self-declaration of freedom from *Mikrocytos mackini* 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 none of the *susceptible species* is species listed in Article 3.1.7.2. are present may make a self-declaration of freedom 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 referred to 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 make a self-declaration of freedom 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 make a self-declaration of freedom 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 has made a self-declaration of freedom from Mikrocytos mackini but in which the

disease is detected may not make a self-declaration of freedom 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone 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 <u>susceptible species</u> species listed in Article 3.1.7.2. is present may be declared 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 referred to 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 be declared 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 be declared 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, 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., as relevant, may maintain its status as Mikrocytos mackini free provided that basic biosecurity conditions are continuously maintained.

A country, 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., as relevant, 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 referred to in Article 3.1.7.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.1.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.7.3.

Article 3.1.7.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 3.1.7.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Mikrocytos mackini*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.7.3.

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 referred to in Article 3.1.7.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Mikrocytos mackini*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.7.3.

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

When importing aquatic animal products of the species referred to in Article 3.1.7.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.2.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.7.3.

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

When importing aquatic animal products of the species referred to in Article 3.1.7.2. 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.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.7.3.

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CHAPTER 3.1.9.

INFECTION WITH PERKINSUS OLSENI

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.9.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Article 3.1.9.1.

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

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

Article 3.1.9.2.

Susceptible species Scope

The recommendations in this Chapter apply to infection with Perkinsus olseni are: primarly venerid clams (Austrovenus stutchburyi, Venerupis pullastra, V. aurea, Ruditapes decussatus and R. philippinarum), abalone (Haliotis rubra, H. laevigata, H. Cyclobates and H. scalaris) and other species (Anadara trapezia, Barbatia novaezelandiae, Macomona liliana, Paphies australis, Crassostrea gigas and C. ariakensis). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Suspected 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 importation 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 referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite.

For the *commodities* referred to 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 importation or transit of the *commodities* of a species referred to in Article 3.1.9.2., other than *commodities* referred to 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. relevant to the *Perkinsus olseni* status of the *exporting country*, *zone* or *compartment*.
- 3. When considering the importation or transit of any other *commodity* from bivalve and gastropod species not referred to 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 3.1.9.4.

Perkinsus olseni free country

A country may make a self-declaration of freedom 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 make a self-declaration of freedom from *Perkinsus olseni* 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 <u>susceptible species</u> species listed in Article 3.1.9.2. are present but there has never been any observed occurrence of the <u>disease</u> 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 <u>Aquatic Manual</u>, may make a self-declaration of freedom from <u>Perkinsus olseni</u> when <u>basic biosecurity conditions</u> have been met continuously in the country for at least the past 3 years and infection with <u>Perkinsus olseni</u> 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 make a self-declaration of freedom 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 has made a self-declaration of freedom from *Perkinsus olseni* but in which the disease is detected may not make a self-declaration of freedom 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone 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 the susceptible species 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 be declared 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 be declared free from Perkinsus olseni when:
 - a) basic biosecurity conditions have been met continuously for at least the past 3 years; and
 - b) targeted surveillance as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual has been in place for at least the past 3 years without detection of Perkinsus olseni.

OR

- 3. A zone previously declared free from *Perkinsus olseni* but in which the disease is detected may not be declared free from *Perkinsus olseni* again until the following conditions have been met:
 - a) on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and

- b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
- c) targeted surveillance, as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual, has been in place for at least the past 3 years without detection of Perkinsus olseni.

Article 3.1.9.6.

Maintenance of free status

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

A country, zone or compartment that is declared free from Perkinsus olseni following the provisions of point 2) of Articles 3.1.9.4. or 3.1.9.5., as relevant, may discontinue targeted surveillance and maintain its status as Perkinsus olseni free provided that conditions that are conducive to clinical expression of infection with Perkinsus olseni, as described in Chapter X.X.X. of the Aquatic Manual, exist and basic biosecurity conditions are continuously maintained.

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

Article 3.1.9.7.

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

When importing live aquatic animals of the species referred to in Article 3.1.9.2. from a country, zone or compartment declared free from Perkinsus olseni, the Competent Authority of the importing country should require an international aquatic animal health certificate issued by the Competent Authority of the exporting country or a certifying official approved by the importing country.

This certificate must certify, on the basis of the procedures described in Articles 3.1.9.4. or 3.1.9.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Perkinsus olseni*.

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

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.9.3.

Article 3.1.9.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 3.1.9.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Perkinsus olseni*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.9.3.

Article 3.1.9.9.

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 referred to in Article 3.1.9.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Perkinsus olseni*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.9.3.

Article 3.1.9.10.

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

When importing aquatic animal products of the species referred to in Article 3.1.9.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.2.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.9.3.

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 referred to in Article 3.1.9.2. 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:

- 1) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products referred to in point 1) of Article 3.1.9.3. or other products authorised by the *Competent Authority*; and
- 2) all effluent and waste material <u>from the processing</u> are treated in a manner that ensures inactivation of *Perkinsus olseni*.

This Article does not apply to <i>commodities</i> referred to in point 1) of Article 3.1.9.3.

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CHAPTER 3.1.8.

INFECTION WITH PERKINSUS MARINUS

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.8.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Article 3.1.8.1.

For the purposes of the 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 Scope

The recommendations in this Chapter apply to For the purposes of the 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 shell clam (Mercenaria mercenaria). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Suspected 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 importation 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 referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite.

For the *commodities* referred to 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 importation or transit of the *commodities* of a species referred to in Article 3.1.8.2., other than commodities referred to 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. relevant to the *Perkinsus marinus* status of the *exporting country*, *zone* or *compartment*.
- 3. When considering the importation or transit of any other *commodity* from bivalve species not referred to 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*: The *exporting country* should be informed of the outcome of this assessment.

Article 3.1.8.4.

Perkinsus marinus free country

A country may make a self-declaration of freedom 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 make a self-declaration of freedom from *Perkinsus marinus* 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 none of the *susceptible species* is species listed in Article 3.1.8.2. are present may make a self-declaration of freedom 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 referred to 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 make a self-declaration of freedom 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 make a self-declaration of freedom 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 has made a self-declaration of freedom from *Perkinsus marinus* but in which the disease is detected may not make a self-declaration of freedom 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, one or more areas of the remaining *territory* may be declared free *zones*, part of the non-affected area may be declared a free *zone* 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. In a country of unknown status for *Perkinsus marinus*, a zone or *compartment* where none of the <u>susceptible</u> <u>species</u> species listed in Article 3.1.8.2. are is present may be declared free from *Perkinsus marinus* when *basic biosecurity conditions* have been met continuously in the zone or *compartment* 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 referred to 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 be declared 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 be declared 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, 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., as relevant, may maintain its status as *Perkinsus marinus* free provided that *basic biosecurity conditions* are continuously maintained.

A country, 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., as relevant, 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 referred to in Article 3.1.8.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.1.

This Article does not apply to commodities referred to in point 1) of Article 3.1.8.3.

Article 3.1.8.8.

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

When importing for aquaculture, aquatic animals of the species referred to in Article 3.1.8.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Perkinsus marinus*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.8.3.

Article 3.1.8.9.

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 referred to in Article 3.1.8.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Perkinsus marinus*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.8.3.

Article 3.1.8.10.

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

When importing aquatic animal products of the species referred to in Article 3.1.8.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.2.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.8.3.

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 referred to in Article 3.1.8.2. 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:

1) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products referred to in point 1) of Article 3.1.8.3. or other products authorised by the

2)	all effluent and waste material	from 1	the 1	processing	are	treated in	a manne	r that	ensures	inact	ivation	of
	Perkinsus marinus.											

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.8.3.

CHAPTER 3.1.11.

INFECTION WITH XENOHALIOTIS CALIFORNIENSIS

Community Position

The Community supports the proposed chapter.

However, the Community would ask the OIE AAC to re-consider its position on the Community comment on Article 3.1.11.10. Those requirements seem inconsistent taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals), when Article 3.1.5.10 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 unjustifiable.

Finally, the Community continues to request a clarification of the meaning of "shell" in point 1 a) iii) of Article 3.1.11.3. Since this describes a safe commodity, it must be beyond doubt what is meant by that word.

Article 3.1.11.1.

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

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

Article 3.1.11.2.

Susceptible species Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for infection with Xenohaliotis 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). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

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

Article 3.1.11.3.

Commodities

- 1. When authorising importation or transit of the following commodities, Competent Authorities should not require any Xenohaliotis californiensis related conditions, regardless of the Xenohaliotis californiensis status of the exporting country, zone or compartment:
 - a) From the species referred to 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the parasite;
 - iii) off the shell, eviscerated abalone (chilled or frozen) packaged for direct retail trade.

For the *commodities* referred to 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 importation or transit of the *commodities* of a species referred to in Article 3.1.11.2., other than *commodities* referred to 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. relevant to the *Xenohaliotis californiensis* status of the *exporting country*, *zone* or *compartment*.
- 3. When considering the importation or transit of any other *commodity* from bivalve mollusc species not referred to in Article 3.1.11.2. (especially those of the genus *Haliotis*) from an *exporting country*, *zone* or *compartment* not declared free of *Xenohaliotis californiensis*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Xenohaliotis 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 3.1.11.4.

Xenohaliotis californiensis free country

A country may make a self-declaration of freedom 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 make a self-declaration of freedom from *Xenohaliotis californiensis* 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 none of the *susceptible species* is species of the genus *Haliotis* is present may make a self-declaration of freedom 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 referred to 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 make a self-declaration of freedom 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 make a self-declaration of freedom 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 has made a self-declaration of freedom from *Xenohaliotis californiensis* but in which the disease is detected may not make a self-declaration of freedom 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 Xenohaliotis californiensis.

In the meantime, one or more areas of the remaining *territory* may be declared free *zones*, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3) of Article 3.1.11.5.

Article 3.1.11.5.

Xenohaliotis californiensis free zone or free compartment

A zone or compartment free from Xenohaliotis californiensis may be established within the territory of one or more countries of infected or unknown status for infection with Xenohaliotis 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 Xenohaliotis 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 *Xenohaliotis californiensis*, a zone or compartment where none of the <u>susceptible species</u> species of the genus *Haliotis* is present may be declared free from *Xenohaliotis 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 *Xenohaliotis californiensis*, a zone or compartment where any species referred to 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 be declared free from *Xenohaliotis californiensis* when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 2 years and infection with *Xenohaliotis 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 be declared 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 *zone* previously declared free from *Xenohaliotis californiensis* but in which the disease is detected may not be declared 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 Xenohaliotis californiensis.

Article 3.1.11.6.

Maintenance of free status

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

A country, zone or compartment that is declared free from Xenohaliotis californiensis following the provisions of point 3) of Articles 3.1.11.4. or 3.1.11.5., as relevant, may discontinue targeted surveillance and maintain its status as Xenohaliotis californiensis free provided that conditions that are conducive to clinical expression of infection with Xenohaliotis 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 *Xenohaliotis 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 *Xenohaliotis* californiensis

When importing live aquatic animals of the species referred to in Article 3.1.11.2. from a country, zone or compartment declared free from Xenohaliotis 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 *Xenohaliotis californiensis*.

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

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.11.3.

Article 3.1.11.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 3.1.11.2. 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 from the processing are treated in a manner that ensures inactivation of *Xenohaliotis californiensis*.

This Article does not apply to commodities referred to in point 1) of Article 3.1.11.3.

Article 3.1.11.9.

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 referred to in Article 3.1.11.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *Xenobaliotis californiensis*.

This Article does not apply to *commodities* referred to in point 1) of Article 3.1.11.3.

Article 3.1.11.10.

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

When importing aquatic animal products of the species referred to in Article 3.1.11.2. 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 should be in accordance with the Model Certificate in Appendix 6.3.2.

This Article does not apply to *commodities* listed in point 1) of Article 3.1.11.3.

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 referred to in Article 3.1.11.2. 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.

should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to commodities referred to in point 1) of Article 3.1.11.3.

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CHAPTER 2.1.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

Community position

The Community can support this chapter provided the OIE AAC undertakes a proper assessment of the justification that the Community will submit together with its comments on Part B of the report of its March meeting, before 10 September 2006, with regard to the Community comments on Articles 2.1.1. 3 and 2.1.1.11 from February 2006.

Article 2.1.1.1.

For the purposes of the *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 Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for EHN are: redfin perch (Perca fluviatilis) and rainbow trout (Oncorhynchus mykiss). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Article 2.1.1.3.

Commodities

- 1) When authorising importation 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the pathogen;
- <u>iii)</u> 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 and sun dried).
- c) For species other than those in Article 2.1.1.2., all aquatic animal products.

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

- 2) When authorising importation or transit of the following commodities of a species referred to 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. relevant to the EHN status of the exporting country, zone or compartment.
 - a) aquatic animals;
 - b) aquatic animal products.
- 3) When considering the importation or transit of any live commodity of a species not referred to 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 EHNV 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. The exporting country should be informed of the outcome of this assessment.

Article 2.1.1.4.

EHN free country

A country may make a self-declaration of freedom from EHN if it meets the conditions in points 1), 2), 3) or 4) below.

If a country shares a *zone* or *compartment mater catchment* with one or more other countries, it can only make a self-declaration of freedom from EHN 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 <u>susceptible species</u> species listed in Article 2.1.1.2. is present may make a self-declaration of freedom 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 referred to 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 make a *self-declaration of freedom* 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 make a *self-declaration of freedom* 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 EHNV.

OR

- 4) A country that has made a *self-declaration of freedom* from EHN but in which the disease is subsequently detected may not make a *self-declaration of freedom* from EHN again until the following conditions have been met:
 - a) on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - c) targeted surveillance, as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual, has been in place for at least the last 2 years without detection of EHNV.

In the meantime, one or more areas of the remaining territory may be declared free zone, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 3) of Article 2.1.1.5.

Article 2.1.1.5.

EHN free zone or free compartment

A zone or compartment within the territory of one or more countries not declared free from EHN may be declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in points 1), 2), 3) or 4) below.

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

1) A zone or compartment where none of the <u>susceptible species</u> species listed in Article 2.1.1.2. is present may be declared 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 referred to 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 be declared free from EHN when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 10 years.

- 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 be declared 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 EHNV.

OR

- 4) A *zone* previously declared free from EHN but in which the disease is detected may not be declared free from EHN again until the following conditions have been met:
 - a) on detection of the disease, the affected area was declared an *infected zone* and a *buffer zone* was established; and
 - b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
 - c) targeted surveillance, as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual, has been in place for at least the last 2 years without detection of EHNV.

Article 2.1.1.6.

Maintenance of free status

A country, *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., as relevant, may maintain its status as EHN free provided that *basic biosecurity conditions* are continuously maintained.

A country, *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., as relevant, 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 referred to in Article 2.1.1.2. 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 should be in accordance with the Model Certificate in Appendix 6.1.1. No. 1 given in Part 6. of this Aquatic Code.

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.1.3.

Article 2.1.1.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 2.1.1.2. 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
- all effluent and waste material are treated in a manner that ensures inactivation of EHNV.

This Article does not apply to commodities referred to in point 1) of Article 2.1.1.3.

Article 2.1.1.9.

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

When importing, for processing and/or for human consumption, aquatic animals of the species referred to in Article 2.1.1.2. 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 referred to in point 1) of Article 2.1.1.3. or other products authorised by the *Competent Authority*; and
- 2) all effluent and waste material <u>from the processing</u> are treated in a manner that ensures inactivation of EHNV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.1.3.

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 referred to in Article 2.1.1.2. 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 from the processing are treated in a manner that ensures inactivation of EHNV.

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.1.3.

Article 2.1.1.10.

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

When importing aquatic animal products of the species referred to in Article 2.1.1.2. 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 should be in accordance with the Model Certificate in Appendix 6.2.1. No. 2 given in Part 6. of this Aquatic Code.

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.1.3.

Article 2.1.1.11.

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

When importing aquatic animal products of the species referred to in Article 2.1.1.2. 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:

- 1) the consignment is delivered directly to and held in facilities for processing to one of the products referred to in point 1) of Article 2.1.14.3. 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.

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.1.3.

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CHAPTER 2.1.2.

INFECTIOUS HAEMATOPOIETIC NECROSIS

Community position

The Community can support this chapter provided the OIE AAC undertakes a proper assessment of the justification that the Community will submit together with its comments on Part B of the report of its March meeting, before 10 September 2006, with regard to the Community comments on Articles 2.1.2.3 and 2.1.2.11 from February 2006.

Article 2.1.2.1.

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

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

Article 2.1.2.2.

Susceptible species Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for HIN are: rainbow trout or steelhead (Oncorhynchus mykiss), the Pacific salmon species (chinook [O. tshanytscha], sockeye [O. nerka], chum [O. keta], masou [O. masou], pink [O. rhodurus] and coho [O. kisutch]), and Atlantic salmon (Salmo salar). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Article 2.1.2.3.

Commodities

- 1) When authorising importation 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the pathogen;
- 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 and sun dried).
- c) For species other than those in Article 2.1.2.2., all aquatic animal products.

For the *commodities* referred to 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 importation or transit of the *commodities* of a species referred to 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. relevant to the IHN status of the *exporting country*, *zone* or *compartment*.
- 3) When considering the importation or transit of any live *commodity* of a species not referred to 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.2.4.

IHN free country

A country may make a *self-declaration of freedom* 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 make a *self-declaration* of freedom from IHN 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 <u>susceptible species</u> species listed in Article 2.1.2.2. is present may make a self-declaration of freedom 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 referred to 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 make a *self-declaration of freedom* from IHN when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

- 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 make a *self-declaration of freedom* 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 has made a *self-declaration of freedom* from IHN but in which the disease is subsequently detected may not make a *self-declaration of freedom* 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 3) of Article 2.1.2.5.

Article 2.1.2.5.

IHN free zone or free compartment

A zone or compartment within the territory of one or more countries not declared free from IHN may be declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in points 1), 2), 3) or 4) below.

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

1) A zone or compartment where none of the <u>susceptible species</u> species listed in Article 2.1.2.2. is present may be declared 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 referred to 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 be declared free from IHN when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 10 years.

- 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 be declared 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, 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., as relevant, may maintain its status as IHN free provided that basic biosecurity conditions are continuously maintained.

A country, *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., as relevant, 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 referred to in Article 2.1.2.2. 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 should be in accordance with the Model Certificate in Appendix 6.1.1.

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.2.3.

Article 2.1.2.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species referred to in Article 2.1.2.2. 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.

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.2.3.

Article 2.1.2.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species referred to in Article 2.1.2.2. 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 referred to in point 1) of Article 2.1.2.3. or other products authorised by the *Competent Authority*; and
- 2) all effluent and waste material <u>from the processing</u> are treated in a manner that ensures inactivation of IHNV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.2.3.

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 referred to in Article 2.1.2.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.2.3.

Article 2.1.2.10.

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

When importing aquatic animal products of the species referred to in Article 2.1.2.2. 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 should be in accordance with the Model Certificate in Appendix 6.2.1.

This Article does not apply to *commodities* referred to in point 1) of Article 2.1.2.3.

Article 2.1.2.11.

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

When importing aquatic animal products of the species referred to in Article 2.1.2.2. 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:

- 1) the consignment is delivered directly to and held in biosecure/quarantine facilities for processing to one of the products referred to 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.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.2.3.

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CHAPTER 2.1.4.

SPRING VIRAEMIA OF CARP

Community position

The Community can support this chapter provided the OIE AAC undertakes a proper assessment of the justification that the Community will submit together with its comments on Part B of the report of its March meeting, before 10 September 2006, with regard to the Community comments on Articles 2.1.4.3 and 2.1.4.11 from February 2006.

Article 2.1.4.1.

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

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

Article 2.1.4.2.

Susceptible species Scope

The recommendations in this Chapter apply to For the purposes of the 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). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Article 2.1.4.3.

Commodities

- 1) When authorising importation 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the pathogen;
- 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 and sun dried).

c) For species other than those in Article 2.1.4.2., all aquatic animal products.

For the *commodities* referred to 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 importation or transit of the *commodities* of a species referred to 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. relevant to the SVC status of the *exporting country*, *zone* or *compartment*.
- 3) When considering the importation or transit of any live *commodity* of a species not referred to 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.4.4.

SVC free country

A country may make a *self-declaration of freedom* 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 make a *self-declaration* of freedom from SVC 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 referred to in Article 2.1.4.2. is present may make a *self-declaration* of freedom 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 <u>susceptible species</u> 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 make a *self-declaration of freedom* from SVC when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

- 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 make a *self-declaration of freedom* 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 has made a *self-declaration of freedom* from SVC but in which the disease is subsequently detected may not make a *self-declaration of freedom* 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, one or more areas of the remaining territory may be declared free zones, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 3) of Article 2.1.4.5.

Article 2.1.4.5.

SVC free zone or free compartment

A zone or compartment within the territory of one or more countries not declared free from SVC may be declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in points 1), 2), 3) or 4) below.

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

1) A zone or compartment where none of the <u>susceptible species</u> species listed in Article 2.1.4.2. is present may be declared 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 referred to 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 be declared free from SVC when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 10 years.

- 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 be declared 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, *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., as relevant, may maintain its status as SVC free provided that *basic biosecurity conditions* are continuously maintained.

A country, *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., as relevant, 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 referred to in Article 2.1.4.2. 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 should be in accordance with the Model Certificate in Appendix 6.1.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.4.3.

Article 2.1.4.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 2.1.4.2. 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.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.4.3.

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 referred to in Article 2.1.4.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of SVCV

This Article does not apply to commodities listed in point 1) of Article 2.1.4.3.

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 referred to in Article 2.1.4.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of SVCV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.4.3.

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

When importing aquatic animal products of the species referred to in Article 2.1.4.2. 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.

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

This Article does not apply to *commodities* listed in point 1) of Article 2.1.4.3.

Article 2.1.4.11.

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

When importing aquatic animal products of the species referred to in Article 2.1.4.2. 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:

- 1) 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
- 2) all effluent and waste material are treated in a manner that ensures inactivation of SVCV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.4.3.

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CHAPTER 2.1.5.

VIRAL HAEMORRHAGIC SEPTICAEMIA

Community position

The Community can support this chapter provided the OIE AAC undertakes a proper assessment of the justification that the Community will submit together with its comments on Part B of the report of its March meeting, before 10 September 2006, with regard to the Community comments on Articles 2.1.5.3 and 2.1.5.11 from February 2006.

Article 2.1.5.1.

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

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

Article 2.1.5.2.

Susceptible species Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for VHS are: rainbow trout (Oncorhynchus mykiss), brown trout (Salmo trutta), grayling (Thymallus thymallus), white fish (Coregonus spp.), pike (Esox lucius), turbot (Scophthalmus maximus), herring and sprat (Clupea spp.), Pacific salmon (Oncorhynchus spp.), Atlantic cod (Gadus morhua), Pacific cod (G. macrocephalus), haddock (G. aeglefinus) and rockling (Onos mustelus). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

Atlantic salmon (Salmo salar), Atlantic cod (Gadus morbua), Atlantic herring (Clupea harengus), black cod (Anaplopoma fimbria), blue whiting (Micromesistius poutassou), brook trout (Salvelinus fontinalis), brown trout (Salmo trutta), chinook salmon (Oncorhynchus tshanytscha), coho salmon (O. kisutch), common dab (Limanda limanda), English sole (Paraphrys 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 namayeush), lesser argentine (Argentina sphyraena), Norway pout (Trisopterus esmarkii), Pacific cod (Gadus macrocephalus), Pacific hake (Merluccius productus), Pacific herring (Clupea harengus pallasi), Pacific mackerel (Scomber japonicus), Pacific sandlance (Ammodytes hexapterus), pike (Esox lucius), pilehard (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 (Thalcichthys 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).

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

Article 2.1.5.3.

Commodities

1) When authorising importation 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the pathogen;
 - 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 and sun dried).
- e) 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 importation or transit of the *commodities* of a species referred to 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. relevant to the VHS status of the *exporting country*, *zone* or *compartment*.
- 3) When considering the importation or transit of any live *commodity* of a species not referred to 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.5.4.

VHS free country

A country may make a *self-declaration of freedom* 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 make a *self-declaration* of freedom from VHS 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 <u>susceptible species</u> 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 make a *self-declaration of freedom* 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 make a *self-declaration of freedom* 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 has made a *self-declaration of freedom* from VHS but in which the disease is subsequently detected may not make a *self-declaration of freedom* 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, one or more areas of the remaining territory may be declared free zone, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 2) of Article 2.1.5.5.

Article 2.1.5.5.

VHS free zone or free compartment

A zone or compartment within the territory of one or more countries not declared free from VHS may be declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in points 1), 2) 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 <u>susceptible species</u> 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 be declared 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 be declared free from VHS when:

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- a) basic biosecurity conditions have been met continuously for at least the past 2 years; and
- b) targeted surveillance as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual has been in place for at least the last 2 years without detection of 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, *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., as relevant, may maintain its status as VHS free provided that *basic biosecurity conditions* are continuously maintained.

A country, *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., as relevant, 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 referred to in Article 2.1.5.2. 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 should be in accordance with the Model Certificate in Appendix 6.1.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.5.3.

Article 2.1.5.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species referred to in Article 2.1.5.2. 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.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.5.3.

Article 2.1.5.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species referred to in Article 2.1.5.2. 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 from the processing are treated in a manner that ensures inactivation of VHSV.

This Article does not apply to commodities listed in point 1) of Article 2.1.5.3.

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 referred to in Article 2.1.5.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of VHSV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.5.3.

Article 2.1.5.10.

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

When importing aquatic animal products of the species referred to in Article 2.1.5.2. 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 should be in accordance with the Model Certificate in Appendix 6.2.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.5.3.

Article 2.1.5.11.

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

When importing aquatic animal products of the species referred to in Article 2.1.5.2. 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:

- 1) 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
- 2) all effluent and waste material are treated in a manner that ensures inactivation of VHSV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.5.3.

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CHAPTER 2.1.9.

INFECTIOUS SALMON ANAEMIA

Community position

The Community can support this chapter provided the OIE AAC undertakes a proper assessment of the justification that the Community will submit together with its comments on Part B of the report of its March meeting, before 10 September 2006, with regard to the Community comments on Articles 2.1.9.3 and 2.1.9.11 from February 2006.

Article 2.1.9.1.

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

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

Article 2.1.9.2.

Susceptible species Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for ISA are: Atlantic salmon (Salmo salar), brown and sea trout (S. trutta), pollock (Pollachius virens), and rainbow trout (Onchorynchus mykiss) cod (Gadus morhua). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Article 2.1.9.3.

Commodities

- 1) When authorising importation 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the pathogen;
- 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 and sun dried);
- e) 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 importation or transit of the *commodities* of a species referred to 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. relevant to the ISA status of the *exporting country*, *zone* or *compartment*.
- 3) When considering the importation or transit of any live *commodity* of a species not referred to 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.9.4.

ISA free country

A country may make a *self-declaration of freedom* 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 make a *self-declaration* of freedom from ISA 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 <u>susceptible species</u> species listed in Article 2.1.9.2. is present may make a self-declaration of freedom 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 referred to 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 make a *self-declaration of freedom* 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 make a *self-declaration of freedom* 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 has made a *self-declaration of freedom* from ISA but in which the disease is subsequently detected may not make a *self-declaration of freedom* 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, one or more areas of the remaining territory may be declared free zone, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 3) of Article 2.1.9.5.

Article 2.1.9.5.

ISA free zone or free compartment

A zone or compartment within the territory of one or more countries not declared free from ISA may be declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in points 1), 2), 3) or 4) below.

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

1) A zone or compartment where none of the <u>susceptible species</u> species listed in Article 2.1.9.2. is present may be declared 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 referred to 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 be declared free from ISA when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 10 years.

- 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 be declared 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, 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., as relevant, may maintain its status as ISA free provided that basic biosecurity conditions are continuously maintained.

A country, *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., as relevant, 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 referred to in Article 2.1.9.2. 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 should be in accordance with the Model Certificate in Appendix 6.1.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.9.3.

Article 2.1.9.8.

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

When importing, for *aquaculture*, *aquatic animals* of the species referred to in Article 2.1.9.2. 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.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.9.3.

Article 2.1.9.9.

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

When importing, for processing for human consumption, aquatic animals of the species referred to in Article 2.1.9.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of ISAV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.9.3.

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 referred to in Article 2.1.9.2. 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 from the processing are treated in a manner that ensures inactivation of ISAV

This Article does not apply to *commodities* listed in point 1) of Article 2.1.9.3.

Article 2.1.9.10.

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

When importing aquatic animal products of the species referred to listed in Article 2.1.9.2. 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 should be in accordance with the Model Certificate in Appendix 6.2.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.9.3.

Article 2.1.9.11.

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

When importing aquatic animal products of the species referred to in Article 2.1.9.2. 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:

- 1) 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
- 2) all effluent and waste material are treated in a manner that ensures inactivation of ISAV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.9.3.

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CHAPTER 2.1.10.

EPIZOOTIC ULCERATIVE SYNDROME

Community position

The Community can support this chapter provided the OIE AAC undertakes a proper assessment of the justification that the Community will submit together with its comments on Part B of the report of its March meeting, before 10 September 2006, with regard to the Community comments on Articles 2.1.10.3 and 2.1.10.11 from February 2006.

Article 2.1.10.1.

For the purposes of the *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 Scope

The recommendations in this Chapter apply to For the purposes of the 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), torpedoshaped 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. and 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 (Osphonemus gourami), dusky flathead (Platycephalus fuscus), spiny turbot (Psettodes sp.), Tairiku-baratanago (Rhodeus ocellatus), Keti-Bangladeshi (Rohtee sp.), rudd (Scaridinius erythrophthalmus), therapon (Terapon sp.) and three-spot gouramy (Trichogaster trichopterus). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Article 2.1.10.3.

Commodities

- 1) When authorising importation 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 referred to 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) that have been heat treated in a manner to ensure the inactivation of the pathogen;
 - 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 and sun dried).
- e) 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 importation or transit of the *commodities* of a species referred to 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. relevant to the EUS status of the *exporting country*, *zone* or *compartment*.
- 3) When considering the importation or transit of any live *commodity* of a species not referred to 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. The exporting country should be informed of the outcome of this assessment.

Article 2.1.10.4.

EUS free country

A country may make a self-declaration of freedom 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 make a *self-declaration* of freedom from EUS 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 <u>susceptible species</u> 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 make a *self-declaration of freedom* from EUS when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

- 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 make a *self-declaration of freedom* 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 has made a *self-declaration of freedom* from EUS but in which the disease is subsequently detected may not make a *self-declaration of freedom* 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, one or more areas of the remaining territory may be declared free zone, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 2) of Article 2.1.10.5.

Article 2.1.10.5.

EUS free zone or free compartment

A zone or compartment within the territory of one or more countries not declared free from EUS may be declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in points 1), 2) 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 <u>susceptible species</u> 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 be declared 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 be declared 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.

- 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

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- b) infected populations have been safely destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the disease, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
- c) targeted surveillance, as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual, has been in place for at least the last 2 years without detection of A. invadans.

Article 2.1.10.6.

Maintenance of free status

A country, 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., as relevant, may maintain its status as EUS free provided that basic biosecurity conditions are continuously maintained.

A country, 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., as relevant, 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 referred to in Article 2.1.10.2. 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 should be in accordance with the Model Certificate in Appendix 6.1.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.10.3.

Article 2.1.10.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 2.1.10.2. 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.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.10.3.

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 referred to in Article 2.1.10.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *A. invadans*.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.9.3.

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 referred to in Article 2.1.10.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of *A. invadans*.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.10.3.

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

When importing aquatic animal products of the species referred to in Article 2.1.10.2. 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 should be in accordance with the Model Certificate in Appendix 6.2.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.10.3.

Article 2.1.10.11.

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

When importing *aquatic animal products* of the species referred to in Article 2.1.10.2. 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:

- 1) 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
- 2) all effluent and waste material are treated in a manner that ensures inactivation of A. invadans.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.10.3.

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CHAPTER 2.1.15.

RED SEA BREAM IRIDOVIRAL DISEASE

Community position

The Community can support this chapter provided the OIE AAC undertakes a proper assessment of the justification that the Community will submit together with its comments on Part B of the report of its March meeting, before 10 September 2006, with regard to the Community comments on Articles 2.1.15.3 and 2.1.15.11 from February 2006.

Article 2.1.15.1.

For the purposes of the *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 Scope

The recommendations in this Chapter apply to For the purposes of the Aquatic Code, susceptible species for RSIVD are: red sea bream (Pagrus major), yellowtail (Seriola quinqueradiata), amberjack (Seriola dumerili), sea bass (Lateolabrax sp. and Lates calcarifer), Albacore (Thunnus thynnus), Japanese parrotfish (Oplegnathus fasciatus), striped jack (Caranx delicatissimus), mandarin fish (Siniperca chuatsi), red drum (Sciaenops ocellatus), mullet (Mugil cephalus) and groupers (Epinephelus spp.). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

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

Article 2.1.15.3.

Commodities

- 1) When authorising importation 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 2.1.15.2., 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 referred to in Article 2.1.15.2. 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) that have been heat treated in a manner to ensure the inactivation of the pathogen;
- 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 and 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 importation or transit of the *commodities* of a species referred to in Article 2.1.15.2., other than those listed in point 1) of Article 2.1.15.3., *Competent Authorities* should require the conditions prescribed in Articles 2.1.15.7. to 2.1.15.11. relevant to the RSIVD status of the *exporting country*, *zone* or *compartment*.
- 3) When considering the importation or transit of any live *commodity* of a species not referred to in Article 2.1.15.2. 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*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.15.4.

RSIVD free country

A country may make a *self-declaration of freedom* 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 make a *self-declaration* of freedom from RSIVD 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 <u>susceptible species</u> species listed in Article 2.1.15.2. is present may make a self-declaration of freedom 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 referred to 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 make a *self-declaration of freedom* from RSIVD when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

- 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 make a *self-declaration of freedom* 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 has made a *self-declaration of freedom* from RSIVD but in which the disease is subsequently detected may not make a *self-declaration of freedom* 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, one or more areas of the remaining territory may be declared free zone, part of the non-affected area may be declared a free zone provided that they meet the conditions in point 3) of Article 2.1.15.5.

Article 2.1.15.5.

RSIVD free zone or free compartment

A zone or compartment within the territory of one or more countries not declared free from RSIVD may be declared free by the Competent Authority(ies) of the country(ies) concerned, if the zone or compartment meets the conditions referred to in points 1), 2), 3) or 4) below.

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

1) A zone or compartment where none of the <u>susceptible species</u> species listed in Article 2.1.15.2. is present may be declared 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 referred to 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 be declared free from RSIVD when basic biosecurity conditions have been met continuously in the zone or compartment for at least the past 10 years.

- 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 be declared 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.

- 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, *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., as relevant, may maintain its status as RSIVD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *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., as relevant, 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 referred to in Article 2.1.15.2. 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 should be in accordance with the Model Certificate in Appendix 6.1.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.15.3.

Article 2.1.15.8.

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

When importing, for aquaculture, aquatic animals of the species referred to in Article 2.1.15.2. 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.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.15.3.

Article 2.1.15.9.

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

When importing, for processing for human consumption, *aquatic animals* of the species referred to in Article 2.1.15.2. 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 2.1.15.3. or other products authorised by the *Competent Authority*; and
- 2) all effluent and waste material <u>from the processing</u> are treated in a manner that ensures inactivation of RSIV.

This Article does not apply to commodities listed in point 1) of Article 2.1.15.3.

Article 2.1.15.9.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 referred to in Article 2.1.15.2. 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 <u>from the processing</u> are treated in a manner that ensures inactivation of RSIV.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.15.3.

Article 2.1.15.10.

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

When importing aquatic animal products of the species referred to in Article 2.1.15.2. 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 should be in accordance with the Model Certificate in Appendix 6.2.1.

This Article does not apply to *commodities* listed in point 1) of Article 2.1.15.3.

Article 2.1.15.11.

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

When importing aquatic animal products of the species referred to in Article 2.1.15.2. 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:

- 1) 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
- 2) all effluent and waste material are treated in a manner that ensures inactivation of RSIV.

This Article does not apply to commodities listed in point 1) of Article 2.1.15.3.

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