

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

Paris, 9–13 March 2009

The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 9 to 13 March 2009.

Dr Sarah Kahn, Head of the OIE International Trade Department, welcomed the Aquatic Animals Commission on behalf of Dr Bernard Vallat, OIE Director General who was away on mission. Dr Kahn noted that this meeting should focus on the upcoming OIE General Session and ensure finalisation of all texts proposed for adoption. She also informed the Commission of decision by the OIE Administrative Commission to propose an amendment of the mandate of the Commission to include aquatic animal production food safety and aquatic animal welfare issues.

As a result of Dr Eva-Maria Bernoth standing down as President of the Aquatic Animals Commission in October 2008 because of a career change, Dr Barry Hill, Vice-President had agreed to be Acting President until the 77th General Session in May 2009 when Commission elections are due. Dr Hill opened the meeting and welcomed participants.

Details of participants and the adopted agenda are given at [Annexes I and II](#).

The Aquatic Animals Commission recognised the contribution of the following Members in providing comments: Argentina, Australia, Canada, Chinese Taipei, European Union (EU), Japan, Mexico, New Zealand, Norway, Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA), Switzerland, Thailand and the United States of America (USA). The OIE Animal Welfare Working Group, animal welfare NGO's and an OIE expert also submitted comments.

The Aquatic Animals Commission reviewed various *Aquatic Code* draft texts from its October 2008 report in the light of Member comments. The outcome of the Commission's work is presented at [Annexes III to XVIII](#) in this report. Amendments made during the October 2008 meeting are shown as double underlined text, with deleted text in strikethrough, while those made at this meeting (March 2009) are shown in a similar fashion but with coloured background to distinguish the two groups of proposals.

The table below summarises the texts as presented in the Annexes. Part I: [Annexes III to XI](#) are proposed text for adoption at the 77th General Session in May 2009; Part II: [Annexes XII and XIV](#) is presented for Member comment; Part III: [Annexes XV to XVIII](#) for Members information.

Members are invited to submit their comments to the OIE on [Annexes XII and XIV](#) of this report prior to **21 August 2009**. The comments should be sent preferably by electronic mail to the following address: trade.dept@oie.int. The Aquatic Animals Commission will address the comments received at its next meeting in September 2009.

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Diseases listed by the OIE (Chapter 1.2.3.)	Annex IV
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Meeting with the Director General

Dr Vallat, Director General of the OIE joined the Aquatic Animals Commission for a discussion of key issues on the final day of the meeting. Dr Vallat began by thanking the Commission members for their ongoing support of the OIE and the considerable work that had been successfully undertaken in the past year. Dr Vallat welcomed the Commission's proposal that the next OIE International Conference on Aquatic Health be held in 2011 in Asia, with the theme: 'The Contribution of Aquatic Animal Health to Global Food Security'.

Dr Vallat agreed with the decision of the Aquatic Animals Commission to remove de-listed diseases from the 2009 edition of the *Aquatic Animal Health Code* (hereafter referred to as *Aquatic Code*) and that the relevant chapters in the *Manual of Diagnostic Tests for Aquatic Animals* (hereafter referred to as the *Aquatic Manual*), which are out of date, should be removed from the 2009 edition of the *Aquatic Manual*. Dr Vallat also agreed with the Aquatic Animals Commission that the OIE should accept the offer from Members to update these texts and agreed that such information could be made available on the Commission webpage after review by the Commission.

Noting the proposed expansion of the Aquatic Animals Commission's mandate to cover animal welfare, Dr Vallat endorsed the decision of the Commission to propose for adoption a draft chapter on welfare of farmed fish during transport. He noted that this chapter had been extensively revised to address the concerns raised by Members and suggested that the position taken by Members in considering the adoption of the proposed text would provide useful direction for the Commission when considering the development of any further texts on fish welfare.

Dr Hill informed Dr Vallat that Member comments on the criteria for considering aquatic animal commodities safe for the purpose of international trade had been thoroughly reviewed by the Aquatic Animals Commission. Dr Vallat agreed with the Commission decision that the proposed criteria should be proposed for adoption and the draft modifications to specific disease chapters should be proposed for another round of Member comment.

Dr Hill informed Dr Vallat of the proposal to restructure the *Aquatic Code* along similar lines to the 2008 edition of the *Terrestrial Animal Health Code* (hereafter referred to as *Terrestrial Code*), i.e. grouping horizontal chapters in one part and disease specific (vertical) chapters in another part. Dr Vallat suggested that the Aquatic Animals Commission also consider as a middle term option the possibility of the OIE producing the *Terrestrial* and *Aquatic Codes* as a single publication comprising three volumes in future.

Dr Hill informed Dr Vallat that some Members had commented on the draft model certificates for aquatic animals, which were in large part based on texts adopted in the *Terrestrial Code* in 2008. Dr Vallat agreed with the Aquatic Animals Commission's proposal that the draft model international aquatic animal health certificates be proposed for adoption in the *Aquatic Code* and that Member comments of a generic nature be discussed with the Terrestrial Animal Health Standards Commission (hereafter referred to as the *Code Commission*), at their meeting in September 2009. Any changes agreed by the two Commissions could then be proposed simultaneously in the relevant texts in the *Terrestrial* and *Aquatic Codes*.

Dr Vallat agreed with the Aquatic Animals Commission decision to propose the adoption of a new chapter in the *Aquatic Code* on the quality of competent authorities responsible for aquatic animal health. Member comments that were relevant to the chapter on quality of veterinary services currently found in the *Terrestrial Code* would be referred to the *ad hoc* Group on the Evaluation of Veterinary Services with a request for the *ad hoc* Group to make recommendations to both the Code Commission and the Aquatic Animals Commission on the modification of relevant texts in the two Codes. In addition, the Aquatic Animals Commission proposed to include a chapter on the evaluation of competent authorities for possible adoption by Members in 2010.

Noting that the Code Commission had proposed to replace the concept of the buffer zone by the new concept of a protection zone, Dr Hill informed Dr Vallat that the Aquatic Animals Commission would review the use of the buffer zone concept in the *Aquatic Code* in light of the International Committee's decision on amendments to the *Terrestrial Code* in May 2009.

Noting the proposal to expand the mandate of the Aquatic Animals Commission to cover animal production food safety, Dr Hill advised Dr Vallat that the Commission would address the issue of antimicrobial resistance as a priority. As a first step, the Commission requested that the OIE Scientific and Technical Department review the relevant chapters in the *Terrestrial Code* to determine what modifications to this text were required to prepare it for consideration by Members for inclusion in the *Aquatic Code*.

In response to the presentation by Dr. Subasinghe on the recent outbreak of Epizootic Ulcerative Syndrome (EUS) in Southern Africa, Dr Vallat advised that the FAO could continue to rely on the OIE's close collaboration and the Aquatic Animals Commission's technical support for these activities. Dr Vallat made reference to the OIE/FAO *Vademecum* and the Chart which set out the role and responsibilities of the two organizations regarding terrestrial animals, and proposed that the FAO Fisheries and Aquaculture Department review this, in liaison with the OIE, with a view to adopting the same approach to the collaboration between the OIE and FAO on aquatic animals.

1. Activities and progress of *ad hoc* Groups

1.1. Report of the *ad hoc* Group on Aquatic Animal Health Surveillance – January 2009

Dr Hill, Chair of the *ad hoc* Group, gave a summary of progress made at the meeting held from 19 to 21 January 2009 at the OIE Headquarters, Paris. The *ad hoc* Group revised the manuscript of the *Handbook on Aquatic Animal Health Surveillance* taking into consideration comments received from the three reviewers and made some final adjustments. In response to one reviewer's comments, the *ad hoc* Group decided to change the title of the publication to *Guide for Aquatic Animal Health Surveillance*. After scrutinising the manuscript, the Aquatic Animals Commission gave endorsement for its publication and congratulated the *ad hoc* group for producing such a comprehensive text in a relatively short time. The manuscript will be sent for copy editing and publication is expected to be in mid 2009.

Dr Hill reported that the *ad hoc* Group also reviewed the task of developing a disease specific surveillance chapter on viral haemorrhagic septicaemia but had insufficient time to spend on this task due to the time spent completing the manuscript for the Guide (the outcome of the discussion and proposed next steps are described in Item 3.1.).

The *ad hoc* Group Report is provided at [Annex XV](#).

1.2. Report of the *ad hoc* Group on Safety of Products Derived from Aquatic Animals – February 2009

Dr Franck Berthe, Chair of the *ad hoc* Group, gave a summary of progress made at the meeting held from 17 to 19 February 2009 at the OIE Headquarters, Paris. Dr Berthe reported that the *ad hoc* Group considered Member comments on the criteria to assess the safety of aquatic animal commodities and the criteria to assess the safety of aquatic animal products destined for human consumption, and text intended for Example Articles to be included in disease chapters, and made relevant amendments. The *ad hoc* Group recommended that the two sets of criteria be included in the *Aquatic Code* as a new chapter.

Details on the specific proposed amendments are provided in Agenda Items 2.8., 2.12. and 2.13.

The *ad hoc* Group reviewed the available published literature and assessed whether disinfection of salmonid eggs prevents egg surface associated transmission and concluded that, for viral haemorrhagic septicemia, infectious hepatopoietic necrosis and infectious salmon anaemia, disinfected eggs could be considered as a safe commodity provided they were disinfected using a standardised protocol and other relevant mitigation measures applied. The Aquatic Animals Commission agreed with the conclusions of the *ad hoc* Group on this matter and requested that the *ad hoc* Group develop a new article for inclusion in the relevant disease chapters of the *Aquatic Code*. This article should include all appropriate mitigation measures (e.g. level of infection in brood stock, quality of water) that must be met in order to ensure the disinfection protocol was effectively applied.

The meeting report of the *ad hoc* Group is provided for information at [Annex XVI](#).

Dr Hill thanked Dr Berthe and the *ad hoc* Group for their excellent work. The Aquatic Animals Commission recommended that the *ad hoc* Group be reconvened at a suitable time to continue their work and complete a report prior to the next Commission meeting in September 2009.

2. *Aquatic Animal Health Code* – Members’ comments

2.1. General comments

The Aquatic Animals Commission was pleased to note that a large number of Member comments had been submitted but noted that some comments were not provided in the requested format and did not include a science based rationale. The Commission strongly encourages Members to participate in the development of the OIE’s international standards by submitting comments and would be grateful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Proposed deletions should be indicated in ~~strikeout~~ and proposed additions with double underline.

2.2. Definitions (Chapter 1.1.1.)

Following a Member comment, the Aquatic Animals Commission amended the definition for aquatic animals to include fish used for ornamental purposes, as reference is made in the *Aquatic Code* to ornamental fish.

A Member objected to the proposed deletion of the existing definition for Compartmentalisation. The Commission however, agreed that the proposed deletion should stand and advised the Member that the definition for ‘Compartment’ is given in Chapter 1.1.1. of the current *Aquatic Code*.

Several members commented that the definition for ‘Outbreak of disease’ should be consistent with that laid down in the *Terrestrial Code*, i.e. ‘means the occurrence of one or more *cases* in an *epidemiological unit*’. The Aquatic Animals Commission agreed and amended the definition for ‘outbreak’ accordingly and also added a definition of ‘case’ as defined in the *Terrestrial Code*.

Several Members commented that the definitions for *Veterinary Administration* and *Veterinary Authority* still remain in the current *Aquatic Code* while they were merged into one single definition for *Veterinary Authority* in the *Terrestrial Code*. The Aquatic Animals Commission deleted the definition for *Veterinary Administration* and amended the definition for *Veterinary Authority* to be consistent with the *Terrestrial Code* definition.

The Aquatic Animals Commission amended the definition of ‘sanitary measure’ to be consistent with that in the *Terrestrial Code*, as part of the ongoing harmonisation of the two Codes.

In the October 2008 report of the Aquatic Animals Commission, it was pointed out that the definitions for ‘Communication, Crisis, Crisis Communication, Outbreak Communication’ would not be used in the *Aquatic Code* until an appropriate text on communication has been developed for the *Aquatic Code*. These are not being proposed for adoption at the General Session in May 2009.

The updated Chapter on Definitions (1.1.1.) that will be proposed to the OIE International Committee for adoption at the 77th General Session in May 2009 is presented at [Annex III](#).

2.3. Diseases listed by the OIE (Chapter 1.2.3.)

The USA requested that *Oncorhynchus masou* virus disease (OMVD) be re-listed on the grounds that it meets all the necessary criteria for listing. However, the Aquatic Animals Commission considered that the conclusion reached by the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Fish Team), that the disease did not meet all the necessary criteria for listing, remains relevant today. The de-listing of *Oncorhynchus masou* virus disease was adopted in 2005. The relevant text from the 2004 *ad hoc* Group report is shown below:

'Potential for international spread including via live animals, their products and inanimate objects: The disease is still only found in northern Japan despite over 25 years having passed since its first detection, Japan does not currently, or look likely to, export live fish or eggs of the susceptible species so there appears to be no significant likelihood of international transfer. The most likely international trade to develop would be in eyed eggs. It is believed that the disease may be transmitted vertically via the egg (egg-associated) but the risk is considerably reduced by use of iodophor disinfection at the eyed stage (Yoshimisu et al., 1993. Surveillance and control of infectious hematopoietic necrosis virus and Oncorhynchus masou virus of wild salmonid fish retruning to the northern part of Japan 1976-1991. Fisheries Res., 17, 163-173).'

The Aquatic Animals Commission invited USA to provide evidence that circumstances have changed and that Criterion B6, 'Potential for international spread including via live animals, their products or fomites', is now satisfied.

The Aquatic Animals Commission considered Members' comments on the proposed listing of the sabellid worm *Terebrasabella heterouncinata*. There was a significant difference of opinion among Members' comments as to whether the sabellid worm has a significant economic impact and therefore whether this disease does meet criterion A1. A number of Members strongly questioned the listing of this disease. The Commission reviewed again the assessment made by the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Mollusc Team) in January 2008 (the report was annexed to the March 2008 Aquatic Animals Commission report) and decided that in the absence of additional evidence quantifying the economic impact of the disease, the proposed listing of the sabellid worm should be withdrawn.

A number of Members supported the proposed redefinition and renaming of the abalone viral mortality complex (AVM) to abalone herpes-like virus disease. The Aquatic Animals Commission considered Members' comments and concluded that the listing of this disease as Infection with abalone herpes-like virus should be proposed for adoption at the 77th General Session in May 2009.

The Aquatic Animals Commission endorsed the draft Chapter on Infection with abalone herpes-like virus that had been prepared by the *ad hoc* Group on OIE List of Aquatic Animal Diseases (Mollusc Team). This draft chapter will be proposed for adoption at the 78th General Session in May 2010 provided that the International Committee adopts the listing of this disease at the 77th General Session in May 2009.

The draft chapter is presented at [Annex XIV](#) for Member comment.

No Member comments were received objecting to the proposed deletion of Tetrahedral baculovirus (*Baculovirus penaei*) and Spherical baculovirus (*Penaeus monodon*-type baculovirus), nor on the proposed deletion of two diseases (hepatopancreatic parvovirus disease and Mourilyan virus disease) listed as 'under study'. The Aquatic Animals Commission proposed to adopt these deletions at the 77th General Session in May 2009.

Canada did not support listing of necrotising hepatopancreatitis (currently listing of this diseases is under study) and provided a brief list of reasons. No other comments were received from Members. The Aquatic Animals Commission proposed that necrotising hepatopancreatitis remain 'under study' for an additional year and requested that Canada provide a more thorough science based rationale to support their recommendation that the disease should not be listed. The Commission requested that this information be provided to OIE Headquarters by the end of June 2009 to allow the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Crustacean Team) to consider and report their conclusions prior to the next meeting of the Commission in September 2009.

A Member and an expert commented that milky haemolymph disease of spiny lobsters (*Panulirus* spp.) should not be listed as an emerging disease. Since the initial assessment by the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Crustacean Team), a treatment has been shown to be effective for controlling the disease, and the incidence of the disease has dropped significantly and therefore would not meet the Criteria A1 of Article 1.2.2.2. (production losses). In light of this development, the Aquatic Animals Commission proposed that this disease should not be listed as an emerging disease but rather be placed ‘under study’ and the original assessment for its listing be referred back to the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Crustacean Team) for further consideration.

The Aquatic Animals Commission noted that in Chapter 1.2.3. white tail disease was still footnoted as ‘listed according to Article 1.2.2.2.’ (i.e. as an emerging disease). The Aquatic Animals Commission requested this be corrected in the 2009 edition of the *Aquatic Code* because the listing of White tail disease had been adopted in May 2007.

The updated Chapter on Diseases listed by the OIE (1.2.3.) that will be proposed to the OIE International Committee for adoption at the 77th General Session in May 2009 is presented at Annex IV.

2.4. General obligations related to certification (Chapter 1.3.1.) and 2.5. Certification procedures (Chapter 1.3.2)

Several Members commented on the proposed text. The Aquatic Animals Commission noted that a number of these were of a generic nature and of equal relevance to the *Terrestrial Code* chapters. Following a discussion with Dr Thiermann, the President of the Code Commission, it was agreed that these comments should be addressed by the Code Commission at its meeting in September 2009. The Aquatic Animals Commission requested that the OIE Central Bureau make arrangements for this to occur.

The Aquatic Animals Commission considered Member comments that were specific to aquatic animals and amended the text accordingly.

The amended chapters on General Obligations related to Certification (Chapter 1.3.1.) and Certification Procedures (Chapter 1.3.2) that will be proposed to the OIE International Committee for adoption at the 77th General Session in May 2009 are presented at Annexes V and VI respectively.

2.6. Quality of Competent Authorities (Chapter 1.4.3.)

The Aquatic Animals Commission considered Member comments and made relevant amendments. The Commission asked Members to note that this draft text will replace all of the current text in Chapter 1.4.3. ‘Evaluation of Competent Authorities’ and the title will be amended to ‘Quality of Competent Authorities’.

A Member pointed out that, for consistency with the *Terrestrial Code*, it would be necessary to develop an equivalent text to ‘Chapter 3.2. Evaluation of Veterinary Services,’ for the *Aquatic Code*. The Aquatic Animals Commission agreed and requested that the *ad hoc* Group on Evaluation of Veterinary Services develop the text for such a chapter and provide this to the Aquatic Animals Commission prior to their next meeting in September 2009.

The updated Chapter on Quality of Competent Authorities that will be proposed to the OIE International Committee for adoption at the 77th General Session in May 2009 is presented at Annex VII.

2.7. Measures concerning international transport of aquatic animal disease agents and pathological material (Chapter 1.5.6.)

In their report to the Aquatic Animals Commission (Annex XVI), the *ad hoc* Group on the Safety of Products Derived from Aquatic Animals proposed the addition of text in the *Aquatic Code* Article 1.5.6.1. to address the issue of biological samples preserved for diagnostic applications.

The Aquatic Animals Commission recommended the addition of the proposed text to Article 1.5.6.1. for Member comment - see [Annex XII](#).

2.8. Crayfish plague (Chapter 2.3.7.)

A Member questioned the broad taxonomic categories for the susceptible species listed in this chapter and in the chapter on white spot disease. Although a number of crayfish species and genera are known to be susceptible, they were of the view that extrapolation to Family is not scientifically justified. The Aquatic Animals Commission agreed that where the number of species known to be susceptible was insufficient for concluding that all species within one or more families should be regarded as susceptible, the individual susceptible species should be listed instead.

However, this is a general issue that needs to be addressed for all the listed diseases for which there is evidence of wide taxonomic host susceptibility, and the Aquatic Animals Commission acknowledged the need to develop criteria to decide when a sufficient number of species have been demonstrated to be susceptible that the entire genus or family could reasonably be considered to be susceptible. The Commission will develop such criteria at its next meeting in September 2009 and seek Members comments. Once finalised, the criteria will be proposed for adoption at the OIE General Session in May 2010 or 2011. If adopted, the Commission will apply the criteria initially to the hosts of crayfish plague, white spot disease and other listed diseases for which there is evidence of wide taxonomic host susceptibility. The Commission will seek Members comments on the outcome of the assessments. The Commission agreed that in the meantime, the text in Article 2.3.7.2 for crayfish plague (and Article 2.3.2.2 on white spot disease) should be retained.

The EU and Norway commented on the absence of options for regaining freedom for previously-free compartments after the detection of the disease. The Aquatic Animals Commission noted the proposed conditions suggested by the Members and will take these into account when preparing relevant text for all the disease chapters that will be developed at the next meeting for the Commission in September 2009.

The updated Chapter on Crayfish Plague that will be proposed for adoption at the 77th General Session in May 2009 is presented at [Annex VIII](#).

2.9. Example Article X.X.X.3; X.X.X.9; X.X.X.12

Several Members commented that this issue cannot be approached in a uniform way for all listed diseases and that a disease specific approach should be followed. The Aquatic Animals Commission clarified that in the text provided for comment (in the October 2008 report Aquatic Animals Commission) spring viraemia of carp (SVC) was used as the working example. Specific recommendations on safe commodities to be listed in point 1 of Article 2.X.X.12. in each disease chapter would be established using a disease specific approach.

The Aquatic Animals Commission reviewed the amended text on Example Articles X.X.X.3; X.X.X.9; X.X.X.12. as proposed by the *ad hoc* Group on the Safety of Products Derived from Aquatic Animals, after considering Member comments, and made some additional amendments.

The updated text on Example Articles X.X.X.3; X.X.X.9; X.X.X.12, is presented for Member comment at [Annex XIII](#).

2.10. Necrotising hepatopancreatitis (Chapter 2.3.X.)

Refer to item 2.3. Diseases listed by the OIE.

2.11. Milky haemolymph disease of spiny lobsters (*Panulirus* spp.) (Chapter 2.3.X.)

Refer to item 2.3. Diseases listed by the OIE.

2.12. Model international aquatic animal health certificates

Several Members commented on the proposed Model International Aquatic Animal Health Certificates. The Aquatic Animals Commission noted that a number of these comments were of a generic nature and of equal relevance to the equivalent *Terrestrial Code* Model Veterinary Health Certificates. On the basis of a discussion with the President of the Code Commission, it was agreed that these comments should be addressed by the Terrestrial Commission at its meeting in September 2009. The Aquatic Animals Commission requested that the OIE Central Bureau take the necessary steps for this to occur.

The Aquatic Animals Commission considered the Member comments that were specific to aquatic animals and amended the Model International Aquatic Animal Health Certificates accordingly. These will be proposed to the OIE International Committee for adoption at the 77th General Session in May 2009, see [Annex IX](#).

2.13. Criteria to assess the safety of aquatic animal commodities (X.X.X.) and

2.14. Criteria to assess the safety of aquatic animal products destined for human consumption (X.X.X.)

The Aquatic Animals Commission reviewed two sets of criteria proposed by the *ad hoc* Group on the Safety of Products Derived from Aquatic Animals, on the basis of its review of Member comments, and made a small number of amendments.

The Aquatic Animals Commission noted that an introductory text had been proposed by the *ad hoc* Group in response to a Member request. This text is of an explanatory nature and does not affect the proposed criteria. The Aquatic Animals Commission agreed that the two sets of criteria should be included in a new chapter of the *Aquatic Code*.

The updated criteria to assess the safety of aquatic animal commodities (X.X.X.) and criteria to assess the safety of aquatic animal products destined for human consumption (X.X.X.) are proposed to the OIE International Committee for adoption at the 77th General Session in May 2009 - see [Annex X](#).

2.15. Welfare of farmed fish during transport (Appendix 3.4.2.)

The Aquatic Animals Commission reviewed comments received from Members, the OIE Animal Welfare Working Group and animal welfare NGO's on the draft text and made amendments as appropriate. Some Members suggested that the scope of the chapter should not be limited to farmed fish. The Aquatic Animals Commission reminded Members that Article 3.4.1.1. in Appendix 3.4.1. (adopted in May 2008) states that the OIE will develop guidelines for the welfare of farmed fish (excluding ornamental species) during transport, slaughter, and destruction for disease control purposes. For this reason the chapter on welfare during transport only covers farmed fish.

The updated draft text on the Welfare of Farmed Fish during Transport (Appendix 3.4.2.) is proposed to the OIE International Committee for adoption at the 77th General Session in May 2009 - see [Annex XI](#).

2.16. Handling and disposal of carcasses and wastes of aquatic animals (Appendix X.X.X.)

A large number of Member comments were received on the draft chapter appended to the report of the October 2008 meeting of the Aquatic Animals Commission. The Commission considered these comments and noted that some expressed opposing viewpoints. The Commission referred these to be the expert who had prepared the latest draft.

3. Aquatic Animal Health Code – other items

3.1. Disease specific surveillance chapters and Model for authors

Dr Hill re-iterated that, in the report of its meeting in January, the *ad hoc* Group on Aquatic Animal Health Surveillance had explained that it had not had sufficient time to deal with this item and requested that the *ad hoc* Group be re-convened to complete the work over two 3-day meetings. The first meeting would have one day devoted to the refinement of the template outlining what information is required for the disease specific surveillance chapters, and the second and third days would involve working with experts on the chosen diseases explaining what would be required to complete the draft chapters. The *ad hoc* Group thought it would be most beneficial to work on three chapters at the meeting, one fish disease, one mollusc disease and one crustacean disease, and had requested guidance from the Commission as to which 3 diseases to consider. Experts would then use the outcomes of the first meeting to draft their nominated chapter prior to the second 3-day meeting to be convened 6 months later. At the second meeting, experts would present their chapter and together with the *ad hoc* Group would finalise the Chapters and the template for future chapters. The *ad hoc* Group had requested that the Aquatic Animal Health Standards Commission approve this approach for the future development of disease specific surveillance chapters.

The Aquatic Animals Commission discussed this proposal and agreed that this would be a good approach to this a complex and time consuming task. The Commission proposed that the diseases to serve as models for fish, mollusc and crustaceans should be (i) viral haemorrhagic septicaemia (ii) infection with *Bonamia ostreae*, and (iii) white spot disease. While amphibian diseases have recently been OIE-listed, OIE Reference Laboratories and designated experts are still to be appointed. Therefore, the Commission considered it would be premature to request the *ad hoc* Group to also develop model surveillance chapters for the listed amphibian diseases.

The Aquatic Animals Commission recommended that this approach be adopted and that the *ad hoc* Group be reconvened in 2009 for the first of the two meetings and provides a progress report to the March 2010 meeting of the Commission.

3.2. Additional welfare chapters

The Aquatic Animals Commission agreed that once the chapter on Welfare of Farmed Fish during Transport is adopted, the Commission would consider whether development of additional chapters on slaughter and on humane killing for disease control should be undertaken and the modalities for this.

3.3. Restructured 2009 Aquatic Code/De-listed diseases

Member comments supported the proposed removal of the chapters on de-listed diseases from the 2009 *Aquatic Code*. The Aquatic Animals Commission agreed that the 2009 *Aquatic Code* would only include OIE-listed diseases and that it would be restructured in a similar manner to the recently restructured *Terrestrial Code*.

The List of Contents for the proposed restructured *Aquatic Code* is presented at [Annex XVII](#) for information of Members.

3.4. Antimicrobials - prudent use

In light of the proposal to expand the mandate of the Aquatic Animals Commission to cover animal production food safety, the Aquatic Animals Commission discussed the need to address the issue of antimicrobial resistance as a priority. As a first step, the Aquatic Animals Commission requested that the OIE Scientific and Technical Department review the relevant chapters in the *Terrestrial Code* to determine if modifications could be made to make this text suitable for consideration by Members for inclusion in the *Aquatic Code*.

3.5. References to non-susceptible species.

At the October 2008 meeting of the Aquatic Animals Commission it was agreed that the species considered not to be susceptible [under point 1b) of Article X.X.X.3. in Chapter 2.2.1. Infection with *Bonamia ostreae*, Chapter 2.2.4. Infection with *Marteilia refringens* and Chapter 2.2.5. *Mikrocytos mackini*] should be moved to Article X.X.X.2. of the *Aquatic Code*. However, the Commission noted that Article X.X.X.2. is used throughout each chapter in reference to susceptible species only. To make the changes agreed at the October 2008 meeting would have trade implications and introduce inconsistencies with other *Aquatic Code* chapters. The Aquatic Animals Commission agreed that these changes should not be proposed and that, instead, the information provided in Article X.X.X.3. point 1b) should be deleted from Chapters 2.2.2., 2.2.4. and 2.2.5. and the information be transferred to an appropriate subsection of Section 2.2. in relevant *Aquatic Manual* chapters.

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

The Aquatic Animals Commission was joined by Dr Thiermann, President of the Code Commission. Dr Thiermann provided an update on the proposed definition for protection zone in the *Terrestrial Code* which incorporates the concepts that were previously included in the buffer zone and surveillance zone. The idea is to broaden the application of measures to protect susceptible sub-populations beyond a strict reference to physical separation and to incorporate other protection measures. Dr Thiermann also commented on the ongoing work to incorporate wildlife into disease chapters where they play a role in the epidemiology of the disease. The current thinking is to encourage reporting in wildlife, with a clear indication that the presence and reporting of these diseases in wildlife would not affect the status of the country in terms of trade.

The Aquatic Animals Commission and Dr Thiermann discussed how to deal with comments of a generic nature that were relevant to both *Codes*. It was decided that Member comments submitted to the Aquatic Animals Commission, which were in large part based on texts adopted in the *Terrestrial Code* in 2008, would be discussed with the Code Commission at their meeting in September 2009. Any changes agreed by the two Commissions could then be proposed simultaneously for adoption by the International Committee in the relevant texts in the *Terrestrial* and *Aquatic Codes*.

5. Conferences of OIE Regional Commissions

5.1. 19th Conference of the OIE Regional Commission for the Americas

Dr Ricardo Enriquez, Secretary General of the OIE Aquatic Animals Commission, attended the 19th Conference of the OIE Regional Commission for the Americas in La Havana, Cuba, 17 – 21 November 2008. Dr Enriquez presented a summary of OIE's activities in the field of aquatic animal health during 2008 and outlined amendments to the *Aquatic Code* that had been adopted at the 76th General Session in May 2008. Dr Enriquez also reported on proposed *Aquatic Code* texts that would be submitted for adoption at the General Session in May 2009.

Dr Enríquez pointed out to the Conference that challenges continued to arise in the aquatic animal health area, giving the example of outbreaks of emerging diseases that were occurring in new species of farmed aquatic animals. In addition, intensive production in the aquatic ecosystem increased the need to control infectious and contagious diseases and was a challenge given the limited availability of antimicrobials for use in aquatic animals. Dr Enriquez also drew attention of participants to the fact that the *Aquatic Code* contained tools, standards and procedures for organising veterinary services in the field of aquatic animal health. Dr Enriquez concluded by stressing the importance of the work of the focal points for aquatic animal health in each OIE Member Country.

5.2. 18th Conference of the OIE Regional Commission for Africa

Professor Katunguka Rwakishaya attended the 18th Conference of the OIE Regional Commission for Africa in N'Djamena, Chad, 22-26th February 2009. He presented a paper entitled 'Update on developments in aquatic animal health'. A brief overview of aquatic animal production was given with an emphasis on the increasing role of aquaculture in meeting the increased demand for food of aquatic animal origin. Other issues addressed which relate to the work of the Aquatic Animals Commission included the concept of safe commodities, harmonisation of the *Aquatic* and *Terrestrial Codes*, emphasis on cooperation between veterinary and fisheries officers, guidelines for the welfare of farmed fish, guidelines for the control of aquatic animal health hazards in aquatic animal feeds, guidelines for aquatic animal health surveillance and inclusion of diseases of amphibians in the *Aquatic Code*.

OIE Delegates were encouraged to read the Aquatic Animals Commission reports and submit comments. They were also requested to take a keen interest in the developments in aquatic animal health and to strengthen the interaction between veterinary and fisheries officers in the control and reporting of aquatic animal diseases.

6. Other OIE presentations

6.1. Third Meeting of the OIE Inter-American Aquatic Animal Health Committee

Dr Enriquez attended the Third Meeting of the OIE Inter-American Aquatic Animal Health Committee (11-13 November 2008, Mazatlan, Mexico) and provided an update on activities of the Aquatic Animals Commission.

6.2. 7th Annual General Meeting of NACA Regional Advisory Group on Aquatic Animal Health

Dr Hill gave a report of his participation this meeting, which was held during 15-17 December 2008 at the NACA Secretariat, Bangkok, Thailand. Dr Bernoth, as the President of Aquatic Animals Commission, had been the Aquatic Animals Commission's permanent representative at the annual Regional Advisory Group (RAG) meetings since 2001 but was unable to participate this year because of her change of employment. Dr Hill participated in the meeting as Acting-President of Aquatic Animals Commission and described the outcomes from the 76th General Session of the OIE (May 2008) and the meeting of the Aquatic Animals Health Standards Commission in October 2008, with emphasis on the principle changes in the Aquatic Code adopted in 2008 and those proposed for adoption in 2009. He informed the RAG that other developments for 2009 include an updated edition of the *Aquatic Manual* and the new OIE Guide for Aquatic Animal Health Surveillance. Dr Hill also gave a presentation on the amended OIE list of aquatic animal diseases and the status of global reporting to OIE.

During the three-day meeting, the RAG also addressed key aquatic animal health issues in Asia, including a review of emerging aquatic animal disease problems in the region, WAHIS, FAO supported aquatic animal health activities, the regional quarterly aquatic animal disease (QAAD) reporting system and the list of diseases for reporting in 2009, implementation of the Asia Regional Technical Guidelines and ways to further strengthen regional and international cooperation in Asian aquatic animal health management.

6.3. XV Conference of the Italian Society of Fish Pathologists

At the invitation of the Society's President, Dr Hill attended the XV Conference of the Italian Society of Fish Pathologists held during 22-24 October 2008 in Sicily, Italy to give a keynote presentation "The role of OIE in setting international standards for preventing spread of aquatic animal diseases". The presentation described the latest changes to the OIE standards for aquatic animal health, the way that the standards are developed by the Aquatic Animals Commission and approved by OIE Members prior to publication in the *Aquatic Code* and the *Aquatic Manual*, other key functions of the Commission and its *modus operandi*.

7. Cooperation with FAO

Dr Subasinghe presented an update on the recent outbreak of Epizootic Ulcerative Syndrome (EUS) in Southern Africa, the activities undertaken by FAO in addressing the issue, current status of the disease, and the planned and needed activities in the future. He mentioned that this outbreak is a significant concern to the countries sharing the Zambezi River basin.

It has been confirmed that the disease is now present in Botswana, Namibia, and Zambia and it is suspected to be in several countries in the Zambezi River basin. The disease is spreading both upstream and downstream in these countries. Considering that a large population depends on the Zambezi River resources for their livelihoods (23 million people), it is timely to consider some concerted action in addressing the issue. Dr Subasinghe mentioned that, the previous week, during the 28th Session of the FAO Committee on Fisheries (COFI), the FAO Members agreed that the establishment of a regional programme towards improving aquatic biosecurity in Southern Africa was a priority.

This outbreak of serious disease has exposed serious aquatic biosecurity weaknesses in the Southern African region. Several medium to long-term actions are required to improve aquatic biosecurity in the region and strengthen capacity to deal with such situations, including emergency preparedness, fish disease diagnosis and control, quarantine, responsible movement of live aquatic animals, development of appropriate policy and regulatory frameworks, and implementation of better aquatic animal health management programmes in the region.

Dr Subasinghe thanked the OIE Central Bureau, the OIE Regional Representation for Africa and the OIE Sub-Regional Representation for the Southern Africa Development Community for the collaborative partnership with FAO in addressing the issue so far. He said that a well planned concerted action is required to bring the attention of the governments to this devastating situation and proposed organizing a high-level meeting of Fisheries and Veterinary Authorities of the regional countries to this effect. Development of a joint programme between FAO, OIE, WfC, under the overall leadership of New Economic Partnership for Africa's Development (NEPAD), aiming at capacity building in aquatic animal health and biosecurity management in the region is considered timely. Dr Subasinghe requested OIE's continuing collaboration and the Aquatic Animals Commission's technical support for these activities. He accepted to take into consideration the suggestion of Dr Vallat to use the Vademecum and the Chart as a framework for the FAO/OIE cooperation.

8. *Manual of Diagnostic Tests for Aquatic Animals*

8.1. Sixth edition 2009

8.1.1. Update on progress – review of comments on the draft chapters

Ms Sara Linnane, Scientific Editor, from the Scientific and Technical Department, joined the meeting for this agenda item.

Comments had been received from Members and reviewers on the batch of draft chapters that had been sent out in early December 2008. The Consultant Editor, Dr Chris Rodgers, would deal with technical comments or would address them to the authors.

The Commission reviewed the remaining comments, which were general in nature or which were on policy or procedure. It acknowledged the comment from Australia that not enough time had been given for Members to properly review all the chapters sent. Production of the *Aquatic Manual* had met with some problems when the original Consultant Editor had to be replaced at short notice. These were exceptional circumstances and led to a reduction in the review time (to 11 weeks). It is unlikely that the problem would be repeated for future editions of the *Aquatic Manual*. Malaysia had requested guidelines on feed safety and Ireland had requested information on fallowing. The Commission pointed out that texts are available on these two topics in the *Aquatic Code* (Appendix 3.5.1 and Chapter 1.7.1, respectively). The USA had requested that the sample sizes recommended in the OIE protocols be re-evaluated. The issue of sampling has been addressed in the OIE *Guide for Aquatic Animal Health Surveillance* (2009), which will be published later this year, and will also be addressed in the disease-specific surveillance chapters that are to be prepared for inclusion in the *Aquatic Code*.

A number of Member comments had been received requesting that de-listed diseases be listed again. Delegates are reminded for a disease to be listed, it must satisfy the criteria for listing aquatic animal diseases, which are given in Chapter 1.2.2 of the *Aquatic Code*. Members must provide the scientific justification to prove that the disease meets the listing criteria. All submissions would be studied by the *ad hoc* Group on the List of Aquatic Animal Diseases. In the October 2008 report of the meeting of the Aquatic Animals Commission, the Commission had stated that the *Aquatic Manual* (2009) would include chapters on de-listed diseases in a separate section.

Some Members requested that the de-listed diseases chapters be retained in the 2009 edition of the *Aquatic Manual*, while other Members requested that these chapters be removed. Several Members did however consider that access to Manual chapters on de-listed diseases is still useful for some purposes and suggested that deleted chapters are held in an accessible archive on the OIE website, purely for reference. The Aquatic Animals Commission considered these comments and the conflicting opinions and decided that the 2009 edition of the *Aquatic Manual* will only include chapters on listed diseases. The Aquatic Animals Commission noted that some Members had offered to update information on the de-listed diseases and agreed that such information could be made available on the Aquatic Animals Commission webpage after review by the Aquatic Animals Commission.

Malaysia had asked if diagnostic test protocols other than those described in the *Aquatic Manual* could be used, in particular could commercial kits be used. The Commission pointed out that all test methods used must be validated as 'fit for purpose' and shown to be equivalent to the method described in the *Aquatic Manual*. The Commission reminded Delegates of the OIE Register of Diagnostic Tests. Should a Member wish to add a test to the OIE Register, the proposal must be accompanied with all the required validation data in accordance with the OIE validation template.

8.1.2. Diseases of amphibians

In May 2008, the International Committee adopted two diseases of amphibians for inclusion in Chapter 1.2.3 of the *Aquatic Code*. These are: Infection with *Batrachochytrium dendrobatidis* and Infection with ranavirus. Two applications have now been received for OIE Reference Laboratories for these two disease (see item 9.3.2). Should these nominations be adopted by the International Committee in May this year, the experts will be asked to draft *Aquatic Manual* chapters on the two diseases, which could be proposed for adoption in May 2010 and, if adopted, included in the web version of the *Aquatic Manual*.

9. OIE Reference Laboratories

9.1. Annual reports of OIE Reference Laboratory activities

Reports had been received from all but two of the OIE Reference Laboratories for Aquatic Animals. The Aquatic Animals Commission was impressed with the quality of the work carried out by the laboratories and expressed its gratitude to the experts for their efforts.

9.2. Infection with abalone herpes-like virus

The Commission encourages applications for Reference Laboratory status from Members where expertise exists.

9.3. Diseases of amphibians

9.3.1. New applications for Reference Laboratory status

The Commission reviewed and recommended acceptance of the following applications for OIE Reference Laboratory status:

OIE Reference Laboratory for Infection with *Batrachochytrium dendrobatidis*:
 Australian Animal Health Laboratory, CSIRO Livestock Industries, 5 Portarlington Road,
 East Geelong, Victoria 3220, AUSTRALIA.
 Tel.: (+61-3) 52.27.54.19; Fax: (+61-3) 52.27.55.55; E-mail: alex.hyatt@csiro.au;
 Designated Reference Expert: Dr A. Hyatt

OIE Reference Laboratory for Infection with ranavirus:
¹Faculty of Veterinary Science, University of Sydney, 425 Werombi Road, Private Bag 3,
 Camden NSW 2570, AUSTRALIA
 Tel.: (61-2) 93.51.16.19., Fax: (61-2) 93.51.16.18; E-mail: r.whittington@usyd.edu.au
 Designated Reference Expert: Prof. R. Whittington

²Australian Animal Health Laboratory, CSIRO Livestock Industries, 5 Portarlington Road,
 East Geelong, Victoria 3220, AUSTRALIA.
 Tel.: (+61-3) 52.27.54.19; Fax: (+61-3) 52.27.55.55; E-mail: alex.hyatt@csiro.au;
 Designated Reference Expert: Dr A. Hyatt

^{1&2}Note: this is a joint designation.

10. Disease Cards

The Aquatic Animals Commission noted that the current disease card for the Abalone Viral Mortality (AVM) complex needs to be revised in light of the proposal to focus the case definition on infection with abalone herpes-like virus. The Aquatic Animals Commission requested that the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Mollusc Team) develop a new disease card specific to infection with abalone herpes-like virus to replace the existing disease card.

11. Any other business

11.1. Second Global Conference on Aquatic Animal Health

Member comments indicated positive support for the OIE to hold a follow-up conference to the first Global Conference on Aquatic Animal Health held in Bergen, Norway in 2006. The Aquatic Animals Commission recommended that the theme of the second conference should be the 'The Contribution of Aquatic Animal Health to Global Food Security' and that it be held in Asia in 2011.

1.1.2. Update of the Commission's web pages

Dr Hill, Chief Editor for the Commission's web pages, reported that he had continuously maintained the information to be up to date, particularly with respect to the latest disease reports to OIE. At its last meeting, the Commission decided it would be helpful to add a link to the Aquatic Animal Health Standards Commission Report presented at the 76th General Session of the International Committee May 2008, for users' convenience. This had been done on the home page under 'Focus on' where direct links have also been provided to the report (English version) of the Commission's meeting in October 2008 and to the web version of the 2008 edition of the *Aquatic Code*. The French and Spanish versions of the report of the October meeting had also been added to the reports section as soon as they became available. Dr Hill reported that the disease cards are now limited to those for the more recently added diseases in the *Aquatic Code*; the cards for the other listed diseases have been removed since the information they contained is in need of updating by the authors.

11.3. Review of the Aquatic Animals Commission's work plan for 2009/2010

The Aquatic Animals Commission reviewed and updated its work plan, which is attached at Annex XVIII for Members' information.

12. Date of the next meeting

28 September to 2 October 2009

.../Annexes

**MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 9-13 March 2009**

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MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 9-13 March 2009

Adopted agenda

Welcome from the Director General

1. Activities and progress of *ad hoc* Groups

- 1.1. Report of the *ad hoc* Group on Aquatic Animal Health Surveillance – January 2009
- 1.2. Report of the *ad hoc* Group on Safety of Products Derived from Aquatic Animals – February 2009

2. *Aquatic Animal Health Code* – Members' comments

- 2.1. General comments
- 2.2. Definitions (Ch. 1.1.1.)
- 2.3. Diseases listed by the OIE (Ch. 1.2.3.)
- 2.4. General obligations related to certification (Ch. 1.3.1.)
- 2.5. Certification procedures (Ch. 1.3.2.)
- 2.6. Quality and Evaluation of Competent Authorities (Ch1.4.3.)
- 2.7. Measures concerning international transport of aquatic animal disease agents and pathological material (Ch. 1.5.6.)
- 2.8. Crayfish plague (Ch. 2.3.7.)
- 2.9. Example Article X.X.X.3; X.X.X.9; X.X.X.12
- 2.10. Necrotising hepatopancreatitis (Ch. 2.3.X.)
- 2.11. Milky haemolymph disease of spiny lobsters (*Panulirus* spp.) (Ch. 2.3.X.)
- 2.12. Model international aquatic animal health certificates
- 2.13. Criteria to assess the safety of aquatic animal commodities (X.X.X.)
- 2.14. Criteria to assess the safety of aquatic animal products destined for human consumption (X.X.X.)

Annex II (contd)

2.15. Welfare of farmed fish during transport (App. 3.4.2.)

2.16. Handling and disposal of carcasses and wastes of aquatic animals (App. X.X.X.)

3. *Aquatic Animal Health Code* – other items

3.1. Disease specific surveillance chapters and Model for authors

3.2. Additional welfare chapters

3.3. Restructured 2009 *Aquatic Code*/De-listed diseases

3.4. Antimicrobials - prudent use

3.5. References to non-susceptible spp.

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

5. Regional Commissions Conferences

5.1. 19th Conference of the OIE Regional Commission for the Americas

5.2. 18th Conference of the OIE Regional Commission for Africa

6. OIE Meetings

6.1. Third Meeting of the OIE Inter-American Aquatic Animal Health Committee

6.2. 7th Annual General Meeting of NACA Regional Advisory Group on Aquatic Animal Health

6.3. XV Conference of the Italian Society of Fish Pathologists

7. Cooperation with FAO

8. *Manual of Diagnostic Tests for Aquatic Animals*

8.1. Sixth edition 2009

8.1.1. Update on progress – review of comments on draft chapters

8.1.2. Diseases of amphibians

9. OIE Reference Laboratories

9.1. Annual reports of OIE Reference Laboratory activities

9.2. Infection with abalone herpes-like virus

9.3. Diseases of amphibians

9.3.1. New applications for Reference Laboratory status

10. Disease cards

11. Any other business

11.1. Second Global Conference on Aquatic Animal Health

11.2. Update of the Commission's web pages

11.3. Review of the Aquatic Animals Commission's work plan for 2009/10

12. Date of the next meeting

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1.

For the purpose of the *Aquatic Code*:

Acceptable risk

~~means a risk level judged by Members to be compatible with the protection of public health, aquatic animal health and terrestrial animal health within their countries.~~

Approved laboratory

~~means a laboratory in a Member that is approved by the Competent Authority to carry out diagnostic work on diseases listed by the OIE and is responsible for health control work.~~

Aquatic animals

means all life stages (including *eggs* and *gametes*) of fish, molluscs, crustaceans and amphibians originating from *aquaculture establishments* or removed from the wild, for farming purposes, for release into the environment, ~~or~~ for human consumption or for ornamental purposes.

Aquatic Animal Health Standards Commission

~~means the OIE Commission responsible for updating the *Aquatic Code* in the intervals between General Sessions of the OIE International Committee. The *Aquatic Animal Health Standards Commission* is concerned with diseases of fish, molluscs, crustaceans and amphibians.~~

Aquatic animal import unit

~~means a live aquatic animal or its eggs or gametes, or a specified weight of a product of aquatic animal origin.~~

Breeding station

~~means an aquaculture establishment working to improve the genetic standard and production of aquatic animals.~~

Broodstock

~~means sexually mature fish, molluscs or crustaceans.~~

Case

means an individual aquatic animal infected by a pathogenic agent, with or without clinical signs.

Communication

means the discipline of informing, influencing, and motivating individual, institutional and public audiences, preferably on the basis of interactive exchanges, about any issue falling under the mandate of the OIE and the Competent Authority.

Crisis

means a time of great danger, difficulty or uncertainty when problems related to any issue falling under the mandate of the OIE and the Competent Authority requires immediate action.

Annex III (contd)

Crisis Communication

~~means the process of providing information of a potentially incomplete nature within time constraints that allows an individual, affected and/or interested parties, an entire community or the general public to make best possible decisions and/or accept policy decisions during a crisis.~~

Compartmentalisation

~~means identifying compartments for the purpose of disease control or international trade.~~

Crustacean products

~~means fresh crustaceans, processed whole crustaceans or edible products of crustaceans that have been subjected to treatment such as cooking, drying, salting, brining, smoking or freezing.~~

Discharge

~~means blood or water from the slaughtering or processing of aquatic animals.~~

Fish products

~~means fresh fish, processed whole fish or edible products of fish that have been subjected to treatment such as cooking, drying, salting, brining, smoking or freezing.~~

Fish slaughtering premises

~~means premises used for the slaughter of fish for human consumption or other purposes and approved by the Competent Authority for export purposes.~~

~~These premises must meet recognised approved standards for the structural and other veterinary hygiene requirements.~~

Food hygiene

~~comprises conditions and measures necessary for the production, processing, storage and distribution of food of aquatic animal origin designed to ensure a safe, sound, wholesome product fit for human consumption or animal feeding.~~

Free aquaculture establishment

~~means an aquaculture establishment that fulfils the requirements for freedom from diseases listed by the OIE according to the relevant chapter in the Aquatic Code and approved as such by a Competent Authority.~~

Fresh crustaceans

~~means crustaceans that have not been subjected to any treatment or that have been subjected to a treatment that has not irreversibly modified their organoleptic or physicochemical characters; for the purpose of the Aquatic Code, fresh crustaceans include chilled crustaceans.~~

Fresh fish

~~means fish that have not been subjected to any treatment or that have been subjected to a treatment that has not irreversibly modified their organoleptic and physicochemical characters; for the purpose of the Aquatic Code, fresh fish include chilled and frozen fish.~~

Fresh molluscs

~~means oysters/mussels that have not been subjected to any treatment or that have been subjected to a treatment that has not irreversibly modified their organoleptic and physicochemical characters; for the purpose of the Aquatic Code, fresh molluscs include chilled molluscs.~~

Hatcheries

~~means aquaculture establishments raising aquatic animals from fertilised eggs.~~

Imported outbreak

~~means a disease outbreak introduced into a territory from another country.~~

Infected aquaculture establishment

~~means an aquaculture establishment in which a disease referred to in the Aquatic Code has been diagnosed.~~

Laboratory

~~means a laboratory of high technical competence under direct supervision of a veterinarian or other person with competent biological training. Through quality controls and monitoring performance, the Competent Authority approves such a laboratory in regard to testing requirements for export.~~

Lot

~~means a group of aquatic animals of the same species in one aquaculture establishment originating from the same spawning population that has always shared the same water supply.~~

Marketing

~~means placing aquatic animals and aquatic animal products on the market.~~

Mollusc nurseries

~~means aquaculture establishments raising young molluscs from metamorphosed larvae to a maximum 11 months.~~

Outbreak of disease

~~means the occurrence of one or more cases in an epidemiological unit sudden an occurrence of disease in an aquatic animal population.~~

Outbreak communication

~~means the process of communicating in the event of an outbreak. Outbreak communication includes notification.~~

Ova

~~see eggs and gametes.~~

Partial stamping out policy

~~means the carrying out under the authority of the Competent Authority, on confirmation of a disease, of prophylactic animal health measures consisting of killing selected lots of the aquatic animals within an aquaculture establishment. See also stamping out policy.~~

Place of shipment

~~means the place where the aquatic animals, aquatic animal products, biological products and pathological material are loaded into the vehicle/other transporting units or handed to the agency that will transport them.~~

Population

~~means a group of units sharing a common defined characteristic.~~

Annex III (contd)Processing

~~means the subjecting of aquatic animals to actions such as gutting, cleaning, filleting, freezing, thawing or packing.~~

Products of animal origin destined for use in aquatic animal feeding

~~means meat meal, fish meal, liver meal, bone meal, blood meal, feather meal, scraps of pork fat and milk products when intended for use in aquatic animal feeding.~~

Products of aquatic animal origin destined for human consumption

~~means fish, mollusc and crustacean products intended for human consumption.~~

Qualitative risk assessment

~~means an assessment where the conclusions on the likelihood of the outcome or the magnitude of the consequences are expressed in qualitative terms such as high, medium, low or negligible.~~

Quantitative risk assessment

~~means an assessment where the outputs of the risk assessment are expressed numerically, as probabilities or distributions of probabilities.~~

Risk

means the likelihood of the occurrence and the likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health, to public, aquatic animal or terrestrial animal health in the importing country during a specified time period.

Risk assessment

means the evaluation of the likelihood ~~and and/or~~ the biological and economic consequences of entry, establishment, ~~or and~~ spread of a *hazard* within the *territory* of an *importing country*.

Risk communication

is the interactive exchange of information ~~on risk~~ and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions among risk assessors, risk managers, risk communicators, the general public and other interested parties.

Sanitary measure Sanitary measure

~~means measures such as those described in each chapter of the Aquatic Code that are used for risk reduction and are appropriate for particular diseases.~~ means a measure, such as those described in various Chapters of the Aquatic Code, destined to protect aquatic animal or human health or life within the territory of the OIE Member from risks arising from the entry, establishment and/or spread of a hazard.

Sanitary slaughtering

~~means slaughtering of aquatic animals according to particular procedures providing safety against the spread of specific infectious agents.~~

Screening method

~~means the laboratory method in the Aquatic Manual approved for surveillance for a given disease referred to in the Aquatic Code.~~

Sealed vehicle

~~means a vehicle that is properly sealed so that neither water nor aquatic animals can escape during transportation.~~

Sensitivity analysis

~~means the process of examining the impact of the variation in individual model inputs on the conclusions of a quantitative risk assessment.~~

Sexual products

~~means eggs and gametes of sexually mature aquatic animals.~~

Shellfish

~~means fresh molluscs or fresh crustaceans or the edible products of these species that have been subjected to treatment by cooking, drying, salting, brining or smoking.~~

Shipment

~~means a group of aquatic animals or products thereof destined for transportation. See also place of shipment.~~

Sperm

~~means the male gametes of aquatic animals.~~

Subclinical

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

Surveillance zone

~~means a zone in which a systematic series of investigations of a given population of aquatic animals takes place.~~

Transparency

~~means comprehensive documentation of all data, information, assumptions, methods, results, discussion and conclusions used in the risk analysis. Conclusions should be supported by an objective and logical discussion and the document should be fully referenced.~~

Transport

~~means movement of aquatic animals or products thereof to a destination by means of aircraft, motor vehicle or boat.~~

Uncertainty

~~means the lack of precise knowledge of the input values, which is due to measurement error or to lack of knowledge of the steps required, and the pathways from hazard or risk, when building the scenario being assessed.~~

Variability

~~means a real world complexity in which the value of an input is not the same for each case because of natural diversity in a given population.~~

Vertical transmission

~~means the transmission of a pathogen from a parent aquatic animal to its progeny via its sexual products.~~

Annex III (contd)*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.~~

Veterinary Authority

~~means a *Veterinary Service*, under the authority of the *Veterinary Administration*, which is directly responsible for the application of animal health measures in a specified area of the country. It may also have responsibility for the issuing or the supervision of the issuing of international veterinary certificates in that area. the Governmental Authority of an OIE Member, comprising *veterinarians*, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of aquatic animal health and welfare measures, international aquatic animal health certification and other standards and recommendations in the *Aquatic Code* in the whole territory.~~

Zoning

~~means identifying *zones* for the purpose of *disease control* or *international trade*.~~

— Text deleted

CHAPTER 1.2.3.

DISEASES LISTED BY THE OIE

Preamble: The following *diseases* are listed by the OIE according to the criteria for listing an *aquatic animal disease* (see Article 1.2.2.1.) or criteria for listing an *emerging aquatic animal disease* (see Article 1.2.2.2.).

Article 1.2.3.1.

The following *diseases* of fish are listed by the OIE:

- Epizootic haematopoietic necrosis
- Infectious haematopoietic necrosis
- Spring viraemia of carp
- Viral haemorrhagic septicaemia
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease
- Koi herpesvirus disease.

Article 1.2.3.2.

The following *diseases* of molluscs are listed by the OIE:

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*
- Infection with Aabalone herpes-like virus disease viral mortality¹
- Infection with *Terabrasabella heterouncinata*

Article 1.2.3.3.

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)~~

Annex IV (contd)

- Infectious hypodermal and haematopoietic necrosis
- Crayfish plague (*Aphanomyces astaci*)
- Necrotising hepatopancreatitis²
- Infectious myonecrosis
- White tail disease¹
- ~~Hepatopancreatic parvovirus disease²~~
- ~~Mourilyan virus disease²~~
- Milky haemolymph disease of spiny lobsters (*Panulirus spp.*)^{1,2}

Article 1.2.3.4.

The following *diseases* of amphibians are listed by the OIE:

- Infection with *Batrachochytrium dendrobatidis*
- Infection with ranavirus.

 — Text deleted

¹ Listed according to Article 1.2.2.2.

² Listing of this disease is under study.

CHAPTER 1.3.1.

**GENERAL OBLIGATIONS RELATED TO
CERTIFICATION**

Article 1.3.1.1.

~~A combination of health factors should be taken into account to ensure unimpeded international trade in aquatic animals and aquatic animal products, without incurring unacceptable risks to human and aquatic animal health. A combination of factors should be taken into account to facilitate international trade in aquatic animals and aquatic animal products without incurring unacceptable risks to human and aquatic animal health.~~

Because of differences between countries in their ~~the likely variations in~~ aquatic animal health situations, various options are offered by the *Aquatic Code*. The aquatic animal health situation in the *exporting country*, in the *transit country* or *countries* and in the *importing country* should be considered before determining the requirements ~~that have to be met~~ for trade. To maximise harmonisation of the aquatic animal health aspects of *international trade*, *Competent Authorities* of OIE Members should base their import requirements on the OIE standards, ~~guidelines and recommendations~~.

These requirements should be included in ~~the model international aquatic animal health certificates approved by the OIE, which form~~ are included in drawn up in accordance with the model *international aquatic animal health certificates provided for in* Part 4. of the *Aquatic Code*.

Certification should be exact and concise, and should clearly ~~convey~~ address the ~~wishes~~ requirements of the *importing country*. For this purpose, prior consultation between *Competent Authorities* of *importing* and *exporting countries* ~~is useful and~~ may be necessary. ~~It enables the setting out of the exact requirements so that the certifying official can, if necessary, be given a note of guidance explaining the understanding between the Competent Authorities involved.~~

When officials ~~Members of, or representatives acting on behalf of,~~ a *Competent Authority* wish to visit another country for matters of professional interest to the *Competent Authority* of the other country, the latter should be informed prior to any such visit and should be mutually agreed upon.

Article 1.3.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international aquatic animal health certificate* should assure that *commodities* introduced into the *importing country* comply with OIE standards ~~standards~~ the national level of protection. *Importing countries* should restrict their requirements to those justified for such necessary to achieve the national appropriate a level of protection. If these are ~~more~~ stricter than the OIE standards, ~~guidelines and recommendations~~, then they should be based on an import *risk analysis*.
2. The *international aquatic animal health certificate* should not include requirements for the exclusion of *disease agents* or *aquatic animal diseases* that are present ~~within the territory of~~ in the *importing country* and are not subject to any official control programme, except when the strain of the *disease agent* in the *exporting country* is of significantly higher pathogenicity and/or has a larger host range. ~~The requirements applying to disease agents or diseases subject to official control programmes in a country or zone should not provide a higher level of protection on imports than that provided for the same disease agents or diseases by the measures applied within that country or zone. The measures imposed on imports to manage the risks posed by a disease agent or aquatic animal disease should not require a higher level of protection than that provided by measures applied as part of the official control programme operating within the importing country.~~

Annex V (contd)

3. The *international aquatic animal health certificate* should not include ~~requirements for~~ measures against disease agents or diseases that which are not OIE listed, unless the *importing country* has ~~identified the disease agent as presenting a significant risk for that country, after conducting a scientifically based import risk analysis according to the guidelines in Section 1.4.~~ demonstrated through an import risk analysis, carried out in accordance with Section 1.4., that the disease agent or disease poses a significant risk to the importing country.
4. The transmission by the *Competent Authority* ~~or Veterinary Administration~~ of certificates or the communication of import requirements to persons other than the *Competent Authority* ~~or Veterinary Administration~~ of another country necessitates that copies of these documents be also sent to the *Competent Authority* ~~or Veterinary Administration~~. This important procedure avoids delays and difficulties that may arise between traders and *Competent Authorities* ~~or Veterinary Administrations~~ when the authenticity of the certificates or permits is not established.

~~Their transmission of this~~ information is ~~usually~~ the responsibility of ~~Veterinary Administrations or other Competent Authorities~~ of the *exporting country*. However, it can be ~~the responsibility of Veterinary Authorities or other Competent Authorities at the place of origin of the aquatic animals, if different from the exporting country, when it is agreed that the issue of certificates does not require the approval of the Veterinary Administrations or other Competent Authorities.~~ issued by private sector veterinarians at the place of origin of the commodities when this practice is the subject of appropriate approval and authentication by the Veterinary Administrations or other Competent Authorities.

5. Situations may arise that result in changes to the consignee, identification of the means of transportation, or border post after a certificate is issued. If it is determined that Because these do not change the aquatic animal health or public health status of the consignment, then they should not prevent the acceptance of the certificate.

Article 1.3.1.3.

Responsibilities of the exporting country

1. An *exporting country* should, on request, supply the following to *importing countries*:
 - a) information on the *aquatic animal* health situation and national *aquatic animal* health information systems to determine whether that country is free or has *zones* or *compartments* ~~that are~~ free from *OIE-listed diseases* including the regulations and procedures in force to maintain ~~it's~~ the free status;
 - b) regular and prompt information on the occurrence of *OIE-listed diseases*;
 - e) ~~for diseases not listed, information on new findings that are of potential epidemiological significance to other countries;~~
 - ~~c~~d) details of the country's ability to apply measures to control and prevent *OIE-listed diseases*;
 - ~~d~~e) information on the structure of the *Competent Authority* and the authority that they exercise;
 - ~~f~~e) technical information, particularly on biological tests and vaccines applied in all or part of the country national territory;
 - g) ~~identification~~ of the country or location of harvest or production of the product being exported.

2. *Competent Authorities of exporting countries* should:
 - a) have official procedures for the authorisation of *certifying officials*, defining their functions and duties as well as conditions covering possible suspension and termination of their ~~appointment~~ authorisation;
 - b) ensure that relevant instructions and training are provided to *certifying officials*;
 - c) monitor the activities of the *certifying officials* to verify their integrity and impartiality.
3. The ~~Head of the~~ *Competent Authority* of the *exporting country* is ultimately accountable for certification ~~the certifying official~~ used in *international trade*.

Article 1.3.1.4.

Responsibilities in case of an incident ~~occurring after~~ related to importation

1. *International trade* involves a continuing ethical responsibility. Therefore, if within a reasonable period subsequent to an export taking place, the *Competent Authority* becomes aware of the appearance or reappearance of a *disease* that has been specifically included in the *international aquatic animal health certificate* or other *disease* of potential epidemiological importance to the *importing country* there is an obligation for the Competent Authority to notify the *importing country*, so that the imported ~~aquatic animals~~ commodities may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.
2. ~~Equally, if~~ a *disease* condition appears in imported *aquatic animals* within a reasonable period after importation, the *Competent Authority* of the *exporting country* should be informed so as to enable an investigation to be made, because this may be the first available information on the occurrence of the *disease* in a previously free *aquatic animal* population. The *Competent Authority* of the *importing country* should be informed of the result of the investigation because the source of *infection* may not be in the *exporting country*.
3. ~~If, after importation of commodities, if~~ a *disease* condition appears, ~~within a reasonable period after importation, in aquatic animals in the importing country within a reasonable period after importation of commodities,~~ the Competent Authority of the exporting country should be informed so as to enable an investigation to be made, because this may be the first available information on the occurrence of the disease in a previously free aquatic animal population. The Competent Authority of the importing country should conduct trace back investigations because the source of disease may not be in the exporting country.
4. In case of suspicion, on reasonable grounds, that an *international aquatic animal health certificate* may be fraudulent, the *Competent Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated consignments should be kept under official control, pending the outcome of the investigation. ~~The~~ *Competent Authorities* of all countries involved should fully cooperate with the investigation. If the *international aquatic animal health certificate* is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

 — Text deleted

CHAPTER 1.3.2.

CERTIFICATION PROCEDURES

Article 1.3.2.1.

Protection of the professional integrity of the certifying official

Certification should be based on the highest possible ethical standards, the most important of which is that the professional integrity of the *certifying official* must be respected and safeguarded.

It is essential not to include in the requirements additional specific matters that cannot be accurately and honestly signed by a *certifying official*. For example, these requirements should not include certification of an area as being free from *diseases* that are not notifiable in that country, the occurrence of which the signing *certifying official* is not necessarily informed about. Equally, to ask for certification for events that will take place after the document is signed is unacceptable when these events are not under the direct control and supervision of the signing *certifying official*.

~~Certification of freedom from *diseases* based on purely clinical freedom and *aquatic animal* population history is of limited value. This is also true of *diseases* for which there is no specific diagnostic test, or the value of the test as a diagnostic aid is limited.~~

~~The purpose of the note of guidance referred to in Article 1.3.1.1. is not only to inform the signing *certifying official* but also to safeguard professional integrity.~~

Article 1.3.2.2.

Certifying officials

Certifying officials should:

1. be authorised by the *Competent Authority* of the *exporting country* to sign *international aquatic animal health certificates*;
2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party authorised by the *Competent Authority*;
3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the *certifying official* should be in possession of that documentation before signing;
4. have no conflict of interest in the commercial aspects of the *aquatic animals* or *aquatic animal products* being certified and be independent from the commercial parties.

Article 1.3.2.23.

Procedures for the preparation of international aquatic animal health certificates

Annex VI (contd)

Certificates should be drawn up in accordance with the following principles:

1. Certificates should be designed so as to minimise the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should ~~be~~ pre-printed, if possible on one sheet of paper, serially numbered, and issued by the Competent Authority on officially headed notepaper and, if possible, printed using techniques that prevent forgery. bear the official identifier of the issuing Competent Authority. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.
2. They should be written in terms that are as simple, unambiguous and easy to understand as possible, without losing their legal meaning.
3. If so required, they should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the *certifying official*.
4. They should require appropriate identification of *aquatic animals* and *aquatic animal products* except where this is impractical (e.g. eyed eggs).
5. They should not require a *certifying official* to certify matters that are outside his/her knowledge or that he/she cannot ascertain and verify.
6. Where appropriate, they should be accompanied, when presented to the *certifying official*, by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.
7. Their text should not be amended except by deletions that must be signed and stamped by the *certifying official*. ~~The signature and stamp must be in a colour different to that of the printing of the certificate.~~
8. The signature and stamp must be in a colour different from that of the printing of the certificate. The stamp may be embossed instead of being a different colour.
- ~~8.9.~~ Only original certificates should be ~~are~~ accepted ~~able~~ by the *importing country*.
- 9.10. Replacement certificates may be issued by a Competent Authority to replace original certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These ~~duplicates~~ replacements should be provided by the issuing authority and ~~These must~~ be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.

Article 1.3.2.3.

Certifying officials

~~Certifying officials should:~~

1. ~~be authorised by the Competent Authority of the exporting country to sign international aquatic animal health certificates;~~

- ~~2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party approved by the *Competent Authority*;~~
- ~~3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the *certifying official* should be in possession of that documentation before signing;~~
- ~~4. have no conflict of interest in the commercial aspects of the *aquatic animals* or *aquatic animal products* being certified and be independent from the commercial parties.~~

Article 1.3.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Competent Authority* of the *exporting country* to the *Competent Authority* of the *importing country*. Normally, such systems also provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The *certifying official* must have access to all information such as laboratory results and *aquatic animal* identification data.
2. Electronic certificates should carry the same information as conventional certificates.
3. The *Competent Authority* must have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.
4. The *certifying official* must be officially responsible for the secure use of his/her electronic signature. ~~This may be by a personal identification number or a similar secure mechanism.~~

— Text deleted

CHAPTER 1.4.3.

**QUALITY AND EVALUATION OF
COMPETENT AUTHORITIES**

Article 1.4.3.1.

The quality of ~~the~~ *Competent Authorities* depends on multiple factors that include fundamental principles of an ethical, organisational and technical nature. ~~The~~ *Competent Authorities* should conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the *Competent Authorities* of an OIE Member Country or Territory (Member) is important to the establishment and maintenance of confidence in its *international aquatic animal health certificates* by the *Competent Authorities* of other Members.

These fundamental principles are presented in Article 1.4.3.2. Other factors affecting the quality of *Competent Authorities* are described in the *Aquatic Code* (notification, principles of certification, etc.).

The quality of *Competent Authorities* can be measured through an evaluation, the general principles of which are described in Article 1.4.~~4.3~~3. and in Article 1.4.~~4.3~~4.

A procedure for evaluating *Competent Authorities* by OIE experts, on a voluntary basis, is described in Article 1.4.3.5.

Article 1.4.3.2.

Fundamental principles of quality

~~The~~ *Competent Authorities* should comply with the following principles to ensure the quality of their activities:

1. Professional judgement

The personnel of *Competent Authorities* should have the relevant qualifications, scientific expertise and experience to give them the competence to make sound professional judgements.

2. Independence

Care should be taken to ensure that ~~the~~ *Competent Authorities* personnel are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality

~~The~~ *Competent Authorities* should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

Annex VII (contd)4. Integrity

~~The~~ *Competent Authorities* should guarantee that the work of each of their personnel is of a consistently high level of integrity. Any fraud, corruption or falsification should be identified, documented and corrected.

5. Objectivity

~~The~~ *Competent Authorities* should at all times act in an objective, transparent and non-discriminatory manner.

6. General organisation

~~The~~ *Competent Authorities* must be able to demonstrate by means of an appropriate ~~legislation~~ regulatory framework, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of *aquatic animal* health measures, and of international *aquatic animal* health certification activities. ~~Legislation~~ The regulatory framework should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, ~~they~~ such frameworks should define and document the responsibilities and structure of the organisations in charge of the control of *aquatic animal* movements, *aquatic animal* disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

A similar demonstration should be made by *Competent Authorities* if they are in charge of veterinary public health activities.

~~The~~ *Competent Authorities* should have at their disposal effective systems for *aquatic animal* disease surveillance, diagnosis and *notification* of disease problems ~~wherever they~~ that may occur in the national territory, in accordance with the provisions of the *Aquatic Code*. They should at all times endeavour to improve their performance in terms of *aquatic animal* health information systems and *aquatic animal* disease control.

~~The~~ *Competent Authorities* should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international aquatic animal health certificates*.

Each position within the *Competent Authorities* that has an impact on their quality should be described.

These job descriptions should include the requirements for education, training, technical knowledge and experience.

7. Quality policy

~~The~~ *Competent Authorities* should define and document their policy and objectives for, and commitment to, quality, and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The recommendations provided in this Chapter describe ~~for the quality and evaluation of~~ *Competent Authorities* propose a suitable reference system, which should be used if a Member chooses to adopt a quality system.

8. Procedures and standards

~~The~~ *Competent Authorities* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

- a) programming and management of activities, including international *aquatic animal* health certification activities;
- b) prevention, control and *notification* of disease *outbreaks*;
- c) *risk analysis*, epidemiological *surveillance* and *zoning*;
- d) inspection and sampling techniques;
- e) diagnostic tests for *aquatic animal diseases*;
- f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;
- g) border controls and import regulations;
- h) *disinfection*;
- i) treatments intended to inactivate ~~destroy, if appropriate,~~ pathogens in *aquatic animal* products.

Where there are standards in this *Code* or in the *Aquatic Manual*, ~~the~~ *Competent Authorities* should comply with these standards when applying *aquatic animal* health measures and when issuing *international aquatic animal health certificates*.

9. Information, complaints and appeals

~~The~~ *Competent Authorities* should undertake to reply to ~~legitimate~~ requests from *Competent Authorities* of other Members or any other authority, in particular ensuring that any requests for information, complaints or appeals that are presented ~~they may~~ are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by ~~the~~ *Competent Authorities*.

10. Documentation

~~The~~ *Competent Authorities* should have at their disposal a reliable and up-to-date documentation system suited to their activities.

11. Self-evaluation

~~The~~ *Competent Authorities* should undertake periodical self-evaluation especially by documenting achievements against goals, and demonstrating the efficiency effectiveness of their organisational components and resource adequacy.

Annex VII (contd)

A procedure for evaluating *Competent Authorities* by OIE experts, on a voluntary basis, is described in Article 1.4.3.5.

12. Communication

Competent Authorities should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.

13. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Article 1.4.3.3.

For the purposes of the *Aquatic Code*, every Member should recognise the right of another Member to undertake, or request it to undertake, an evaluation of its *Competent Authorities* where the initiating Member is an actual or a prospective importer of *aquatic animals commodities* and/or where the evaluation is to be a component of a *risk analysis* process that is to be used to determine or review sanitary measures which apply to such trade.

A Member has the right to expect that the evaluation of its *Competent Authorities* will be conducted in an objective and transparent manner. A Member undertaking an evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 1.4.3.4.

A Member that intends to conduct an evaluation of another Member's *Competent Authorities* should ~~give them~~ provide notice in writing, and allow sufficient time for the other Member to comply with the request. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Competent Authorities* by another Member, and following bilateral agreement of the evaluation process and criteria, a Member should expeditiously provide the ~~other~~ Member requesting the evaluation with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 1.4.3.1. and in Article 1.4.3.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 1.4.3.1., prevailing in the countries concerned.

The outcome of ~~an~~ the evaluation conducted by a Member should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member which has undergone the evaluation. The evaluation report should detail any findings that affect trade prospects. The Member that conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Members over the conduct or the conclusions of the evaluation of ~~the~~ *Competent Authorities*, the matter should be dealt with in accordance with the procedures set out in Article 1.4.1.3.

Article 1.4.3.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of ~~the~~ *Competent Authorities* of Members. ~~upon request by Members~~ can make a request to the OIE for an evaluation of their *Competent Authority*.

The OIE International Committee may endorse a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE recommends an expert(s) from that list.

The expert(s) facilitate(s) the evaluation of the *Competent Authority*~~s~~ of the Member using the OIE *Tool for the Evaluation of Performance of Veterinary Authorities (OIE PVS Tool)*, applied as appropriate to the context of the evaluation.

The expert(s) produce(s) a report in consultation with the *Competent Authority*~~s~~ of the Member.

The report is submitted to the Director General of the OIE and, with the consent of the Member, published by the OIE.

— Text deleted

CHAPTER 2.3.7.

CRAYFISH PLAGUE

Article 2.3.7.1.

For the purposes of the *Aquatic Code*, crayfish plague means *infection* with *Aphanomyces astaci* Schikora. This organism is a member of a group commonly known as the water moulds (the Oomycetida). Common synonyms are listed in Chapter 4.1.7. of the *Aquatic Manual*.

Information on *surveillance* and methods for diagnosis are provided in the *Aquatic Manual*.

Article 2.3.7.2.

Scope

The recommendations in this Chapter apply to all species of crayfish in all three crayfish families (*Cambaridae*, *Astacidae*, and *Parastacidae*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.3.7.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any crayfish plague related conditions, regardless of the crayfish plague status of the *exporting country, zone* or *compartment*.
 - a) For the species referred to in Article 2.3.7.2. intended for any purpose:
 - i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and some ready to eat meals; and crayfish oil and crayfish *meal* intended for use in *feed*;
 - ii) chemically extracted chitin;
 - iii) crayfish products made non-infectious during processing as dry *feed* (e.g. pelleted or extruded *feed*);

Annex VIII (contd)

- iv) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*;
- v) frozen crayfish products that have been subjected to -20°C or lower temperatures for at least 72 hours.

~~b) The following products destined for human consumption from species referred to in Article 2.3.7.2. which have been prepared and packaged for direct retail trade: The following products destined for human consumption from species referred to in Article 2.3.7.2. which have been prepared and packaged for direct retail trade:~~

~~For the commodities listed in point 1b). Members may wish to consider introducing internal measures to address the risks associated with the commodity being used for any purpose other than for human consumption. (under study) For the commodities listed in point 1b), Members may wish to consider introducing internal measures to prevent the commodity being used for any purpose other than for human consumption. (under study)~~

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.7.2., other than those listed in point 1 of Article 2.3.7.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.7.7. to 2.3.7.11. relevant to the crayfish plague status of the *exporting country, zone or compartment*.
3. When considering the importation/transit from an *exporting country, zone or compartment* not declared free of crayfish plague of a *commodity* of a species not covered in Article 2.3.7.2. but which could reasonably be expected to be a potential mechanical vector for *A. astaci*, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.7.4.

Crayfish plague free country

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

If a country shares a *water catchment* with one or more other countries, it can only make a *self-declaration of freedom* from crayfish plague if all the areas covered by the shared water are declared crayfish plague free countries or *zones* (see Article 2.3.7.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.7.2. is present may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.7.2 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 crayfish plague 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 (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual*) may make a *self-declaration of freedom* from crayfish plague when:
 - a) *basic biosecurity conditions* have been met continuously for at least the past 5 years; and
 - b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *A. astaci*.

OR

4. A country that has previously made a *self-declaration of freedom* from crayfish plague but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from crayfish plague 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 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 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 5 years without detection of *A. astaci*; and
 - d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 5 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 2.3.7.5.

Article 2.3.7.5.

Crayfish plague free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from crayfish plague 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 a crayfish plague free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.7.2. is present may be declared free from crayfish plague when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

Annex VIII (contd)

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.7.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from crayfish plague when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 10 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 25 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual*) may be declared free from crayfish plague when:
- a) *basic biosecurity conditions* have been met continuously for at least the past 5 years; and
 - b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 5 years without detection of *A. astaci*.

OR

4. A *zone* previously declared free from crayfish plague but in which the *disease* is detected may not be declared free from crayfish plague 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 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 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 5 years without detection of *A. astaci*; and
 - d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 5 years.

Article 2.3.7.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of points 1 or 2 of Articles 2.3.7.4. or 2.3.7.5. (as relevant) may maintain its status as crayfish plague free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of point 3 of Articles 2.3.7.4. or 2.3.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as crayfish plague free provided that conditions that are conducive to clinical expression of crayfish plague, 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 crayfish plague, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.7.7.

Importation of live aquatic animals from a country, zone or compartment declared free from crayfish plague

When importing live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, 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* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Annex 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.8.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of all effluent and waste materials in a manner that ensures inactivation of *A. astaci*.
2. If the intention of the introduction is the establishment of a new stock, the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.
3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: <http://www.ices.dk/indexfla.asp>) may be summarised to the following main points:
 - a) identify stock of interest (cultured or wild) in its current location;

Annex VIII (contd)

- b) evaluate stock health/disease history;
- c) take and test samples for *A. astaci*, pests and general health/disease status;
- d) import and quarantine in a secure facility a founder (F-0) population;
- e) produce F-1 generation from the F-0 stock in *quarantine*;
- f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *A. astaci* and perform general examinations for pests and general health/disease status;
- g) if *A. astaci* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as crayfish plague free or specific pathogen free (SPF) for *A. astaci*;
- h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the *country, zone or compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from crayfish plague

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone or compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until consumption; and
2. all effluent, dead *aquatic animals* and waste materials from the *processing* be treated in a manner that ensures inactivation of *A. astaci*.

Members may wish to consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.10.

Importation of aquatic animal products from a country, zone or compartment declared free from crayfish plague

When importing *aquatic animal products* of species referred to in Article 2.3.7.2. from a country, *zone or compartment* declared free from crayfish plague, 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* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the consignment is a country, *zone or compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Annex 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from crayfish plague

When importing *aquatic animal products* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

— Text deleted

APPENDIX 4.1.

**MODEL HEALTH CERTIFICATES
FOR INTERNATIONAL TRADE IN
LIVE AQUATIC ANIMALS AND
PRODUCTS OF AQUATIC ANIMAL ORIGIN**

Article 4.1.1.

Notes for guidance on the health certificates for international trade in live aquatic animals and products of aquatic animal origin

1. General

Please complete the certificate on paper in capital letters. To confirm an option, mark the box with a cross (X). Ensure that no portion of certificate is left blank in a manner that would allow it to be amended. Non-applicable fields may be crossed out.

2. Part I. Details of dispatched consignment

Country:	Name of the country that issues the certificate.
Box I.1.	Name and full address of the natural or legal entity dispatching the consignment. Information on telephone and fax numbers or e-mail address is recommended.
Box I.2.	The certificate reference number is the number used by the Competent Authority of the country to identify the certificate.
Box I.3.	Name of the Competent Authority.
Box I.4.	Name and full address of the natural or legal entity to whom the consignment is destined at the time the certificate is issued.
Box I.5.	Name of the country from which the live aquatic animals or gametes are being exported. For aquatic animal products, name the country(ies) where the finished products were produced, manufactured or packed. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.6.	Name of the zone or compartment of origin, if relevant, in part II of the certificate.
Box I.7.	Name of the country of destination. "ISO code" refers to the international standard two-letter code (ISO 3166-1 Alpha-2 Code) for a country produced by the International Organization for Standardization.
Box I.8.	Name of the zone or compartment of destination, if relevant, in part II of the certificate.
Box I.9.	Name and full address of the place(s) from which the live aquatic animals or aquatic animal products are being exported; and official approval or registration number when required. For live aquatic animals and gametes: the establishment(s) or place of capture. For products of aquatic animal origin: the premises from which the products are to be dispatched.

Annex IX (contd)

Box I.10.	Name of the place from which the live aquatic animals or aquatic animal products are being shipped (this will be a land, sea or airport).
Box I.11.	Date of departure. For live aquatic animals include the expected time of departure.
Box I.12.	<p>Details of the means of transport.</p> <p>Identification of the means of transport at the time the certificate is issued: for air transport, the flight number; for maritime transport, the name of the vessel; for rail transport, the number of the train and the wagon and for road transport, the registration number of the road vehicle and the number of the trailer where used.</p>
Box I.13.	Name of expected border post and, if available, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).
Box I.14.	CITES permit number(s) if the commodity concerns species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora.
Box I.15.	Describe the commodity or use the titles as they appear in the Harmonised System of the World Customs Organization.
Box I.16.	Heading or HS Code of the Harmonized System set up by the World Customs Organization.
Box I.17.	<p>Total quantity or weight of the commodity.</p> <p>For live aquatic animals <u>and gametes</u> give the total count of aquatic animals or weight. For live aquatic animals products <u>and gametes</u> give the gross weight and the net weight in kg of the whole consignment.</p>
Box I.18.	Temperature of products for transport and storage.
Box I.19.	For live aquatic animals or gametes give the total number of containers in which they are being transported. For aquatic animal products give the total number of packages.
Box I.20.	Identify the containers/seal numbers where required.
Box I.21.	Identify the type of packaging of aquatic animal products as defined in Recommendation No. 21 – Code of Passengers, Type of Cargo, Package and Packaging Materials of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business).
Box I.22.	<p>Intended use of the imported live aquatic animals or aquatic animal products.</p> <p>Breeding: applies to gametes and broodstock.</p> <p>Grow out: applies to live aquatic animals, aquatic eggs and aquatic larvae <u>requiring time in culture</u>.</p> <p>Slaughter: applies to live aquatic animals for slaughter.</p> <p>Restocking: applies to live aquatic animals for the purpose of rebuilding stocks.</p> <p>Ornamental: applies to live aquatic animals kept for companionship or enjoyment.</p> <p>Competition/Exhibition <u>Display</u>: applies to live aquatic animals used <u>for display or competition purposes in an exhibition</u>.</p> <p>Human consumption: applies to <u>live</u> aquatic animals (<u>without further aquaculture involved</u>) or aquatic animals products intended for human consumption.</p>

Annex IX (contd)

Box I.22.	Aquatic animal feed: means any product of animal origin (single or multiple), whether processed, semi-processed or raw, that is intended to be fed to aquatic animals.
	Further processing: applies to products of aquatic animal origin that have to be further processed before being suitable for end use. Other technical use: applies to aquatic animal products not intended for human or aquatic animal consumption. These include aquatic animal products that are intended for use in the pharmaceutical, medical, cosmetic and other industries. Such products may be subjected to extensive further processing. Technical use in live aquatic animals: applies to aquatic animal products used in live aquatic animals, e.g. to stimulate ovulation.
Box I.23.	Mark, if appropriate.
Box I.24.	Details on the nature of the commodity sufficient to identify it. For live aquatic animals and gametes: Category (i.e. amphibian, crustacean, fish or mollusc); Wild stocks or Cultured stocks; Species (scientific name); Quantity or Weight, and if required, Identification system; Batch number or other identification details; Age; Sex.
Box I.24.	For products of aquatic animal origin: Category (i.e. amphibian, crustacean, fish or mollusc); Wild stocks or Cultured stocks; Species (Scientific name); Nature of commodity; Treatment type; Approval number of establishment(s) (e.g. processing plant; cold store); Lot identification/date code; Quantity; Number of packages; Net weight.

3. Part II. Zoosanitary information

Box II.	Complete this part in accordance with the requirements agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations in the <i>Aquatic Code</i> .
Box II.a.	Reference number: see box I.2.
Certifying Official	Name, address, official position, date of signature and official stamp of the Competent Authority.

Annex IX (contd)

Article 4.1.2.

Model Health Certificate for International Trade in Live Aquatic Animals and Gametes**COUNTRY :**

Part I: Details of dispatched consignment	I.1. Consignor: Name:		I.2. Certificate reference number:		
	Address:		I.3. Competent Authority:		
	I.4. Consignee: Name: Address:				
	I.5. Country of origin:		ISO code*	I.6. Zone or compartment of origin**:	
	I.7. Country of destination:		ISO code*	I.8. Zone or compartment of destination**:	
	I.9. Place of origin: Name: Address:				
	I.10. Place of shipment:		I.11. Date of departure:		
	I.12. Means of transport		I.13. Expected border post:		
	Aeroplane ? Ship ? Railway Road vehicle ? Other ? wagon ?		I.14. CITES permit No(s).**:		
	Identification:				
	I.15. Description of commodity:		I.16. Commodity code (ISO code):		
			I.17. Total quantity/weight:		
	I.18.		I.19. Total number of containers:		
	I.20. Identification of container/seal number:		I.21. <u>Type of packaging:</u>		
	I.22. Commodities intended for use as:				
	Breeding ? Grow out ? Slaughter ? Restocking ? Ornamental ? Competition/Exhibition ? Other ? If other, specify.....				
	I.23. For import or admission:				
	Definitive import ? Re-entry ? Temporary admission ?				
	I.24. Identification of commodities:				
	Amphibian? Crustacean ? Fish ? Mollusc ?				
	Wild stock ? Cultured stock ?				
	Species (Scientific name)		Quantity / Weight	Identification system*	
	Batch number*		Age *	Sex *	

* Optional and ** If referenced in Part II.

Annex IX (contd)

Article 4.1.3.

**Model Health Certificate for International Trade in Products of Aquatic Animal Origin
COUNTRY :**

Part I: Details of dispatched consignment	I.1. Consignor: Name:		I.2. Certificate reference number:		
	Address:		I.3. Competent Authority:		
	I.4. Consignee: Name: Address:				
	I.5. Country of origin:		ISO code*	I.6. Zone or compartment of origin**:	
	I.7. Country of destination:		ISO code*	I.8. Zone or compartment of destination**:	
	I.9. Place of origin: Name: Address:				
	I.10. Place of shipment:		I.11. Date of departure:		
	I.12. Means of transport: Aeroplane ? Ship ? Railway wagon ? Road vehicle ? Other ?		I.13. Expected border post:		
	Identification:		I.14. CITES permit No(s).**:		
	I.15. Description of commodity:		I.16. Commodity code (ISO code):		
			I.17. Total quantity/weight:		
	I.18. Temperature of product: Ambient ? Chilled ? Frozen ?		I.19. Total number of packages:		
	I.20. Identification of container/seal number:		I.21. Type of packaging:		
	I.22. Commodities intended for use as: Human consumption ? Further processing ? Other ? If other, specify.....		Aquatic animal feed ? Other technical use ? Technical use in live aquatic animals ? If Technical use, specify.....		
I.23.					
I.24. Identification of commodities:					
Amphibian?		Crustacean ?		Fish ? Mollusc ?	
Wild stock ?		Cultured stock ?			
Species (Scientific name)		Nature of commodity		Treatment type	
		Approval number of establishments			
Number of packages		Net weight		Lot ID/date code	

* Optional and ** If referenced in Part II.

CHAPTER X.X.X.

**CRITERIA TO ASSESS THE SAFETY OF
AQUATIC ANIMAL COMMODITIES**

Article X.X.X.1.

Criteria to assess the safety of aquatic animal commodities irrespective of country disease status

In all disease chapters, point 1 of Article X.X.X.3. lists *commodities* that can be traded irrespective of country disease status. The criteria for inclusion of *commodities* in point 1 of Article X.X.X.3. are based on the absence of the *disease agent* in the traded *commodity* or inactivation of the *disease agent* by treatment or *processing*.

The assessment of the safety of the *commodity* using the criteria relating to treatment or *processing* can only be undertaken where treatments or *processing* are well defined. It may not be necessary to provide details of the entire treatment or process undertaken. However, the steps considered critical in the inactivation of the *disease agent* of concern should be detailed.

It is assumed that treatment or *processing* (i) uses standardised protocols, which include the steps considered critical in the inactivation of the *disease agent* of concern; (ii) is conducted according to Good Manufacturing Practices; and (iii) that any other steps in the treatment, *processing* and subsequent handling of the *commodity* do not jeopardise the safety of the traded *commodity*.

For a *commodity* to be considered safe for *international trade* under the provisions of Article X.X.X.3. it should comply with the following criteria:

1. Absence of *disease agent* in the traded *commodity*:
 - 1a. There is strong evidence that the *disease agent* ~~is~~ does not occur ~~present~~ present in the tissues from which the *commodity* is derived;

AND

- 1b. The water (including ice) used to ~~rear or process~~ or transport the *commodity* is not contaminated with the *disease agent* and the processing prevents cross contamination of the *commodity* to be traded final product.

OR

2. Even if the *disease agent* is present in, ~~does occur~~ or contaminates ~~in~~ the tissues from which the *commodity* ~~was~~ is derived, the treatment or processing to produce the ~~final~~ *commodity* to be traded ~~involves processes known to~~ inactivates the *disease agent*:

Annex X (contd)

2a. Physical (e.g. temperature, drying, smoking);

AND/OR

2b. Chemical (e.g. iodine, pH, salting, smoking);

AND/OR

2c. Biological (e.g. fermentation).

Article X.X.X.2.

Criteria to assess the safety of aquatic animal products destined for human consumption irrespective of country disease status

In all disease chapters, point 1 of Article X.X.X.12. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters) lists *aquatic animal products* destined for human consumption. The criteria for inclusion of *aquatic animal products* in point 1 of Article X.X.X.12. include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely quantity of viable *disease agent* in the waste.

For the purpose of this criterion retail means the selling or provision of *aquatic animal products* directly to the consumer with the intended purpose of human consumption. The retail pathway may also include wholesale distribution of the products provided they are not further processed by the wholesale distributor or the retailer, i.e. are not subjected to actions such as gutting, cleaning, filleting, freezing, thawing, cooking, unpacking, packing or repackaging.

It is assumed that the *aquatic animal* product is used for human consumption. It is assumed that treatment or *processing* prior to importation (i) uses standardised protocols, which include the steps considered critical in the inactivation of the *disease agent* of concern; and (ii) is conducted according to Good Manufacturing Practices; and (iii) that any other steps in the treatment, *processing* and subsequent handling of the *aquatic animal products* do not jeopardise the safety of the traded *aquatic animal products*.

For *aquatic animal products* to be considered safe for *international trade* under the provisions of point 1 of Article X.X.X.12. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters) it should comply with the following criteria:

1. The *aquatic animal* product is prepared and packaged for ~~direct~~ retail trade for human consumption;
AND

EITHER:

2. Includes only a small amount of waste tissues;

OR AND

3a. Viable ~~The~~ *disease agent* is unlikely to be present in the waste tissues, because:

a) the *disease agent* is not normally found in the waste tissues;

OR

b) ~~t~~The *disease agent* may be present ~~does occur~~ in the waste tissues but the processing prior to importation (i.e. ~~post importation such as cooking~~) to produce the final consumable product involves processes known to inactivate and/or reduce the load of *disease agent*:

i) Physical (e.g. temperature, drying, smoking);

AND/OR

ii) Chemical (e.g. pH, ~~salting~~, ~~smoking~~);

AND/OR

iii) Biological (e.g. fermentation).

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APPENDIX 3.4.2.

WELFARE OF FARMED FISH DURING TRANSPORT

Preamble: Transport is stressful to fish. This Chapter provides information to minimise the effect of transport on the welfare of farmed fish (hereafter referred to as fish). It applies to their transport ~~of fish~~ by air, by sea or on land within a country and between countries, and only considers the issues related to only their welfare of fish. Recommendations for measures to control the *aquatic animal health risks* related to the transport of fish are included in Chapter 1.5.1. Recommendations for safe transport of *aquatic animals* and *aquatic animal products*

Article 3.4.2.1.

Responsibilities

~~The welfare of farmed fish during their transport is the joint responsibility of a~~ All personnel involved. All parties handling fish throughout the transportation process prior to loading as well as during loading and unloading have a personal are responsibility for ensuring that consideration is given to the potential impact on the welfare of the fish being handled.

The roles of each of the various personnel are defined below:

1. The responsibilities of the *Competent Authority* for the exporting and importing jurisdiction include:
 - a) establishing minimum standards for fish welfare during transport, including examination before, during and after their transport, appropriate certification and record keeping;
 - b) ensuring ~~appropriate~~ awareness and training of personnel involved in transport;
 - c) ensuring implementation of the standards, including possible accreditation of transport companies.
2. Owners and managers of ~~farmed~~ fish at the start and at the end of the journey are responsible for:
 - a) the general health of the fish and their fitness for transport at the start of the journey and to ensure the overall welfare of the fish during the transport regardless of whether these duties are subcontracted to other parties;
 - b) ensuring competent personnel supervise operations at their facilities for fish to be loaded and unloaded in a manner that causes minimum stress and injury;
 - c) having a contingency plan available to enable humane killing of the fish at the start and at the end of the journey, as well as during the journey, if required;
 - d) ensuring the fish have a suitable environment to enter at their destination that ensures their welfare is maintained.

Annex XI (contd)

3. Transport companies, in cooperation with the ~~Competent Authority and~~ farm owner/manager, are responsible for planning the transport to ensure that the transport can be carried out according to fish health and welfare standards including:
 - a) ~~using choosing an appropriate,~~ a well maintained vehicle, that is appropriate to the species to be transported;
 - b) ensuring that competent staff are available for loading and unloading; and to ensure swift, humane killing of the fish, if required;
 - c) having contingency plans to address emergencies and minimise stress during transport;
 - d) selecting ~~appropriate technology~~ suitable equipment for loading and unloading of the *vehicle*.
4. The person in charge of supervising the transport is responsible for all documentation relevant to the transport, and practical implementation of guidelines for welfare of fish during transport.

Article 3.4.2.2.

Competence

All parties supervising transport activities, including loading and unloading, should have ~~an appropriate~~ knowledge and understanding to ensure that the welfare of the fish is maintained throughout the process. Competence may be gained through formal training and ~~or~~ practical experience.

1. All persons handling live fish, or who are otherwise responsible for live fish during transport, should be competent according to their responsibilities listed in Article 3.4.2.1.
2. *Competent Authority*, farm owners/managers, and transport companies have a responsibility in providing ~~appropriate~~ training to their staff and personnel.
3. Any necessary training should address species-specific knowledge and may include practical experience on:
 - a) fish behaviour, physiology, general signs of disease and poor welfare;
 - b) operation and maintenance of equipment relevant to fish health and welfare;
 - c) water quality; and suitable procedures for water exchange;
 - d) methods of live fish handling during transport, loading and unloading (species-specific aspects when relevant);
 - e) methods for inspection of the fish, management of situations frequently encountered during transport such as changes in water quality parameters, adverse weather conditions, and emergencies;
 - f) methods for the humane killing of fish in accordance with Chapter X.X.X. on the Humane Killing of Fish for Disease Control Purposes (in preparation);
 - g) ~~appropriate~~ logbooks and record keeping.

Article 3.4.2.3.

Planning the transport1. General considerations

Adequate planning is a key factor affecting the welfare of fish during transportation. The pre-transport preparation, the duration and route of a transport should be determined by the purpose of the transport e.g. biosecurity issues, transport of fish for stocking farms or resource enhancement, for slaughter/killing for disease control purposes. ~~Adequate planning is a key factor affecting the welfare of fish during transportation.~~ Before the transport starts, plans should be made in relation to:

- a) type of *vehicle* and transport equipment required;
- b) route – such as distance, expected weather and/or sea conditions;
- c) nature and duration of the transport;
- d) need for care of the fish during the transport;
- e) emergency response procedures related to fish welfare;
- f) assessment of the necessary biosecurity level (e.g. washing and *disinfection* practices, safe places for changing water, treatment of transport water (refer to Chapter 1.5.1)).

2. Contingency plans

~~There should be a contingency plan that identifies the important adverse fish welfare events that may be encountered during the transport, the procedures for managing each event and the action to be taken in such an event. For each event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.~~

3. Vehicle design and maintenance

- a) *Vehicles* and *containers* used for transport of fish should be appropriate to the species, size, and weight and number of ~~the~~ fish to be transported.
- b) *Vehicles* and *containers* should be maintained in good mechanical and structural condition to prevent predictable and avoidable damage of the *vehicle* that may directly or indirectly affect the welfare of transported fish.
- c) *Vehicles* (if relevant) and *containers* should have adequate circulation of water and equipment for oxygenation as required to meet variations in the conditions during the journey and the needs of the animals being transported, including the closing of valves in well boats for biosecurity reasons.
- d) The fish should be accessible to inspection en route, if necessary, to ensure that fish welfare standards can be assessed ~~and shortcomings appropriately addressed.~~
- e) Documentation that focuses on fish welfare and thus carried with the *vehicle* should include a transport logbook of stocks received, contact information, mortalities and disposal/storage logs.

Annex XI (contd)43. Water

- a) Water quality (e.g. oxygen, CO₂ and NH₃ level, pH, temperature, salinity) should be appropriate and adequate for the species being transported and method of transportation.
- b) Equipment to ~~maintain adequate water quality (e.g. oxygen, pH, temperature, salinity) and to monitor~~ and maintain water quality may be required depending on the length of the transport.

5. Documentation

- a) ~~Fish should not be loaded until the required documentation is complete.~~
- b) ~~The documentation accompanying the consignment (the transport log) should include:~~
 - i) ~~description of the consignment (e.g. date, time, and place of loading, species, biomass load);~~
 - ii) ~~description of the transport plan (e.g. including route, water exchanges, expected time, date and place of arrival and unloading and receiver contact information);~~
- e) ~~The transport log should be made available to the dispatcher and the receiver of the consignment as well as to the *Competent Authority* upon request. Transport logs from previous journeys should be kept after completion of the transport for a period of time as specified by the *Competent Authority*.~~

46. Preparation of fish for the transport

- a) Prior to transport, feed should be withheld from the fish, taking into consideration the fish species and life stage to be transported.
- b) The ability of the fish to cope with the stress of transport should be assessed based on health status, previous handling and recent transport history of the fish. ~~Except for disease control purposes, o~~Only fish that are fit for transport should be loaded.
- c) ~~Signs~~ Reasons for considering ~~of~~ unfitness of fish for transport includes:
 - i) displaying clinical signs of disease;
 - ii) significant physical injuries or abnormal behaviour; such as rapid ventilation or abnormal swimming;
 - iii) recent exposure to stressors that adversely affect behaviour or physiological state; for example extreme temperatures, chemical agents;
 - iii) ~~history of exposure to disease agents.~~

57. Species-specific recommendations

Transport procedures should take account of variations in the behaviour and specific needs of the transported fish species. Handling procedures that are successful with one species may be ineffective or dangerous for another species.

Some species or life stages may need to be physiologically prepared prior to entering a new environment, such as by feed deprivation or osmotic acclimatisation.

6. Contingency plans

There should be a contingency plan that identifies the important adverse fish welfare events that may be encountered during the transport, the procedures for managing each event and the action to be taken in such an event. For each event, the plan should document the actions to be undertaken and the responsibilities of all parties involved, including communications and record keeping.

Article 3.4.2.4.

Documentation

- a) Fish should not be loaded until the required documentation is complete.
- b) The documentation accompanying the consignment (the transport log) should include:
 - i) description of the consignment (e.g. date, time, and place of loading, species, biomass load);
 - ii) description of the transport plan (e.g. including route, water exchanges, expected time, date and place of arrival and unloading and receiver contact information).
- c) The transport log should be made available to the dispatcher and the receiver of the consignment as well as to the *Competent Authority* upon request. Transport logs from previous journeys should be kept after completion of the transport for a period of time as specified by the *Competent Authority*.

Article 3.4.2.5.

Loading the fish

1. The issues which should be addressed to avoid unnecessary stress and injury to the fish include:
 - a) ~~overcrowding~~ procedure in farm pond, tank, net or cage prior to loading;
 - b) ~~improperly constructed or operated~~ equipment (such as nets, pumps, pipes and fittings) both improperly constructed, for example with sharp bends or protrusions or improperly operated by overloading the system with fish of incorrect size or number of fish per time unit according to the equipments capacity;
 - c) water quality - some species of fish should be acclimatised if there is a likelihood of the fish being transported in water of a significantly different temperature or other water parameters;
 - d) ~~air temperature, tide level and time of the day.~~

Annex XI (contd)

2. The density of fish in a *vehicle* and/or *container* should be in accordance with scientific data where available and not exceed what is generally accepted for a given species and a given situation.
3. Loading should be carried out, or supervised, by operators with knowledge and experience of the behaviour and other characteristics of the fish species being loaded to ensure that the welfare of the fish is maintained.

Article 3.4.2.6.

Transporting the fish1. General considerations

- a) ~~Where necessary, p~~Periodic inspections should take place during the transport to verify that acceptable welfare is being maintained.
- b) ~~Where necessary, the person in charge should e~~Ensure that water quality is monitored and the necessary adjustments made to avoid extreme conditions.
- c) ~~The vehicle operator should f~~Travel in a manner that minimises uncontrolled movements of the fish.

2. Emergency procedures-Sick or injured fish

- a) In the event of a fish health emergency during transport, the *vehicle* operator should initiate the procedure to implement the contingency plan (see point 2 of Article 3.4.2.3.).
- b) If the killing of fish is necessary during the transport, the person in charge should ensure that the killing is carried out humanely in accordance with Chapter X.X.X. on the Humane Killing of Fish for Disease Control Purposes (in preparation), and in compliance with relevant legislation.

Article 3.4.2.7.

Unloading the fish

1. The principles of good fish handling during loading apply equally during unloading.
2. Fish should be unloaded as soon as possible after arrival at the destination, allowing sufficient time to ensure that the unloading procedure does not cause harm to the fish. Some species of fish should be acclimatised if there is a likelihood of the fish being unloaded into water of a significantly different quality (such as temperature, salinity, pH).
3. Moribund or seriously injured fish should be removed and humanely killed in accordance with Chapter X.X.X. on the Humane Killing of Fish for Disease Control Purposes (in preparation).

Article 3.4.2.8.

Post-transport activities

1. The person in charge of receiving the fish should closely observe them during the post-transport period, and keep appropriate records.

2. Fish showing abnormal clinical signs should be humanely killed in accordance with the Chapter X.X.X on the Humane Killing of Fish for Disease Control Purposes (in preparation) or isolated and examined by a veterinarian or other qualified personnel, who may recommend treatment.
3. Significant problems associated with transport should be evaluated to prevent recurrence of such problems.

Article 3.4.2.9.

Actions in the event of an extreme situation

1. ~~Extreme weather conditions are hazards for fish transport and require appropriate *vehicle* and *container* design to minimise risks. Fish should not be transported in extreme weather conditions that threaten fish welfare.~~
2. ~~If fish cannot be unloaded, temporarily or permanently, the welfare of the fish should be given due consideration while attempts are undertaken to rectify such situations. Fish whose welfare may be irrevocably impacted should be humanely killed in accordance with the Chapter on the Humane Killing of Fish for Disease Control Purposes (in preparation).~~

 — Text deleted

CHAPTER 1.5.6.

MEASURES CONCERNING INTERNATIONAL
TRANSPORT OF AQUATIC ANIMAL
DISEASE AGENTS
AND PATHOLOGICAL MATERIAL

Article 1.5.6.1.

Introduction

There is the *risk* that *disease* may occur as a result of the accidental release of *aquatic animal* pathogens during international transport of packaged materials. Such pathogens may already occur in the country or they may have been imported deliberately or inadvertently. It is therefore necessary to have in place measures to prevent their accidental release. These measures may be applied at national borders by prohibiting or controlling the importation of specified *aquatic animal* pathogens or *pathological material*, which may contain them.

Competent Authorities should not require *sanitary measures* for biological samples preserved for diagnostic applications that are treated in such a manner as to inactivate the *disease agent* and will not cause *aquatic animal disease*.

Article 1.5.6.2.

[...]

**REVISED ARTICLES 2.X.X.3. AND 2.X.X.9.
AND ARTICLE 2.X.X.12.**

USING THE SVC CHAPTER ARTICLES AS AN EXAMPLE

Article 2.1.4.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, ~~the~~ *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 referred to in Article 2.1.4.2. intended for any purpose:
 - i) *commodities* treated in a manner that inactivates the *disease agent* (e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish *meal* intended for use in *feed*);
 - ii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.
 - b) ~~The following *commodities* destined for human consumption from the species referred to in Article 2.1.4.2. which have been prepared and packaged for direct retail trade:~~
 - i) ~~*eviscerated fish* (chilled or frozen);~~
 - ii) ~~*fillets or cutlets* (chilled or frozen);~~
 - iii) ~~*dried eviscerated fish* (including air dried, flame dried and sun dried).~~

~~For the *commodities* referred to in point 1b), Members may wish to consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.~~
2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.1.4.2., other than those referred to in point 1 of Article 2.1.4.3., ~~the~~ *Competent Authorities* should require the conditions prescribed in Articles 2.1.4.7. to 2.1.4.12. relevant to the SVC status of the *exporting country, zone or compartment*.
3. When considering the importation ~~or transit~~ of a *commodity* from an *exporting country, zone or compartment* not declared free of SVC ~~of a live *commodity*~~ from a species not covered in Article 2.1.4.2. but which could reasonably be expected to be a potential mechanical vector/fomite for SVC, ~~the~~ *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[...]

Annex XIII (contd)

Article 2.1.4.9.

Importation of live aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from spring viraemia of carp

When importing, for processing for human consumption, live *aquatic animals* of the species referred to in Article 2.1.4.2. and aquatic animal products from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment is delivered directly to and held in *quarantine* facilities for ~~slaughter~~ further and processing to one of the products referred to in point 1 of Article 2.1.4.3., or products described in point 1 2 of Article 2.1.4.12., or other products authorised by the *Competent Authority*; and
2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of SVCV or disposed in a manner that prevents contact of waste with susceptible species.

Members may wish to consider introducing internal measures to address the risk of prevent such *commodities* being used for any purpose other than for human consumption.

~~This Article does not apply to commodities referred to in point 1 of Article 2.1.4.3. or products described in point 1 2 of Article 2.1.4.12.~~

[...]

Article 2.1.4.12.

Importation of aquatic animal products from a country, zone or compartment not declared free from spring viraemia of carp

1. The risk posed by the following products destined for human consumption from the species referred to in Article 2.1.4.2. which have been prepared and packaged for direct retail trade is considered negligible:

- i) *eviscerated fish* (chilled or frozen):
- ii) *fillets or cutlets* (chilled or frozen):
- iii) *dried eviscerated fish* (including air dried, flame dried and sun dried):

For these commodities Members may wish to consider introducing internal measures to prevent the commodity being used for any purpose other than for human consumption.

2. When importing *aquatic animal products*, other than those referred to in point 1 above, 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.

~~3.~~ ~~In the case of dead fish, whether eviscerated or uneviscerated, such~~ Risk mitigation measures may include:

- ~~1.~~a) the direct delivery into and holding of the consignment in biosecure/*quarantine* facilities for processing to one of the products referred to in point 1 of Article 2.1.4.3., or products described in point 1 2 of this Article, or other products authorised by the *Competent Authority*;
- ~~2.~~b) the treatment of all effluent and waste material in a manner that ensures inactivation of SVCV or disposed in a manner that prevents contact of waste with susceptible species.

~~This Article does not apply to commodities referred to in point 1 of Article 2.1.4.3. or products described in point 1 2 of Article 2.1.4.12.~~

— Text deleted

CHAPTER 2.2.X.

INFECTION WITH ABALONE HERPES-LIKE VIRUS

Article 2.2.X.1.

For the purposes of the *Aquatic Code*, infection with abalone herpes-like virus means herpes-like virus associated manifestation in abalone.

Methods for conducting *surveillance*, diagnosis and confirmatory identification of infection with abalone herpes-like virus are provided in the *Aquatic Manual*.

Article 2.2.X.2.

Scope

The recommendations in this Chapter apply to: *Haliotis diversicolor* (subspecies *aquaticilis* and *supertexta*) and in *Haliotis laevegata*, *H. rubra* and hybrids of *H. laevegata* x *H. rubra*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.X.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any abalone herpes-like virus related conditions, regardless of the abalone herpes-like virus status of the *exporting country, zone* or *compartment*:
 - a) For the species referred to in Article 2.2.X.2. intended for any purpose:
 - i) *commodities* treated in a manner that inactivates the *disease agent* e.g. canned or pasteurized products;
 - ii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.
 - b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.X.2. which have been prepared and packaged for direct retail trade:
 - i) off the shell (chilled or frozen).

For the *commodities* referred to in point 1b), Members may wish to consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

Annex XIV (contd)

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.X.2., other than *commodities* referred to in point 1 of Article 2.2.X.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.X.7. to 2.2.X.11. relevant to the abalone herpes-like virus status of the *exporting country, zone or compartment*.
3. When considering the importation/transit from an *exporting country, zone or compartment* not declared free of infection with abalone herpes-like virus of a *commodity* from mollusc species not covered in Article 2.2.X.2. or in point 1b) of Article 2.2.X.3. but which could reasonably be expected to be a potential mechanical vector for abalone herpes-like virus, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.X.4.

Abalone herpes-like virus free country

A country may make a *self-declaration of freedom* from abalone herpes-like virus if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from abalone herpes-like virus if all the areas covered by the shared water are declared abalone herpes-like virus free *zones* (see Article 2.2.X.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.X.2. is present may make a *self-declaration of freedom* from abalone herpes-like virus when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.X.2. are present but there has been no 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 2.2.9. of the *Aquatic Manual*, may make a *self-declaration of freedom* from abalone herpes-like virus when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years and infection with abalone herpes-like virus 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 (e.g. because of the absence of conditions conducive to clinical expression as described in Chapter 2.2.9. of the *Aquatic Manual*) may make a *self-declaration of freedom* from abalone herpes-like virus when:
 - a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and
 - b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and 2.2.9. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of abalone herpes-like virus.

OR

4. A country that has previously made a *self-declaration of freedom* from abalone herpes-like virus but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from abalone herpes-like virus again when 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 destroyed or removed from the *infected zone* by means that minimize 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 3.3.1. of the *Aquatic Code* and 2.2.9. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of abalone herpes-like virus; and
 - d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 2.2.X.5.

Article 2.2.X.5.

Abalone herpes-like virus free zone or free compartment

A *zone* or *compartment* free from abalone herpes-like virus may be established within the *territory* of one or more countries of infected or unknown status for infection with abalone herpes-like virus 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 abalone herpes-like virus 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 abalone herpes-like virus, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.X.2. is present may be declared free from abalone herpes-like virus when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for abalone herpes-like virus, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.X.2. are present but there has been no 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 2.2.9. of the *Aquatic Manual*, may be declared free from abalone herpes-like virus when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years and infection with abalone herpes-like virus is not known to be established in wild populations.

Annex XIV (contd)

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in Chapter 2.2.9. of the *Aquatic Manual*) may be declared free from abalone herpes-like virus when:
- a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and
 - b) *targeted surveillance*, in Chapters 3.3.1. of the *Aquatic Code* and 2.2.9. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of abalone herpes-like virus.

OR

4. A *zone* previously declared free from abalone herpes-like virus but in which the *disease* is detected may be declared free from *M. mackini* again when 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 destroyed or removed from the *infected zone* by means that minimize 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 3.3.1. of the *Aquatic Code* and 2.2.9. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of abalone herpes-like virus; and
 - d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.2.X.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from abalone herpes-like virus following the provisions of points 1 or 2 of Articles 2.2.X.4. or 2.2.X.5. (as relevant) may maintain its status as abalone herpes-like virus free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from abalone herpes-like virus following the provisions of point 3 of Articles 2.2.X.4. or 2.2.X.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as abalone herpes-like virus free provided that conditions that are conducive to clinical expression of infection with abalone herpes-like virus, as described in Chapter 2.2.9. 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 abalone herpes-like virus, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.X.7.

Importation of live aquatic animals from a country, zone or compartment declared free from abalone herpes-like virus

When importing live *aquatic animals* of species referred to in Article 2.2.X.2. from a country, *zone* or *compartment* declared free from abalone herpes-like virus, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.X.4. or 2.2.X.5. (as applicable), whether the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from abalone herpes-like virus.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.X.3.

Article 2.2.X.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from abalone herpes-like virus

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.X.2. from a country, *zone* or *compartment* not declared free from abalone herpes-like virus, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
 - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
 - b) the treatment of all effluent and waste material in a manner that ensures inactivation of abalone herpes-like virus.
2. If the intention of the introduction is the establishment of a new stock, the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.
3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: <http://www.ices.dk/indexfla.asp>) may be summarised to the following main points:
 - a) identify stock of interest (cultured or wild) in its current location;
 - b) evaluate stock health/disease history;
 - c) take and test samples for abalone herpes-like virus, pests and general health/disease status;
 - d) import and quarantine in a secure facility a founder (F-0) population;

Annex XIV (contd)

- e) produce F-1 generation from the F-0 stock in *quarantine*;
- f) culture F-1 stock and at critical times in its development (life cycle) sample and test for abalone herpes-like virus and perform general examinations for pests and general health/disease status;
- g) if abalone herpes-like virus is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone or compartment*, the F-1 stock may be defined as free of infection with *M. mackini* or specific pathogen free (SPF) for abalone herpes-like virus;
- h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.X.3.

Article 2.2.X.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from abalone herpes-like virus

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.X.2. from a country, *zone* or *compartment* not declared free from abalone herpes-like virus, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and
2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of abalone herpes-like virus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.X.3.

Article 2.2.X.10.

Importation of aquatic animal products from a country, zone or compartment declared free from abalone herpes-like virus

When importing *aquatic animal products* of species referred to in Article 2.2.X.2. from a country, *zone* or *compartment* declared free from abalone herpes-like virus, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.X.4. or 2.2.X.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from abalone herpes-like virus.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.X.3.

Article 2.2.X.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from abalone herpes-like virus

When importing *aquatic animal products* of species referred to in Article 2.2.X.2. from a country, *zone* or *compartment* not declared free from abalone herpes-like virus, 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 2.2.X.3.



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REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON AQUATIC ANIMAL HEALTH SURVEILLANCE

Paris (France), 19-21 January 2009

The OIE *ad hoc* Group on Aquatic Animal Health Surveillance (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters in Paris from 19 to 21 January 2009.

The members of the *ad hoc* Group and other participants are listed at [Annex I](#). The Agenda adopted is at [Annex II](#).

Dr Gillian Mylrea, Chargée de Mission, welcomed all members on behalf of the Director General who was travelling. She thanked them for their ongoing contribution to the work of the OIE and for their hard work in the development of an OIE *Handbook on Aquatic Animal Health Surveillance* which was now close to completion.

Dr Barry Hill then took over as Chair of the meeting and acknowledged the large amount of work already done by the *ad hoc* Group and emphasised that the draft manuscript needed to be completed by the end of this meeting.

1. *OIE Handbook on Aquatic Animal Health Surveillance*

The *ad hoc* Group revised the manuscript taking into consideration comments received from the three independent external reviewers and made some additions and final adjustments. In light of reviewers' comments the *ad hoc* Group decided to change the title of the publication to *Guide for Aquatic Animal Health Surveillance*.

The manuscript will be sent for copy editing in February with a view to publication in mid 2009. The draft manuscript will also be sent to the OIE Aquatic Animal Health Standards Commission (hereinafter referred to as the Aquatic Animals Commission) for endorsement at the Commission meeting in March 2009.

Annex XV (contd)**2. Draft Disease - specific surveillance chapter on viral haemorrhagic septicaemia**

The *ad hoc* Group had limited time to spend on this task due to time taken to finalise the manuscript for the Guide. The *ad hoc* Group reviewed the task of developing a disease - specific surveillance chapter on viral haemorrhagic septicaemia. In view of the large amount of work required to draft this chapter and the need to involve experts from Reference Laboratories, the *ad hoc* Group proposed that further meetings be convened to complete this work. The *ad hoc* Group proposed a different approach in which they would devote at least one day to the refinement of the template outlining what information is required for the disease specific surveillance chapters. The second and third days would involve working with three experts on the chosen diseases (one fish disease, one mollusc disease and one crustacean disease) from OIE Reference Laboratories explaining what information would be required to complete the draft chapters. Disease experts would use these discussions to draft their nominated chapter and then the two groups (*ad hoc* group and disease-specific experts) would meet again six months later. Subsequently, experts would present their draft texts and together the experts and the members of the *ad hoc* Group would finalise the chapters and the template to be used in the development of any future disease specific surveillance chapters.

The *ad hoc* Group requested that the Aquatic Animals Commission consider this approach to the development of disease specific surveillance chapters in future. The *ad hoc* Group suggested that it would be most efficient to work on three simultaneous chapters at the meeting, one fish disease, one mollusc disease and one crustacean disease, and requested guidance from the Aquatic Animals Commission as to the three diseases to be considered.

.../Annexes

MEETING OF THE OIE AD HOC GROUP ON AQUATIC ANIMAL SURVEILLANCE**Paris, 19–21 January 2009****List of participants****MEMBERS OF THE AD HOC GROUP****Dr Barry Hill** (*Chair*)

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MEETING OF THE OIE AD HOC GROUP ON AQUATIC ANIMAL SURVEILLANCE**Paris, 19-21 January 2009**

Adopted agenda**Welcome****1. OIE *Handbook on Aquatic Animal Health Surveillance***

Consider peer review comments on draft manuscript for the *Handbook on Aquatic Animal Health Surveillance*, and finalise the manuscript.

2. Draft disease specific surveillance chapter on viral haemorrhagic septicaemia

Draft a Model Chapter 'template' for viral haemorrhagic septicaemia, to provide guidance on surveillance to underpin the declaration of freedom.



Original: English
February 2009

**REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON
THE SAFETY OF PRODUCTS
DERIVED FROM AQUATIC ANIMALS**

Paris, 17-19 February 2009

Dr Bernard Vallat, Director General of the OIE, welcomed participants and thanked them for their ongoing support of the work of the OIE. The issue of safe commodities is particularly important to the OIE because it can provide a pathway for countries to participate in international trade without being obliged to eradicate, in the short term, significant diseases, a task that can be particularly difficult for developing countries. The importance of this work to Members is clear, based on the large number of comments submitted to the OIE Aquatic Animal Health Standards Commission (hereinafter referred to as the Aquatic Animals Commission). Dr Vallat pointed out the parallels in work being undertaken by the OIE Terrestrial Animal Health Standards Commission and commented that, as has been the case in previous years, the OIE would strive for consistency between the OIE *Terrestrial Animal Health Code* and the OIE *Aquatic Animal Health Code* (hereinafter referred to as the *Aquatic Code*), where this is feasible and appropriate. Dr Vallat noted that the mandate of the Aquatic Animals Commission will be discussed at the OIE General Session in May 2009, with a view to expanding the scope to cover food safety. Until that time, the standards in the *Aquatic Code* address aquatic animal health risks and not food safety issues.

Dr Franck Berthe chaired the meeting. He began by thanking all participants and the secretariat, Dr Gillian Mylrea, Chargée de mission in the International Trade Department, for their interest and involvement in this important area of standard setting work.

The adopted agenda is provided in [Annex I](#) and members of the OIE *ad hoc* Group are listed in [Annex II](#).

Annex XVI (contd)

Item 1. Draft texts on (i) Criteria to assess the safety of aquatic animal commodities irrespective of country disease status (Chapter X.X.X.); (ii) Criteria to assess the safety of aquatic animal products destined for human consumption (Chapter X.X.X.); and (iii) 1.3. Example Article X.X.X.3.; X.X.X.9.; X.X.X.12.

Comments were received from Canada, Chinese Taipei, European Union, Norway, an OIE Reference Laboratory, OIRSA (the Regional International Organization for Plant Protection and Animal Health. Member Countries: México, Belize, Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panamá, Dominican Republic), Thailand and the United States of America. The *ad hoc* Group reviewed these comments and amended the text accordingly (refer to Annex III (A) and IV). As quite a large number of amendments were made, the amended text in Annex III (A) is also provided as clean text in Annex III (B) to assist Members in reading and understanding these documents. In Annex IV, text amendments made during the meeting are shown with a coloured background to distinguish them from previously proposed amendments.

While it was not possible to provide a specific reply to every comment received, the *ad hoc* Group provided the following specific advice in regard to certain issues raised by Members.

A number of Members commented on issues that are currently outside the scope of the *Aquatic Code*, e.g. food safety and environmental contaminants. The *ad hoc* Group clarified that current standards in the *Aquatic Code* are currently restricted to international trade and aquatic animal health.

A number of Members requested disease-specific standards for commodities. The *ad hoc* Group wishes to remind Members that the 'Example Articles' (circulated with the October 2008 report of the Aquatic Animals Commission) were provided with the purpose of illustrating how a commodity could be assessed using these criteria. The recommendation of the *ad hoc* Group is that disease specific assessments of the safety of aquatic animal commodities should be developed for inclusion in the appropriate *Aquatic Code* chapters once the OIE adopts the approach recommended, including the criteria for assessment.

The *ad hoc* Group recommended that the two sets of criteria be included in a separate chapter in the *Aquatic Code*. The proposed chapter currently includes an introduction to each set of criteria, outlining the context and assumptions in the development and implementation of these criteria.

The amended texts are presented at Annex III.

During the review of disease specific chapters the *ad hoc* Group noted that provisions for the importation of live aquatic animals for direct human consumption (i.e. without further processing) were lacking in some disease chapters. Recognising the significant trade in this commodity, the *ad hoc* Group recommended that this topic be addressed in future.

Several Members requested clarification on the use of the term 'small amounts of waste tissues'. The *ad hoc* Group advised that the meaning of this terminology will depend on the commodity, and should be described as part of the assessment of each commodity. For example, a skinless fillet would be expected to generate a minimal amount of waste tissues when used by the consumer, whereas a whole shrimp would be expected to generate a larger amount of waste tissues (e.g. shell, legs, head and tail fan), as there is a larger quantity of inedible tissues.

A Member requested that the revised Article X.X.X.12. include provisions for the importation of a commodity that is transferred after importation to retailers without transformation or processing of the commodity (i.e. wholesale trade). The *ad hoc* Group recognized that Article X.X.X.12. as originally proposed specifically addressed the issue of commodities transferred directly to the consumer and noted that pathways involving distribution (i.e. wholesale) may possibly pose a different level of risk. The *ad hoc* Group recommended the deletion of the word 'direct' in the Criteria to assess the safety of aquatic animal products destined for human consumption and in point 1 of Article X.X.X.12. (see Annexes III and IV). In addition the introductory text to this set of criteria explains what is meant by retail trade.

In response to Members' comments on the meaning of 'prepared and packaged' in point 1 of Article X.X.X.12., the *ad hoc* Group noted that although the product may not be packaged for direct purchase by the consumer, this criterion should be considered as satisfied if the commodity has been prepared for display or for serving or otherwise provided direct to the consumer without needing further processing. Such a pathway may pose an equivalent level of risk, and should be assessed according to the criteria.

Item 2. Develop a new article for inclusion in Chapter 1.5.6. addressing the specific fixation treatments to inactivate all OIE-listed disease agents.

Following the request from the Aquatic Animals Commission, the *ad hoc* Group developed new text for Chapter 1.5.6. in the *Aquatic Code*. The *ad hoc* Group recommended the addition of the following new text as a second paragraph in the Introduction section of Article 1.5.6.1.:

Biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* will not cause *aquatic animal disease*. The *Competent Authorities* should not require zoosanitary conditions for these samples.

The *ad hoc* Group did not develop text that specified fixation treatments to inactivate all OIE-listed disease agents as it considered that such a list would be more appropriate for inclusion in the *Aquatic Manual*.

The *ad hoc* Group recommended that the Aquatic Animals Commission consider further harmonization between the *Aquatic* and *Terrestrial Codes and Manuals*, in particular Chapter 1.5.6. of the *Aquatic Code* with the equivalent content in the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* (hereinafter referred to as the *Terrestrial Manual*).

Item 3. Assess whether disinfected salmonid eggs can be considered a safe product

Following the request from the Aquatic Animals Commission as to whether disinfected salmonid eggs should be considered as a safe product, the *ad hoc* Group reviewed and amended a paper prepared by Dr Kim Klotins on the evidence for vertical transmission of OIE-listed viral diseases in salmonids. Provided at Annex V.

The *ad hoc* Group concluded that disinfected salmonid eggs cannot be considered as a safe commodity under Article X.X.X.3. for these four diseases.

After reviewing Dr Klotins' paper, the *ad hoc* Group concluded that published information indicates that vertical transmission of three OIE-listed diseases of salmonids (VHSV, ISAV, IHNV) does not occur.

In the case of EHNV there is lack of published information regarding vertical transmission and the *ad hoc* Group recommended that a formal request for further information be addressed to the OIE Reference Laboratories for EHNV. An evaluation of the likelihood of vertical transmission of EHNV would be provided by the *ad hoc* Group in light of any relevant information received.

The *ad hoc* Group concluded that transmission of these four OIE-listed diseases of salmonids could occur as a result of contamination of the egg surface. While egg disinfection as a mitigation measure is feasible, the *ad hoc* Group recognized that this may not always be effective under all conditions, noting evidence on the reduced effectiveness of disinfection under conditions where eggs have been exposed to high levels of virus or where water quality is variable (see Annex V).

For the four listed diseases of salmonids, disinfected salmonid eggs could potentially be considered a safe commodity for international trade based on a protocol that includes effective disinfection and other relevant mitigation measures.

Annex XVI (contd)

The *ad hoc* Group reviewed the draft text for the *Manual of Diagnostic Tests for Aquatic Animals (Aquatic Manual)* on Guidelines for disinfection of fish eggs and made the following comments:

- the level of infection in broodstock (ovarian fluid and milt) is an important factor in determining efficacy of the disinfection; this should be addressed in the text;
- water parameters such as temperature and pH are key factors in determining efficacy of the disinfection and need to be addressed in the text;
- reference to clean water in the text needs to be qualified, e.g. specific pathogen free;
- it is questioned if the number of rinsing steps listed are common practice. The text should highlight which steps are critical;
- disinfection of eggs cannot be effective in preventing vertical transmission, therefore references to this in the text should be deleted.

Once a suitable protocol has been developed in the *Aquatic Manual*, an appropriate reference should be made in each of the four disease chapters.

The *ad hoc* Group questioned if BKD and IPN should be included in the draft egg disinfection protocol for the *Aquatic Manual* as these diseases are no longer OIE-listed.

Salmonid egg disinfection protocols should also address the issue of egg surface associated transmission of *G. salaris* and EUS. It is evident that *G. salaris* is not vertically transmitted but the probability of vertical transmission of EUS needs to be assessed.

The *ad hoc* Group recommended the conduct of further research on the efficacy of disinfection protocols under different viral exposures for VHSV, ISAV, IHNV and EHN. Research on disinfection protocols for *G. salaris* and EUS would also be valuable.

The *ad hoc* Group recommended that the OIE develop disinfection protocols for eggs of non-salmonid species given there is significant trade in this commodity.

In closing the meeting, Dr Sarah Kahn, Head of the OIE International Trade Department, thanked the participants for their hard work. She noted the recommendations of the *ad hoc* Group regarding further work and undertook to raise with Dr Vallat the possibility of holding a further meeting later in 2009 to address the comments of Members on the draft text.

.../Annexes

**MEETING OF THE OIE *AD HOC* GROUP ON SAFETY OF PRODUCTS
DERIVED FROM AQUATIC ANIMALS**

Paris, 17–19 February 2009

Adopted agenda

Welcome by Director General

Adoption of the agenda

1. OIE *Aquatic Animal Health Code* – Members' comments

- 1.1. Criteria to assess the safety of aquatic animal commodities irrespective of country disease status (Chapter X.X.X.) - Consider Members' comments and revise text as appropriate.
- 1.2. Criteria to assess the safety of aquatic animal products destined for human consumption (Chapter X.X.X.) - Consider Members' comments and revise text as appropriate.
- 1.3. Example Article X.X.X.3.; X.X.X.9.; X.X.X.12. - Consider Members' comments and revise text as appropriate.

2. OIE *Aquatic Animal Health Code* – other items

Develop a new article for inclusion in Chapter 1.5.6. that specifies fixation treatments to inactivate all OIE-listed disease agents.

3. Assess whether disinfected salmonid eggs can be considered a safe product

4. Any other business

**MEETING OF THE OIE AD HOC GROUP ON SAFETY OF PRODUCTS
DERIVED FROM AQUATIC ANIMALS**

Paris, 17–19 February 2009

List of participants

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CHAPTER X.X.X.

Article X.X.X.1**Criteria to assess the safety of aquatic animal commodities irrespective of country disease status**

In all disease chapters, point 1 of Article X.X.X.3. lists *commodities* that can be traded irrespective of country disease status. The criteria for inclusion of *commodities* in point 1 of Article X.X.X.3. are based on the absence of the *disease agent* in the traded *commodity* or inactivation of the *disease agent* by treatment or *processing*.

The assessment of the safety of the *commodity* using the criteria relating to treatment or *processing* can only be undertaken where treatments or *processing* are well defined. It may not be necessary to provide details of the entire treatment or process undertaken. However, the steps considered critical in the inactivation of the *disease agent* of concern should be detailed.

It is assumed that treatment or *processing* (i) uses standardised protocols, which include the steps considered critical in the inactivation of the *disease agent* of concern; (ii) is conducted according to Good Manufacturing Practices; and (iii) that any other steps in the treatment, *processing* and subsequent handling of the *commodity* do not jeopardise the safety of the traded commodity.

For a commodity to be considered safe for *international trade* under the provisions of Article X.X.X.3. it should comply with the following criteria:

1. Absence of *disease agent* in the traded *commodity*:
 - 1a. There is strong evidence that the *disease agent* is not present ~~does not occur~~ in the tissues from which the *commodity* is derived;

AND

- 1b. The water (including ice) used to ~~rear or~~ process or transport the *commodity* is not contaminated with the *disease agent* and the processing prevents cross contamination of the commodity to be traded final product.

OR

2. Even if the *disease agent* is present in, ~~does occur~~ or contaminates ~~in~~ the tissues from which the *commodity* ~~was~~ derived, the treatment or processing to produce the final commodity to be traded involves ~~processes known to~~ inactivates the *disease agent*:

- 2a. Physical (e.g. temperature, drying, smoking);

AND/OR

- 2b. Chemical (e.g. iodine, pH, ~~salting,~~ smoking);

AND/OR

- 2c. Biological (e.g. fermentation).

Annex XVI (contd)

Annex III (A) (contd)

Article X.X.X.2.

Criteria to assess the safety OF aquatic animal products destined for human consumption irrespective of country disease status

In all disease chapters, point 1 of Article X.X.X.12. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters) lists *aquatic animal* products destined for human consumption. The criteria for inclusion of *aquatic animal* products in point 1 of Article X.X.X.12. include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely quantity of viable *disease agent* in the waste.

For the purpose of this criterion retail means the selling or provision of *aquatic animal products* directly to the consumer with the intended purpose of human consumption. The retail pathway may also include wholesale distribution of the products provided they are not further processed by the wholesaler nor the retailer, i.e. subjected to actions such as gutting, cleaning, filleting, freezing, thawing, cooking, unpacking, packing or repackaging.

It is assumed that the *aquatic animal* product is used for human consumption. It is assumed that treatment or *processing* prior to importation (i) uses standardised protocols, which include the steps considered critical in the inactivation of the *disease agent* of concern; and (ii) is conducted according to Good Manufacturing Practices; and (iii) that any other steps in the treatment, *processing* and subsequent handling of the *commodity* do not jeopardise the safety of the traded *commodity*.

For a *commodity* to be considered safe for *international trade* under the provisions of point 1 of Article X.X.X.12. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters) it should comply with the following criteria:

1. The *aquatic animal* product is prepared and packaged for ~~direct~~ retail trade for human consumption;
AND

AND EITHER

2. Includes only a small amount of waste tissues;

OR AND

- 3a. Viable ~~The~~ *disease agent* is unlikely to be present in the waste tissues, because

OR

- a) the *disease agent* is not normally found in the waste tissues; OR

- b) ~~The *disease agent* may be present does occur~~ in the waste tissues but the *processing* prior to importation (i.e. ~~post importation such as cooking~~) to produce the final consumable product involves processes known to inactivate and/or reduce the load of *disease agent*:

- i) Physical (e.g. temperature, drying, smoking);

AND/OR

- ii) Chemical (e.g. pH, ~~salting~~, ~~smoking~~);

AND/OR

- iii) Biological (e.g. fermentation).

— Text deleted

ANNEX III (B) – CLEAN TEXT

CHAPTER X.X.X.

Article X.X.X.1.

Criteria to assess the safety of aquatic animal commodities irrespective of country disease status

In all disease chapters, point 1 of Article X.X.X.3. lists *commodities* that can be traded irrespective of country disease status. The criteria for inclusion of *commodities* in point 1 of Article X.X.X.3. are based on the absence of the *disease agent* in the traded *commodity* or inactivation of the *disease agent* by treatment or *processing*.

The assessment of the safety of the *commodity* using the criteria relating to treatment or *processing* can only be undertaken where treatments or *processing* are well defined. It may not be necessary to provide details of the entire treatment or process undertaken. However, the steps considered critical in the inactivation of the *disease agent* of concern should be detailed.

It is assumed that treatment or *processing* (i) uses standardised protocols, which include the steps considered critical in the inactivation of the *disease agent* of concern; (ii) is conducted according to Good Manufacturing Practices; and (iii) that any other steps in the treatment, *processing* and subsequent handling of the *commodity* do not jeopardise the safety of the traded *commodity*.

For a *commodity* to be considered safe for *international trade* under the provisions of Article X.X.X.3. it should comply with the following criteria:

1. Absence of *disease agent* in the traded *commodity*.
 - 1a. There is strong evidence that the *disease agent* is not present in the tissues from which the *commodity* is derived;

AND

 - 1b. The water (including ice) used to process or transport the *commodity* is not contaminated with the *disease agent* and the *processing* prevents cross contamination of the *commodity* to be traded.

OR
2. Even if the *disease agent* is present in, or contaminates the tissues from which the *commodity* is derived, the treatment or *processing* to produce the *commodity* to be traded inactivates the *disease agent*:
 - 2a. Physical (e.g. temperature, drying, smoking);

AND/OR

 - 2b. Chemical (e.g. iodine, pH, salt, smoke);

AND/OR

 - 2c. Biological (e.g. fermentation).

Annex XVI (contd)Annex III (B) (contd)

Article X.X.X.2.

Criteria to assess the safety of aquatic animal products destined for human consumption irrespective of country disease status

In all disease chapters, point 1 of Article X.X.X.12. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters) lists *aquatic animal* products destined for human consumption. The criteria for inclusion of *aquatic animal* products in point 1 of Article X.X.X.12. include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely quantity of viable *disease agent* in the waste.

For the purpose of this criterion retail means the selling or provision of *aquatic animal products* directly to the consumer with the intended purpose of human consumption. The retail pathway may also include wholesale distribution of the products provided they are not further processed by the wholesaler nor the retailer, i.e. subjected to actions such as gutting, cleaning, filleting, freezing, thawing, cooking, unpacking, packing or repackaging.

It is assumed that the *aquatic animal* product is used for human consumption. It is assumed that treatment or *processing* prior to importation (i) uses standardised protocols, which include the steps considered critical in the inactivation of the *disease agent* of concern; and (ii) is conducted according to Good Manufacturing Practices; and (iii) that any other steps in the treatment, *processing* and subsequent handling of the *commodity* do not jeopardise the safety of the traded *commodity*.

For a *commodity* to be considered safe for *international trade* under the provisions of point 1 of Article X.X.X.12. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters) it should comply with the following criteria:

1. The *aquatic animal* product is prepared and packaged for retail trade for human consumption; AND
EITHER

2. Includes only a small amount of waste tissues;

OR

3. Viable *disease agent* is unlikely to be present in the waste tissues, because:

a) the *disease agent* is not normally found in the waste tissues; OR

b) the *disease agent* may be present in the waste tissues but the processing prior to importation involves processes known to inactivate and/or reduce the load of *disease agent*:

i) Physical (e.g. temperature, drying, smoking);

AND/OR

ii) Chemical (e.g. pH, salt, smoke);

AND/OR

iii) Biological (e.g. fermentation).

**REVISED ARTICLES 2.1.X.3. AND 2.1.X.9.
AND ARTICLE 2.1.X.12.**

**EXAMPLE CHAPTER 2.1.4.
(to be applied across all disease chapters)**

Article 2.1.4.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *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 referred to in Article 2.1.4.2. intended for any purpose:
 - i) *commodities* treated in a manner that inactivates the *disease agent* [e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish *meal* intended for use in *feed*];
 - ii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.
 - b) ~~The following *commodities* destined for human consumption from the species referred to in Article 2.1.4.2. which have been prepared and packaged for direct retail trade:~~
 - i) ~~*eviscerated fish* (chilled or frozen);~~
 - ii) ~~*fillets or cutlets* (chilled or frozen);~~
 - iii) ~~*dried eviscerated fish* (including air dried, flame dried and sun dried).~~

For the ~~*commodities* referred to in point 1b), Members may wish to consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.~~
2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.1.4.2., other than those referred to in point 1 of Article 2.1.4.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.1.4.7. to 2.1.4.12. relevant to the SVC status of the *exporting country, zone or compartment*.
3. When considering the importation ~~or transit~~ of a *commodity* from an *exporting country, zone or compartment* not declared free of SVC ~~of a live *commodity*~~ from a species not covered in Article 2.1.4.2. but which could reasonably be expected to be a ~~potential~~ mechanical vector/fomite for SVC, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[...]

Annex XVI (contd)

Annex IV (contd)

Article 2.1.4.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from spring viraemia of carp

When importing, for *processing* for human consumption, live *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, if justified, 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 2.1.4.3., or products described in point 1 2 of Article 2.1.4.12., or other products authorised by the *Competent Authority*; and
2. all effluent and waste material from the *processing* are treated in a manner that ensures inactivation of SVCV.

Members may wish to consider introducing internal measures to address the risk of prevent such *commodities* being used for any purpose other than for human consumption.

~~This Article does not apply to *commodities* referred to in point 1 of Article 2.1.4.3. or products described in point 1 2 of Article 2.1.4.12.~~

[...]

Article 2.1.4.12.

Importation of aquatic animal products from a country, zone or compartment not declared free from spring viraemia of carp

1. The risk posed by the following products destined for human consumption from the species referred to in Article 2.1.4.2. which have been prepared and packaged for direct retail trade is considered negligible:

- i) *eviscerated fish* (chilled or frozen):
- ii) *fillets or cutlets* (chilled or frozen):
- iii) *dried eviscerated fish* (including air dried, flame dried and sun dried):

For these *commodities* Members may wish to consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When importing *aquatic animal products*, other than those referred to in point 1 above, 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.

Annex XVI (contd)Annex IV (contd)

3. ~~In the case of dead fish, whether eviscerated or uneviscerated, such~~ Risk mitigation measures may include:

~~1.~~ a) the direct delivery into and holding of the consignment in biosecure/*quarantine* facilities for *processing* to one of the products referred to in point 1 of Article 2.1.4.3., or products described in point 1 2 of this Article, or other products authorised by the *Competent Authority*;

~~2.~~ b) the treatment of all effluent and waste material in a manner that ensures inactivation of SVCV.

~~This Article does not apply to commodities referred to in point 1 of Article 2.1.4.3. or products described in point 1 2 of Article 2.1.4.12.~~

 — Text deleted

EVIDENCE FOR VERTICAL TRANSMISSION OF OIE-LISTED SALMONID VIRAL DISEASES

Assumptions

Strong evidence for vertical transmission includes finding the virus within released unfertilized and/or fertilized eggs AND an epidemiological link between infection or disease status in broodstock and infection or disease status in progeny. All mating combinations between positive fish should also be investigated, as well as different levels of infection at the brood stock-level, egg-level, and milt-level. It is well known that eggs have antimicrobial properties, so infection of eggs does not necessarily mean that the pathogen can be successfully transmitted, i.e. is viable. Studies must provide evidence that external contamination of eggs and contamination of rearing waters are not confounding factors.

For the purposes of this paper, the following working definitions apply:

Vertical transmission means the transfer of infection from parents to progeny through infection of the fertilized egg by the pathogen. Eggs are infected during development in the ovaries or when penetrated by contaminated or infected sperm.

Egg surface-associated transmission means the transfer of infection from parents to progeny through contamination of the egg surface with the pathogen. This is a form of horizontal transmission.

Contamination means the presence of a pathogen usually on the external surfaces of the vector (not a susceptible species) or fomite. There is no replication of the pathogen outside of the host. External surfaces of a vector or fomite (such as a carcass) includes the oral cavity, swim bladder, and the gastrointestinal tract because they are normally exposed to the external environment.

Infection of any life stage of the host means the presence of a replicating or latent pathogen in a host that was acquired through a natural route of transmission for the pathogen. The pathogenesis following IM or IP injection of the disease agent may not reflect pathogenesis of the disease under natural field conditions.

Executive Summary

There is no strong evidence for vertical transmission for the four OIE-listed viruses of salmonids (VHSV, ISAV, IHNV, EHNV). In the case of EHNV there is no accessible evidence for vertical transmission and therefore a request for further information needs to be initiated. This assessment is based on a limited number of applicable scientific studies and so there is uncertainty in the evaluation. However, based on experiential evidence, it is more likely that any reports of viral outbreaks in progeny are the result of inadequate disinfection of eggs that came from broodstock that were infected (but not tested) or known to be moderately or severely infected.

There is evidence that disinfection protocols of salmonid eggs are not always effective. Disinfection with 100 ppm iodophor for 60 minutes at 10°C did not result in complete inactivation of IHNV on experimentally infected green and eyed Rainbow trout eggs (Goldes and Mead, 1995). Eggs had been exposed to IHNV (initial titres of $1.8 \cdot 10^6$ pfu/mL to $8.5 \cdot 10^6$ pfu/mL) for 60 minutes (mimicking an exposure scenario of high viral titres in ovarian fluid and shortest duration of exposure prior to spawning). Viable virus titres did decrease by more than 99.98%; however, final titres were still in the order of 10 to 10^4 pfu/mL. It appears that a standardized disinfection protocol needs to consider the health status of broodstock. Water inputs also need to be addressed as well as other potential sources of virus introduction such as equipment and people. More than one standardized protocol may need to be developed to address common practices of salmonid egg producers.

Annex XVI (contd)Annex V (contd)Reference

GOLDES SA. & MEAD S.L. (1995). Efficacy of iodophor disinfection against egg surface-associated Infectious Hematopoietic Necrosis Virus. *The Progressive Fish-Culturist*, **57**, 26-29.

MULCAHY D., PASCHO R.J. & JENES C.K. (1983). Titre distribution patterns of infectious haematopoietic necrosis virus in ovarian fluids of hatchery and feral salmon populations. *Journal of Fish Diseases*, **6**, 183-188.

Viral Hemorrhagic Septicemia Virus (VHSV)Summary

Vertical transmission of VHSV has not been demonstrated to date but VHSV can contaminate the surface of eggs. The published evidence on vertical transmission is sparse, but experiential information does not support vertical transmission.

Evidence for infection of eggs and contamination/infection of sperm

There are no published studies that examined released green eggs or fertilized eggs for VHSV. Studies report the isolation of VHSV from ovarian fluid and milt. Eaton et al. (1991) found one positive pooled milt sample (out of 12 pools of 5 fish each) but it is not clear how the milt samples were collected. If milt was stripped from male fish, then samples could have been environmentally contaminated because of the stripping procedure. Testing of milt from muskellunge and Chinook salmon in a recent survey for VHSV in broodfish in the Great Lakes yielded negative results (G. Whelan, Michigan Department of Natural Resources, personal communication, 2007). However, there is anecdotal evidence that milt can be contaminated with VHSV in highly susceptible species. Positive milt samples have been detected in Pacific herring and sardines (Dr Kyle Garver, 2009, National Reference Laboratory for VHSV and IHNV, Pacific Biological Station, Fisheries and Oceans Canada, personal communication).

Mulcahy and Pascho (1984) found that VHSV (European strain isolated from Rainbow trout) did not adsorb to Chinook salmon sperm. There was no decrease in viral titres in the supernatant, after centrifugation to remove sperm (determined by plaque assay) when compared to control tubes where sperm had not been added. In addition, virus attachment to sperm was not seen with transmission electron microscopy. However, given the different susceptibilities of fish to VHSV (and Chinook salmon are not very susceptible), the use of sperm from Rainbow trout or other highly susceptible species would have provided stronger evidence that VHSV does not adsorb to fish sperm. Adsorption of virus to sperm provides a possible mechanism of VHSV infection of eggs (sperm acts as a mechanical vector) but adsorption would not be enough evidence that vertical transmission actually occurs.

Epidemiological evidence of vertical transmission

Two (2) studies looked at progeny from VHSV-infected parents or contaminated eggs (neither study was designed to examine associations between infected broodstock and the resultant eggs or progeny). Vestergård Jørgensen (1970) performed virus isolation on fry derived from infected Rainbow trout broodstock and from Rainbow trout eggs that were exposed to VHSV by a bath immersion method. No resulting fry, sampled twice a week for 2 weeks and once 4 months later, were found positive in either group. Nishizawa et al. (2006) examined clinically healthy Turbot spawners captured in the Black Sea (selection process not described) and VHSV was detected in 3 of 11 males and 1 of 4 females by virus isolation using a cell culture technique on homogenates of brain, heart, kidney and gonad (unclear if tissues homogenized together or tested separately). Fertilized eggs from these spawners were disinfected with 100 ppm of iodophor for 10 minutes. There was no significant difference in 25-day cumulative mortalities between larvae from VHSV-positive (average: 87.5% ± %) and VHSV-negative spawners (average: 91.0% ± %; statistical analyses were not performed by authors). In addition, VHSV was not detected from any dead larvae by virus isolation or RT-PCR tests. The number of matings was small (n=12) and there were no matings where both fish were positive. There was also no indication whether spawners were heavily infected or not, and gonadal fluids were not tested.

Annex XVI (contd)Annex V (contd)

Experiential information suggests that vertical transmission does not occur because the use of appropriate egg disinfection protocols (with or without broodstock testing) minimizes spread of the virus. This finding has been noted in farmed rainbow trout in Europe (Jørgensen, 1992) and in public salmon hatcheries in Washington (USA) (Amos et al., 1998).

References

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- VESTERGÅRD JØRGENSEN P.E. (1970). The survival of viral hemorrhagic septicaemia (VHS) virus associated with trout eggs. *Rivista Italiana di Piscicoltura e Ittiopatologia*, **5**, 13-14.

Infectious Haematopoietic Necrosis Virus (IHNV)

Summary

IHNV can contaminate the surface of eggs (egg surface-associated transmission). IHNV can be isolated from both ovarian fluid (Mulcahy et al., 1983) and milt samples (Mulcahy et al., 1987) although sample collection methods were not described. IHNV has not been found inside unfertilized and fertilized eggs. Vertical transmission of IHNV has not been demonstrated to date. Research on this topic is sparse.

Evidence for infection of eggs and contamination/infection of sperm

Mulcahy and Pascho (1984) demonstrated that IHNV may adhere to sperm under the following experimental conditions: sperm cells with or without seminal fluid ($2 \cdot 10^9$ spermatozoa/mL; no IHNV was detected in milt prior to the experiment), addition of IHNV suspension (10^5 pfu/mL) for one hour at 15°C, and continual agitation. Viral titres were measured before and after incubation; > 99% of IHNV had adsorbed to the sperm. Adsorption to the surface of the sperm head was visualized using electron microscopy (rarely the tail and not within sperm cells). The adsorption process occurred within one minute after addition of the sperm. Subsequently, they found that adsorption occurs over a temperature range of 1.5°C to 18°C.

Mulcahy and Pascho (1985) sampled eggs and resultant alevins and fry, from two known IHNV-positive wild Sockeye salmon populations. The use of egg disinfection protocols was not described. Sample preparation prior to inoculation of cell cultures was not described. IHNV was isolated from live and dead eggs, and from alevins and fry from some but not all of the known positive broodfish (progeny sample sizes were small). Virus could be cultured from eggs 3 hours after fertilization but not by 24 hours post-fertilization (5 out of 6 IHNV positive female fish). The usefulness of the results are limited because if whole egg or fish homogenates were used then egg surface-associated transmission cannot be discounted. In addition, if eggs were not disinfected, it is possible that virus eluted from the surface of eggs post-hatching.

Annex XVI (contd)Annex V (contd)

Yoshimizu et al. (1989) injected Masou and Chum salmon eggs shortly after fertilization. Eggs had been disinfected with an iodophor (50 mg/L for 20 minutes) prior to injection. Each egg received a dose of $10^{3.75}$ TCID₅₀ and all eggs were incubated in dechlorinated city water ranging in temperature from 10°C to 15°C. Eggs were sampled every two days using a viral assay technique. Ten (10) eggs were pooled from each group for testing but it is unknown whether the homogenates were from whole eggs or egg contents. IHNV could not be detected in Masou salmon eggs by one week after injection, and in Chum salmon eggs by 5 weeks after infection. Mortality was high in egg groups injected with IHNV compared to controls but cause was not determined.

Epidemiological evidence of vertical transmission

Amend (1975) followed progeny from 4 IHNV-positive female rainbow trout and 4 IHNV-negative rainbow trout (ovarian fluid was tested by virus isolation method on FHM cell culture) reared on IHNV-free water (details not provided) at either 10°C or 14°C. Progeny were periodically tested and no IHNV was isolated over the 100-day study period. However, sample sizes were not described. Amend also prepared primary cell cultures from 40 eyed eggs (internal contents) from IHNV-positive females. No virus was detected during 35 subcultures, but the cell subcultures were susceptible to IHNV when virus was added.

One (1) study has been reported on the occurrence of IHNV in progeny from disinfected eggs obtained from IHNV-positive broodfish (females) and reared in virus-free water (deep well water). Roberts (1993) reported 7 years of results rearing natural runs of steelhead at Lyons Ferry Hatchery on the Snake River, a river known to have IHNV-positive fish populations. Hatchery water source came from deep wells. IHNV outbreaks occurred in first feeding fry in 2 out of the 7 years in populations of summer steelhead progeny only. Eggs were disinfected with an iodophor at water hardening (100 ppm for one hour) and at the eyed egg stage (100 ppm for 10 minutes). However, it was unclear whether eggs from summer run steelhead were reared in other years. In addition, other infectious disease control measures practiced in the hatchery were not described. Finally, it was suggested that viral titres may have been so high in ovarian fluid that disinfection protocols were insufficient.

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Infectious Salmon Anemia Virus (ISAV)Summary

ISAV can contaminate the surface of eggs (egg surface-associated transmission). ISAV has been isolated from ovarian fluid (Melville and Griffiths, 1999) although there is uncertainty whether the sampling method was aseptic or not. There are no reports of examination of milt for ISAV. ISAV has not been found inside unfertilized and fertilized eggs.

Annex XVI (contd)Annex V (contd)

Vertical transmission of ISAV has not been demonstrated to date. Anecdotally, outbreaks of ISAV in freshwater systems were rarely seen in Norway over a 14-year period (1985 to 1999). Research on this topic is sparse and results are of limited value. Evidence to date points towards a lack of vertical transmission in the epidemiology of this disease, or if it does occur, it is not an important route of transmission.

Evidence for infection of eggs and contamination/infection of sperm

Nylund et al. (1995) studied the location of ISAV in experimentally-challenged Atlantic salmon. They found the virus, using TEM, in the gonadal tissue (and other tissues) of IP-challenged smolts but not in control fish. Virus isolation on cell culture and other tests to diagnose ISAV had not yet been developed. Virus was seen free in the lumen of gonadal blood vessels and budding from the surface of endothelial cells. Free virus was also seen in intercellular spaces outside blood vessels and in leukocytes. There were no other findings reported for the gonads. Atlantic salmon smolts (still in freshwater) were challenged by IP injection of ascitic fluid or blood obtained from fish experiencing an outbreak of ISA. The value of these findings is limited given that the route of infection is unlikely a natural one, fish were only sampled once, 18 days post-exposure, and there was no finding of virus within eggs or associated with spermatogenic areas of the testes.

Epidemiological evidence of vertical transmission

Nylund et al. (1999) identified ISAV, virus culture (monoclonal antibody for virus identification and TEM examination) and RT-PCR, associated with mortality in populations of first-feeding fry (hatched from disinfected eyed eggs – this was the traded commodity). The tissues used for virus isolation or RT-PCR were not described (external contamination cannot be ruled out). No testing had been conducted on broodfish and all other sources of VHSV were not well described. In addition, the actual egg disinfection protocol used and performed treatments were not confirmed. However, 7% seawater was used to treat the fry (no other information about the seawater source is known). It is unclear whether the fry subjected to this treatment were tested or not. This finding could not be repeated upon subsequent sampling of these fry populations by the veterinary authority in Norway (Work Package 1 Report, QLK2-CT-2002-01546: Fish egg trade, VESA, Oslo, Norway, pg. 15). The value of this finding is limited as definitive cause of mortality was not established, virus may not have come from within fish, and no epidemiological links were made between broodfish and resultant progeny.

Melville and Griffiths (1999) selected ISAV positive and negative grilse (origin: net-pen sites that were previously identified as positive for ISAV) for the mating experiment. ISAV status of broodfish was determined by virus isolation (organ tissue [gill, spleen, pyloric caecae and kidney] and ovarian fluid) and identification of the virus by RT-PCR. Eggs from a single female were fertilized with milt from a single male and disinfected with Ovadine (100ppm for 10 minutes). There were a total of 13 matings; however, 8 matings were unsuccessful. There were 3 matings between positive female fish (ovarian fluid positive) and negative male fish, and 2 matings between negative female fish (negative results for both ovarian fluid and organ tissues) and negative male fish. Five (5) virus isolation replicates were performed for each mating (sampling and tissue preparation methods were not described). All test results were negative. Alevins (one week post-hatching) were pooled from 3 matings using positive fish (n=30) and whole fish homogenates were tested for ISAV by virus isolation and RT-PCR. All test results were negative. Fry (3 weeks post-first feeding) were tested from each of the 3 matings using positive fish using whole fish homogenates (n=10 were pooled for each mating). All test results were negative. Mortalities also tested negative for ISAV. Parr were also tested 16 months and 23 months after fertilization using gill (including mucus) and kidney tissues (a different set of primers and protocol was used for the RT-PCR). All test results were negative. No mortalities occurred during the experiment that could be contributed to ISAV. The study was conducted under 'quarantine conditions' but they were not described. No positive link was demonstrated between broodfish and progeny. However, sample sizes were too small for interpretation of disease freedom both at the mating level and at the progeny level (there was no indication of how sample sizes were calculated, but the sample sizes do not meet the international standards of the OIE for disease freedom). In addition, pooling of samples had not been validated for these viral detection methods, further decreasing the degree of certainty in interpretation of disease freedom. Finally, the strain of ISAV was unknown; it may have been a strain with low pathogenicity.

Annex XVI (contd)Annex V (contd)

Vike, et al. (2009) looked at the genetic similarity between ISAV isolates from Chile, Canada, Scotland, Faroe Islands and Norway using sequences from genome segments 2, 5 or 6. No analysis was done comparing all 3 regions at the same time, likely because sample size was small for phylogenetic analysis. There has been a recent outbreak of ISA in farmed Atlantic salmon; the origin of these salmon were imported eggs from Norway. The recent Chilean isolates were most similar to up to 4 of the isolates from Norway (segments 5 and 6 only). However, import permit conditions were not described (e.g. egg disinfection protocols not described or verified), nor the biosecurity practices in the Chilean hatcheries and rearing sites. Eggs have been imported from Norway for many years and cross-contamination was not ruled out in this study.

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Epizootic Haematopoietic Necrosis Virus (EHNV)Summary

There is no reported research on this topic, but given the negligible to very low likelihood of vertical transmission of the other salmonid viruses, and that Rainbow trout (the only identified susceptible salmonid to EHNV) are not highly susceptible to EHNV, it is very unlikely that significant vertical transmission of EHNV occurs.

RESTRUCTURED 2009 OIE AQUATIC ANIMAL HEALTH CODE

Old numbering	New numbering	Item
	Foreword	Foreword
	Guide to the use of the Aquatic Animal Health Code	Guide to the use of the Aquatic Animal Health Code
Chapter 1.1.1.	Glossary	Glossary
	SECTION 1.	AQUATIC ANIMAL DISEASE DIAGNOSIS, SURVEILLANCE AND NOTIFICATION
Chapter 1.2.1.	Chapter 1.1.	Notification of diseases and epidemiological information
Chapter 1.2.2.	Chapter 1.2.	Criteria for listing aquatic animal diseases
Chapter 1.2.3.	Chapter 1.3.	Diseases listed by the OIE
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	SECTION 2.	RISK ANALYSIS
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	SECTION 3.	QUALITY OF COMPETENT AUTHORITIES
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	SECTION 4.	GENERAL RECOMMENDATIONS: DISEASE PREVENTION AND CONTROL
Chapter 1.4.4.	Chapter 4.1.	Zoning and compartmentalisation
Appendix 3.2.1.	Chapter 4.2.	General recommendations on disinfection
Appendix 3.2.2.		Disinfection of aquaculture establishments
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Chapter 1.6.1.	Chapter 4.3.	Contingency planning
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Chapter 1.5.2.	Chapter 5.5.	Aquatic animal health measures applicable before and at departure
Chapter 1.5.3.	Chapter 5.5.	Aquatic animal health measures applicable during transit from the place of departure in the exporting country to the place of arrival in the importing country
Chapter 1.5.4.	Chapter 5.6.	Frontier posts in the importing country

Annex XVII (contd)

Old numbering	New numbering	Item
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Chapter 1.5.6.	Chapter 5.8.	Measures concerning international transport of aquatic animal disease agents and pathological material
Appendix 4.1.1.		International health certificates for live fish and gametes
Appendix 4.1.2.		International health certificates for live molluscs and gametes
Appendix 4.1.3.		International health certificates for live crustaceans
Appendix 4.2.1.		International health certificates for dead fish
Appendix 4.2.2.		International health certificates for dead crustaceans
	Chapter 5.9.	<u>Model health certificates for international trade in live aquatic animals and products of aquatic animal origin</u>
	SECTION 6.	<u>VETERINARY PUBLIC HEALTH</u>
	SECTION 7.	WELFARE OF FARMED FISH
Appendix 3.4.1.	Chapter 7.1.	Introduction to recommendations for the welfare of farmed fish
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SECTION 2.3. DISEASES OF CRUSTACEANS	SECTION 9.	DISEASES OF CRUSTACEANS
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Chapter 2.3.6.	Chapter 9.2.	Infectious hypodermal and haematopoietic necrosis
Chapter 2.3.9.	Chapter 9.3.	Infectious myonecrosis
Chapter 2.3.5.		Spherical baculovirus (<i>Ponaeus monodon</i> type baculovirus)
Chapter 2.3.8.		Spawner isolated mortality virus disease
Chapter 2.3.1.	Chapter 9.4.	Taura syndrome
Chapter 2.3.4.		Tetrahedral baculovirus (<i>baculovirus ponaei</i>)
Chapter 2.3.2.	Chapter 9.5.	White spot disease
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Chapter 2.1.6.		Channel catfish virus disease (Herpesvirus of <i>Ictaluridae</i> type 1)
Chapter 2.1.12.		Enteric septicemia of catfish (<i>Edwardsiella ictaluri</i>)
Chapter 2.1.1.	Chapter 10.1.	Epizootic haematopoietic necrosis
Chapter 2.1.10.	Chapter 10.2.	Epizootic ulcerative syndrome

Annex XVII (contd)

Chapter 2.1.14.	Chapter 10.3.	Gyrodactylosis (<i>Gyrodactylus salaris</i>)
Chapter 2.1.2.	Chapter 10.4.	Infectious haematopoietic necrosis
Chapter 2.1.8.		Infectious pancreatic necrosis
Chapter 2.1.9.	Chapter 10.5.	Infectious salmon anaemia
Chapter 2.1.17.	Chapter 10.6.	Koi herpesvirus disease
Chapter 2.1.3.		Oncorhynchus masou virus disease (Salmonid herpesvirus type 2 disease)
Chapter 2.1.13.		Piscirickettsiosis (<i>Piscirickettsia salmonis</i>)
Chapter 2.1.15.	Chapter 10.7.	Red sea bream iridoviral disease
Chapter 2.1.4.	Chapter 10.8.	Spring viraemia of carp
Chapter 2.1.7.		Viral encephalopathy and retinopathy
Chapter 2.1.5.	Chapter 10.9.	Viral haemorrhagic septicaemia
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SECTION 2.2. DISEASES OF MOLLUSCS	SECTION 11.	DISEASES OF MOLLUSCS
	Chapter 11.1.	<u>Infection with abalone herpes-like virus</u>
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Chapter 2.2.2.	Chapter 11.3.	Infection with <i>Bonamia exitiosa</i>
Chapter 2.2.3.		Infection with <i>Haplosporidium nelsoni</i>
Chapter 2.2.4.	Chapter 11.4.	Infection with <i>Marteilia refringens</i>
Chapter 2.2.5.		Infection with <i>Mikrocytos mackini</i>
Chapter 2.2.6.	Chapter 11.5.	Infection with <i>Perkinsus marinus</i>
Chapter 2.2.7.	Chapter 11.6.	Infection with <i>Perkinsus olseni</i>
Chapter 2.2.8.	Chapter 11.7.	Infection with <i>Xenohalotis californiensis</i>

NOTE: Highlighted text indicates proposals for adoption at the General Session in May 2009.

AQUATIC ANIMALS COMMISSION WORK PLAN FOR 2009/2010

<i>Aquatic Animal Health Code</i>
<ul style="list-style-type: none"> • Ongoing review of the list of diseases • Review emerging diseases
<ul style="list-style-type: none"> • Prepare text for disease chapters for gaining and regaining freedom for compartments
<ul style="list-style-type: none"> • Harmonise horizontal chapters with those in the <i>Terrestrial Code</i>
<ul style="list-style-type: none"> • Develop disease specific surveillance model chapters (1 fish, 1 mollusc, 1 crustacean)
<ul style="list-style-type: none"> • Finalise new chapter on Handling and disposal of carcasses and wastes of aquatic animals
<ul style="list-style-type: none"> • Prepare and finalise chapters on welfare for farmed fish (human killing and disease control)
<ul style="list-style-type: none"> • Antimicrobial resistance in the field of aquatic animals – contribute to OIE work
<ul style="list-style-type: none"> • Identify commodities that can be considered safe for trade and be included in the <i>Aquatic Code</i>
<ul style="list-style-type: none"> • Develop criteria for deciding when to list susceptible hosts as individual species or higher taxonomic level
<i>Manual of Diagnostic Tests for Aquatic Animals</i>
<ul style="list-style-type: none"> • Prepare disease chapters for amphibian diseases
<ul style="list-style-type: none"> • Prepare disease chapter for Infection with abalone herpes-like virus disease
Meetings
<ul style="list-style-type: none"> • Make presentations on the activities of the Aquatic Animals Commission at the conferences of the OIE Regional Commissions
<ul style="list-style-type: none"> • Be proactive in presenting the activities of the Aquatic Animals Commission at scientific conferences
<i>Other issues</i>
<ul style="list-style-type: none"> • Keep the Commission's web pages up to date
<ul style="list-style-type: none"> • Consider new candidates for OIE Reference Laboratories for listed diseases
<ul style="list-style-type: none"> • Provide input into the PVS to ensure its applicability to the evaluation of aquatic animal health systems
<ul style="list-style-type: none"> • Contribute to FAO/OIE Regional Aquatic Biosecurity Framework Project for Africa
<ul style="list-style-type: none"> • Provide input into the review of the OIE Handbook on Import Risk Analysis

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