ANNEX 2

EU POSITIONS AND COMMENTS

ON THE OIE AAHSC REPORT MAY 2010

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REPORT OF THE MEETING OF THE

OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 22–26 February 2010

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The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 22 to 26 February 2010.

Details of participants are listed at Annex I and the agenda adopted at Annex II.

On behalf of Dr Bernard Vallat, Director General, Dr Sarah Kahn, Head International Trade Department, welcomed members and thanked them for their ongoing work in support of the OIE.

The Aquatic Animals Commission thanked the following Members for providing written comments: Australia, Canada, Chile, Chinese Taipei, European Union (EU), Japan, New Zealand, Norway, Switzerland, Thailand, and the United States of America. The OIE Animal Production Food Safety Working Group (APFSWG) and the Terrestrial Animal Health Code Commission also submitted comments.

The Aquatic Animals Commission strongly encouraged Members to participate in the development of the OIE's international standards by sending comments on this report. The Aquatic Animals Commission reiterated that it would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Members are requested not to use the automatic 'track-change' function provided by word processing software in preparation of their comments. The Commission also reminded Members that they should follow the established convention in recommending modification of text in the *Aquatic Animal Health Code* (hereinafter referred to as the *Aquatic Code*), i.e. propose new text (shown as double underline) and propose text deletions (shown as ~~strike through~~) and provide a scientific justification for all changes proposed.

The Aquatic Animals Commission reviewed various *Aquatic Code* draft texts from its September 2009 report in the light of Member comments. The outcome of the Commission's work is presented at Annexes III to XXXVI in this report. Amendments made to the *Aquatic Code* chapters during the September 2009 meeting are shown as double underlined text, with deleted text in ~~strikeout~~, while amendments made at this meeting (February 2010) are shown in a similar manner but with coloured background to distinguish the two groups of amendments.

The table below summarises the texts as presented in the Annexes. Part I: Annexes III to XXVIII are proposed text for adoption at the 78th General Session in May 2010; Part II: Annex XXIX is presented for Member comment; Part III: Annexes XXX to XXXVI for Members information.

Members are invited to submit their comments to the OIE on Annex XXIX of this report. Comments must reach OIE Headquarters prior to **10 September 2010** in order to be considered at the next meeting of the Aquatic Animals Commission 11-15 October 2010. Comments should be sent to the International Trade Department at: trade.dept@oie.int.

Part I: Texts proposed for adoption	**Annex number**
Glossary	Annex III
Diseases listed by the OIE (Ch. 1.3.)	Annex IV
Example Article X.X.3.; X.X.9.; X.X.12.	Annex V
Criteria to assess the safety of aquatic animal commodities (Ch 5.3.)	Annex VI
Amended text for epizootic haematopoietic necrosis (Articles 10.1.3., 10.1.9., 10.1.12.), Taura syndrome (Articles 9.4.3., 9.4.9., 9.4.11.) and for infection with *Bonamia ostreae* (Articles 11.2.3., 11.2.9., 11.2.11.)	Annex VII (A and B)
Measures concerning international transport of aquatic animal disease agents and pathological material (Ch 5.9.)	Annex VIII
Import Risk Analysis (Ch 2.2.)	Annex IX
Quality of Aquatic Animal Health Services (Ch 3.1.)	Annex X
Zoning and compartmentalisation (Ch 4.1.)	Annex XI
Application of compartmentalisation (Ch 4.X.)	Annex XII
Control of hazards in aquatic animal feeds (Ch 4.5.)	Annex XIII
General obligations related to certification (Ch. 5.1.)	Annex XIV
Certification procedures (Ch. 5.2.)	Annex XV
Model international aquatic animal health certificates (Ch 5.10.)	Annex XVI
Welfare of farmed fish during transport (Ch 7.2.)	Annex XVII
Article X.X.8 for all disease specific chapters	Annex XVIII
Infection with abalone herpes-like virus (Ch 11.X.)	Annex XIX
Necrotising hepatopancreatitis (Ch 9.X.)	Annex XX
Disinfection of salmonid eggs – (Article 10.4.X., Article 10.5.X., Article 10.9.X.)	Annex XXI
Welfare aspects of stunning and killing of farmed fish for human consumption (Ch 7.3.)	Annex XXII
Introduction to the recommendations for controlling antimicrobial resistance (Ch 6.1.)	Annex XXIII
Control of aquatic animal health risks associated with transport of aquatic animals (Ch 5.4.)	Annex XXIV
Handling, disposal and treatment of aquatic animal waste (Ch X.X.)	Annex XXV
Aquatic Manual - references to non-susceptible species in mollusc chapters	Annex XXVI
New *Aquatic Manual* Chapter Infection with abalone herpes-like virus	Annex XXVII
Contact details for new Collaborating Centre and Reference Laboratory	Annex XXVIII
Part II: Annexes for Members' comment	**Annex number**
Responsible and prudent use of antimicrobial agents in veterinary medicine (Ch 6.2.)	Annex XXIX
Part III: Annexes for Members' information	**Annex number**
Report of the *ad hoc* Group on Aquatic Animal Health Surveillance	Annex XXX
Report of the *ad hoc* Group on Disposal of Aquatic Animals	Annex XXXI
Report of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals	Annex XXXII
Report of the *ad hoc* Group on Crustacean Diseases	Annex XXXIII
Report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals	Annex XXXIV
FAO report	Annex XXXV
Aquatic Animals Commission Work Plan 2010/2011	Annex XXXVI

Meeting with Dr Vallat

Dr Vallat, Director General of the OIE, joined the Aquatic Animals Commission for a discussion of the strategic priorities of the OIE and provided an update on the state of play with the 5th Strategic Plan, which would soon be sent to Members for comment, prior to proposed adoption at the General Session in May 2010.

Dr Vallat indicated that the Aquatic Animals Commission is engaged in many important areas of work and that he was committed to providing resources to support the meetings of the *ad hoc* Groups currently developing texts for the *Aquatic Code*. In this regard, Dr Vallat noted the following important topics.

Dr Vallat commended the valuable work of the *ad hoc* Group, chaired by Dr Hill, that produced the Guide for Aquatic Animal Health Surveillance.

On the important topic of preventing antimicrobial resistance, Dr Vallat expressed his appreciation for the work undertaken to date and asked the Aquatic Animals Commission to prioritise its consideration of this work. While harmonisation of the approaches taken by the Aquatic Animal and Terrestrial Code Commissions is an important goal, Dr Vallat acknowledged that there would inevitably be some differences in the recommendations on prudent use of antimicrobials in aquatic and terrestrial animals, for example in the extent of involvement of veterinarians and aquatic animal health professionals in prescribing the use of antimicrobials.

Dr Vallat also thanked the Aquatic Animals Commission for continuing to progress texts for the *Aquatic Code* on the defining of safe products derived from aquatic animals. He agreed with the approach proposed by Dr Berthe, chair of the *ad hoc* Group on Aquatic Animal Commodities, i.e. to fully document the scientific rationale for the assessments of safe commodities and to provide this advice to OIE Members via a supporting document on the OIE website and a separate publication in the next pluri-thematic edition of the OIE Scientific and Technical Review.

Dr Vallat informed the Aquatic Animals Commission that the OIE would ask the Philippines to consider hosting the Global Conference on the Contribution of Aquatic Animal Health to Food Security, which is planned to take place in June 2011. Dr Vallat also hoped to involve the Southeast Asian Fisheries Development Center (SEAFDEC) in the conference organisation as they have an official agreement with the OIE.

Dr Vallat noted that the Aquatic Animals Commission would propose a new draft chapter on the slaughter of aquatic animals for human consumption for adoption in May 2010, and that the development of the chapter on killing of fish for disease control purposes was the next priority.

The pilot OIE PVS evaluation of an OIE Member's aquatic animal health services was briefly discussed. Dr Vallat supported the proposal to develop a parallel PVS Tool for use in the evaluation of aquatic animal health services. He undertook to encourage Members to request evaluations and noted that the OIE considered the strengthening of both aquatic animal health services and veterinary services as a global priority.

Dr Vallat noted the mandate of the Aquatic Animals Commission now included animal production food safety and encouraged the Commission to consider this aspect in their future work.

Dr Hill on behalf of the Aquatic Animals Commission thanked Dr Vallat for his update and support of the work of the Commission.

1. Activities and progress of *ad hoc* Groups

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

Dr Hill, as Chair of the *ad hoc* Group, informed the Aquatic Animals Commission that the *OIE Guide for Aquatic Animal Health Surveillance* was published in November 2009 and he anticipated that there would be a good demand for it.

Dr Hill then gave a summary of progress made at the meeting of the *ad hoc* Group held at OIE Headquarters in Paris from 8 to 10 February 2010 to develop the template for the disease specific surveillance chapters. As recommended by the Aquatic Animals Commission at its meeting in March 2009, on the first day the *ad hoc* Group simplified and refined the template and for the following two days they were joined by the three disease experts from OIE Reference Laboratories for viral haemorrhagic septicaemia (Dr Niels Olesen), infection with *Bonamia ostreae* (Dr Isabelle Arzul) and white spot disease (Professor Grace Lo) to discuss what would be required to prepare the model chapters for these diseases. Good progress was made and the *ad hoc* Group and experts agreed on the nature and detail of the information that should be included under each heading/subheading of the template. The next step will be for the experts to draft the disease specific chapters for which they are the designated expert. Each chapter will be drafted with the assistance of a selected member of the *ad hoc* Group and it was proposed that to complete the drafting, the nominated member would meet with the respective disease expert at a mutually agreed location. The draft chapters will be collectively reviewed by the *ad hoc* Group and experts at the second joint meeting, to be held in July 2010, and then will be submitted to the Aquatic Animals Commission for consideration at its meeting in October 2010.

The *ad hoc* Group had also been given the task to review and simplify the *Aquatic Manual* disease chapter template but after a brief discussion it was agreed that it would be preferable to wait to see the content of the three model disease-specific surveillance chapters before deciding what changes to make to the template. It is hoped that a start on this will be made at the joint meeting with the disease experts in July 2010.

The Aquatic Animals Commission acknowledged the work of this *ad hoc* Group and look forward to reviewing the draft model chapters at their next meeting.

The *ad hoc* Group report is provided for information at Annex XXX.

1.2. Report of the *ad hoc* Group on Disposal of Aquatic Animal Waste

Dr Colin Johnston, Chair of the *ad hoc* Group, submitted a written summary of progress made at the meeting held from 26 to 28 January 2010 at the OIE Headquarters. Dr Johnston reported that the *ad hoc* Group considered Member comments on the draft Chapter on *Handling and disposal of carcasses and wastes of aquatic animals* and noted relevant technical amendments to the intent of the Articles. The *ad hoc* Group noted the necessity to review the draft Chapter to improve logical flow, remove duplication, clarify potentially contradictory sections and align this Chapter with the equivalent one in the *Terrestrial Code*.

See also details in Item 2.24.

The Aquatic Animals Commission acknowledged the work of this *ad hoc* Group and wished to thank them for their very comprehensive work.

The *ad hoc* Group report is provided for information at Annex XXXI.

1.3. Report of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals

Dr Franck Berthe, Chair of the *ad hoc* Group, gave a summary of progress made at the meeting held from 1 to 3 February 2010 at the OIE Headquarters. Dr Berthe reported that the *ad hoc* Group considered Member comments on several draft chapters and made relevant amendments.

See also details provided under Agenda Item 2.4., 2.5., 2.6., 2.7. and 2.20., respectively.

Dr Hill thanked Dr Berthe and the *ad hoc* Group for their very comprehensive work on this complex subject. The Aquatic Animals Commission noted that the detailed product assessments are not appropriate for inclusion in the *Aquatic Code*, and agreed with the *ad hoc* Group proposal to develop a reference document setting out the rationale of assessments and make this document available to Members on the OIE website. The Aquatic Animals Commission recommended that the *ad hoc* Group continued the aquatic animal product assessments for other disease chapters, including necrotising hepatopancreatitis, infection with abalone herpes-like virus and amphibian diseases, and complete a report prior to the next Commission meeting in October 2010.

The *ad hoc* Group report is provided for information at Annex XXXII.

1.4. Report of the *ad hoc* Group on Crustacean Diseases

Prof. Don Lightner, Chair of the *ad hoc* Group, submitted a written summary of progress made by the *ad hoc* Group on the OIE List of Aquatic Animal Diseases - Crustacean Team for the OIE *Aquatic Animal Health Code* that worked electronically between December 2009 and February 2010. The *ad hoc* Group reviewed milky haemolymph disease of spiny lobsters (*Panulirus* spp.), currently OIE listed as 'under study', and recommended that it should not be listed.

See details provided under Agenda Item 2.3.

The Aquatic Animals Commission acknowledged the excellent work of this *ad hoc* Group undertaken promptly in response to the request from the Aquatic Animals Commission.

The *ad hoc* Group report is provided for information at Annex XXXIII.

1.5. Report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals

The *ad hoc* Group on the Responsible Use of Antimicrobials in Aquatic Animals met at OIE Headquarters from 19 - 21 January 2010. The *ad hoc* Group developed a draft chapter on Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine and recommended that work on other relevant topics, i.e. the harmonisation of national antimicrobial resistance surveillance and monitoring programs; risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals and monitoring of the quantities of antimicrobials used in animal husbandry be developed at later meetings.

The *ad hoc* Group also developed recommendations on prudent use in aquatic animals and proposed that this document be published on the OIE website as an advisory document to assist OIE Members in developing and/or updating their governance systems for antimicrobial use in aquatic animals.

See also details in Item 2.22. and 3.1.

The Aquatic Animals Commission acknowledged the excellent work of this *ad hoc* Group. The Aquatic Animals Commission agreed with the proposed strategy to develop advisory document to be published on the OIE website. The Aquatic Animals Commission asked the OIE Headquarters to undertake this work.

The *ad hoc* Group report is provided for information at Annex XXXIV.

2. OIE *Aquatic Animal Health Code* – Member comments

2.1. General comments

The EU welcomes the explanation given by the AAC as regards the different lists of susceptible species in the Code and the Manual. However, the EU would request the AAC to reassess whether the susceptible species for the purpose of the Aquatic Animal Health Code should all be explicitly listed in Article X.X.2 of each disease chapter of the Code, instead of also having a reference to the species listed in the Manual. This is the approach used in the Terrestrial Code.

The descriptions of the susceptible species in several of the chapters of the OIE Manual, are formulated in a manner that give rise to uncertainties as to which species mentioned fulfill the critera set out in the definition of susceptible species in the Glossary of the OIE Code and for which the trade restrictions may be applied (see for instance the proposed amendments to the Manual in Annex XXVI and XXVII to this report). In this context

the EU highly appreciates the work of the AAC in establishing a guidance document on considering species as susceptible to diseases.

A Member commented on the different lists of susceptible species between the *Aquatic Code* and the *Aquatic Manual*. The Aquatic Animals Commission wished to clarify that the *Aquatic Code* only included those susceptible species that are traded internationally, while the *Aquatic Manual* includes a wider list of susceptible species because it includes species not known to be traded internationally.

The Commission noted that some words in the *Aquatic Code* appear in italics when they are no longer defined terms the Glossary, e.g. OIE listed diseases. The Commission asked OIE Headquarters to correct this in the 2010 edition of the *Aquatic Code*.

The 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 encouraged 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.

When preparing their comments Members are encouraged to address substantive scientific issues or essential clarification rather than making comments of an editorial nature. Additionally, having regard to the need to prioritise work on the Aquatic Animals Commission agenda, Members should focus on new text or proposed text revisions and not comment on current text unless there is a pressing need to update the scientific content.

The Aquatic Animals Commission also noted that by OIE convention the word 'should' is to be used throughout the *Aquatic Code*, and asked the International Trade Department to check the entire *Aquatic Code* and change 'must' to 'should' throughout.

The Aquatic Animals Commission agreed that it is important to continue to harmonise the *Aquatic* and *Terrestrial Codes* but recognized there are inherent differences in some areas where harmonisation is not feasible. To facilitate the process of review and harmonisation, the Commission encouraged Members to ensure that their comments on relevant horizontal text are submitted to both the Terrestrial Code and Aquatic Animals Commissions.

2.2. Glossary

The Aquatic Animals Commission reviewed the *Aquatic Code* Glossary and made a number of amendments.

The following definitions were amongst those amended, to be consistent with the equivalent definitions in the *Terrestrial Code*, as part of the ongoing harmonisation of the two Codes: infected zone and international aquatic animal health certificate.

A new definition was developed for Aquatic Animal Health Services which is proposed to replace Competent Authority in Chapter 3.1. as this term more accurately reflects the aquatic animal health services of many Members.

Veterinary Services and Feed additives are proposed to be deleted as these terms are not used in the *Aquatic Code*.

The revised Glossary proposed for adoption at the 78th General Session in May 2010 is presented at Annex III.

EU position

The EU supports the adoption of the revised Glossary.

2.3. Diseases listed by the OIE (Chapter 1.3.)

The *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Crustacean Team) assessed whether milky haemolymph disease of spiny lobsters (*Panulirus* spp.) currently listed as 'under study' should be listed as an emerging disease. The *ad hoc* Group concluded that milky haemolymph disease of spiny lobsters (*Panulirus* spp.) does not meet the criteria for listing as outlined in Articles 1.2.1 and 1.2.2 of the *Aquatic Code* and therefore should not be listed as either an emerging disease or a listed disease. Full justification is provided in the Crustacean *ad hoc* Group Report (Annex XXXIII).

The Aquatic Animals Commission endorsed the Crustacean *ad hoc* Group recommendation not to list milky haemolymph disease of spiny lobsters (*Panulirus* spp.).

No Member comments were received objecting to the proposed listing of necrotising hepatopancreatitis (NHP), currently under study. Therefore, the Aquatic Animals Commission proposed listing of NHP.

A Member proposed the name for NHP be changed to Texas NHP. The Aquatic Animals Commission consulted with an OIE expert who advised that there was no scientific justification for a name change and recommended it remain as is.

A Member requested that the Commission should consider the inclusion of pancreas disease in the listed diseases but did not provide their reasons for this. The Aquatic Animals Commission encouraged the Member to submit relevant information supporting the listing for consideration by the ACC at its October 2010 meeting. If the Aquatic Animals Commission considered that it was warranted, the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Fish Team) could be convened to undertake an assessment of this disease against the listing criteria in Ch 1.2.

Consequent to the adoption of Resolution XXIX at the 73rd General Session, the Aquatic Animals Commission proposed to modify the preamble in Chapter 1.3., providing that any changes to the OIE List of diseases made at the General Session would come into effect on 1 January of the following year.

The Commission discussed a Member comment about the obligations of Members to notify the OIE of the finding of a disease that is listed 'under study' in chapter 1.3. The Commission considered that this was a rather complex issue, which needed to be addressed on a case by case basis, having regard to the disease and the arguments for and against listing the disease. The Commission noted that the decisions to not list milky haemolymph disease of spiny lobsters (Panulirus spp.) and to list necrotising hepatopancreatitis meant that there would be no diseases listed on an 'under study' basis in the 2010 edition of the *Aquatic Code*. The Commission decided to keep this matter under review.

The revised Chapter 1.3. Diseases listed by the OIE proposed for adoption at the 78th General Session in May 2010 is presented at Annex IV.

EU position

The EU supports the adoption of the revised chapter.

2.4. Example Articles X.X.3., X.X.9. and X.X.12.

. The Aquatic Animals Commission reviewed the recommendations of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals in response to Member comments on the 'Example Articles X.X.3., X.X.9. and X.X.12.' to be included in all disease specific chapters and endorsed their recommendations. (Refer to the *ad hoc* Group Report in Annex XXXII).

The Aquatic Animals Commission reminded Members the scope of each of these articles is as follows:

Article X.X.3. addressed the importation of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from 'Disease X'.

Article X.X.9. addressed the importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from 'Disease X'.

Article X.X.12. (fish chapters) /Article X.X.11. (crustacean and mollusc chapters) addressed the importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from 'Disease X'.

The revised Articles X.X.3., X.X.9. and X.X.12. (fish chapters) /Article X.X.11. (mollusc and crustacean chapters) to be applied across all disease specific chapters) proposed for adoption at the 78th General Session in May 2010 is presented at Annex V.

EU position
The EU supports the adoption of the revised example Articles.

2.5. Criteria to assess the safety of aquatic animal commodities (Chapter 5.3)

The Aquatic Animals Commission reviewed the recommendations of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals in response to Member comments on amendments in Article 5.3.1. and Article 5.3.2. The Aquatic Animals Commission agreed with the proposed amendments.

The revised Chapter 5.3. Criteria to assess the safety of aquatic animal commodities proposed for adoption at the 78th General Session in May 2010 is presented at Annex VII.

EU position
The EU supports the adoption of the revised chapter.

2.6. Amended text for epizootic haematopoietic necrosis (Articles 10.1.3., 10.1.9. and 10.1.12.), Taura syndrome (Articles 9.4.3., 9.4.9. and 9.4.11.) and infection with *Bonamia. ostreae* (Articles 11.2.3., 11.2.9. and 11.2.11.)

The Aquatic Animals Commission reviewed the recommendations of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals in response to Member comments on amendments of epizootic haematopoietic necrosis (Articles 10.1.3., 10.1.9. and 10.1.12.), Taura syndrome (Articles 9.4.3., 9.4.9. and 9.4.11.) and for infection with *B. ostreae* (Articles 11.2.3., 11.2.9. and 11.2.11.). The Aquatic Animals Commission agreed with the proposed amendments.

The Aquatic Animals Commission welcomed the change in aquatic animal product descriptions as this improved clarity.

The Aquatic Animals Commission noted that assessments undertaken by the *ad hoc* Group that supported the amendments to the aquatic animal products listed in Article X.X.3. and X.X.11/12 of these chapters are provided in the *ad hoc* Group report (See Appendix IV in Annex XXXII).

For readability the clean version is provided in Annex VIIA. A tracked text version is provided in Annex VIIB.

The revised Articles for epizootic haematopoietic necrosis (Articles 10.1.3., 10.1.9. and 10.1.12.), Taura syndrome (Articles 9.4.3., 9.4.9. and 9.4.11.) and for infection with *Bonamia ostreae* (Articles 11.2.3., 11.2.9. and 11.2.11.) proposed for adoption at the 78th General Session in May 2010 is presented at Annex VIIA (clean text).

EU position

The EU supports the adoption of the modified Articles.

2.7. Measures concerning international transport of aquatic animal disease agents and pathological material (Chapter 5.9.)

The Aquatic Animals Commission reviewed the recommendations of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals in response to Member comments on amendments in Chapter 5.9. Measures Concerning International Transport of Aquatic Animal Disease Agents and Pathological Material. The Aquatic Animals Commission agreed with the proposed amendments.

The revised Chapter 5.9. Measures Concerning International Transport of Aquatic Animal Disease Agents and Pathological Material proposed for adoption at the 78th General Session in May 2010 is presented at Annex VIII.

EU position

The EU supports the adoption of the modified chapter.

2.8. Import risk analysis (Chapter 2.2.).

The Aquatic Animals Commission considered Member comments and made relevant amendments.

The revised Chapter 2.2. Import Risk Analysis proposed for adoption at the 78th General Session in May 2010 is presented at Annex IX.

EU position

The EU supports the adoption of the modified chapter.

2.9. Quality and evaluation of Competent Authorities (Chapter 3.1.)

The Aquatic Animals Commission considered Member comments and amendments proposed by the Terrestrial Code Commission to the relevant chapter in the *Terrestrial Code*, and made relevant amendments.

The Commission proposed replacing the term Competent Authority/ies throughout this chapter with Aquatic Animal Health Service(s), as they believed this term was more appropriate for this chapter. Similar substitutions will be considered for other relevant chapters in future work.

The revised Chapter 3.1. Quality of Aquatic Animal Health Services proposed for adoption at the 78th General Session in May 2010 is presented at Annex X.

EU position

The EU supports the adoption of the modified chapter.

However, in the first paragraph of Article 3.1.5, Competent Authorities should be replaced by Aquatic Animal Health Services at the end of the sentence, in the interest of consistency in wording. This paragraph should read:

The OIE has established procedures for the evaluation of ~~*Competent Authorities*~~ *Aquatic Animal Health Services* of Members. Members can make a request to the OIE for an evaluation of their ~~***Competent Authorities***~~ ***Aquatic Animal Health Services***

2.10. Zoning and compartmentalisation (Ch 4.1.)

The Aquatic Animals Commission considered Member comments and amendments proposed by the Terrestrial Code Commission to the relevant chapter in the *Terrestrial Code*, and made relevant amendments.

The revised Chapter 4.1. Zoning and Compartmentalisation proposed for adoption at the 78th General Session in May 2010 is presented at Annex XI.

EU position

The EU supports the adoption of the revised chapter.

2.11. Application of compartmentalisation (Ch 4.X.)

The Aquatic Animals Commission considered Member comments and amendments proposed by the Terrestrial Code Commission to the relevant chapter in the *Terrestrial Code*, and made relevant amendments.

The Aquatic Animals Commission acknowledged the prioritised list of diseases provided by Norway and EU for restoring disease free status for compartments and zones and will note these for future work.

Some Members suggested that chapters 4.X. and 4.1. should be combined and edited to remove duplication and redundancy. The Aquatic Animals Commission was of the view that, in order to

remain harmonised with the *Terrestrial Code* this should not be done at this time but considered it to be a good idea for the future and would raise this with the Terrestrial Code Commission .

A number of Members had comments on the definition for protection zone and recommended modifications to the definition. The Aquatic Animals Commission noted the work in progress by the Terrestrial Code Commission on this topic and decided to await further developments.

The revised Chapter 4.X. Application of Compartmentalisation proposed for adoption at the 78th General Session in May 2010 is presented at Annex XII.

EU position

The EU supports the adoption of the revised chapter.

2.12. Control of aquatic animal health hazards in aquatic animal feed (Chapter 4.5.)

The Aquatic Animals Commission considered Member comments and comments received from the APFSWG and Terrestrial Code Commission and made relevant amendments.

Noting that this chapter was only adopted at the last General Session in 2009, and mindful of the higher priority of other work, the ACC decided not to review in detail the extensive comments received from one Member but instead to wait for another year and then see if it was necessary to update the chapter.

It was proposed to delete references to safe commodities in Article 4.5.8 as this is now covered in proposed amendments dealing with aquatic animal products listed in article X.X.3 for all chapters.

The revised Chapter 4.5. Control of Hazards in Aquatic Animal Feeds proposed for adoption at the 78th General Session in May 2010 is presented at Annex XIII.

EU position

The EU supports the adoption of the revised chapter.

However, the EU wishes the AAC to take the following comment into account in future revisions of this chapter:

In Article 4.5.8 the point 1 b) and point 1 c) the possible risk mitigating measures referred to are formulated quite differently. For instance, whereas point 1 b) i) refers to "disease free country, free zone or free compartment", point 1 c) refers to "sourcing fish only from stocks where there is no evidence of infection with any of the OIE diseases". The question is whether the wording of these two points could be better harmonised.

2.13. General obligations related to certification (Chapter 5.1.)

The Aquatic Animals Commission considered Member comments and amendments proposed by the Terrestrial Code Commission to the relevant chapter in the *Terrestrial Code*, and modified the chapter accordingly.

The revised Chapter 5.1. General Obligations Related to Certification proposed for adoption at the 78th General Session in May 2010 is presented at Annex XIV.

EU position

The EU supports the adoption of the revised chapter.

2.14. Certification procedures (Chapter 5.2.)

The Aquatic Animals Commission considered Member comments and amendments proposed by the Terrestrial Code Commission to the relevant chapter in the *Terrestrial Code*, and made relevant amendments.

The revised Chapter 5.2. Certification Procedures proposed for adoption at the 78th General Session in May 2010 is presented at Annex XV.

EU position

The EU supports the adoption of the revised chapter.

2.15. Model international aquatic animal health certificates (Chapter 5.10.)

The Aquatic Animals Commission considered Member comments and made relevant amendments.

The revised Chapter 5.10. Model International Aquatic Animal Health Certificates proposed for adoption at the 78th General Session in May 2010 is presented at Annex XVI.

EU position

The EU supports the adoption of the revised chapter.

2.16. Welfare of farmed fish during transport (Chapter 7.2.)

The Aquatic Animals Commission considered Member comments and made relevant amendments.

The revised Chapter 7.2. Welfare of Farmed Fish During Transport proposed for adoption at the 78th General Session in May 2010 is presented at Annex XVII.

EU position

The EU can support the adoption of the revised Chapter.

2.17. Article X.X.8. for inclusion in all disease specific chapters

The Aquatic Animals Commission considered Member comments and made relevant amendments.

The Commission reminded Members that the recommendations in the *Aquatic Code* for OIE Members to apply the provisions of the ICES Code are limited to issues under the OIE mandate and do not extend to the specific ICES provisions for the assessment of invasiveness when establishing measures for the translocation of aquatic animals. The principles of the ICES Code apply also to non marine species and therefore the Aquatic Animals Commission did not accept the recommendation of a Member to only include the reference to ICES in chapters dealing with diseases of marine species.

The revised Article X.X.8. for inclusion in all disease specific chapters proposed for adoption at the 78th General Session in May 2010 is presented at Annex XVIII.

EU position

The EU supports the adoption of the revised Article.

However, the EU requests the AAC to provide an explanation for why the EU suggestions presented to the AAC before its Februay meeting for point 4 of Article X.X.8 were not taken on board.

2.18. Infection with abalone herpes-like virus (Chapter 11.X.)

The Aquatic Animals Commission considered Member comments and made relevant amendments. The chapter was also amended to include generic changes proposed for Articles 11.X.3, 11.X.8., 11.X.9. and 11.X.11.

The Aquatic Animals Commission proposed that aquatic animal products listed under Articles X.X.3 and X.X.11 be 'under study'. The Aquatic Animals Commission requested the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals assess products that would be eligible for those articles when it meets later this year.

The new Chapter 11.X. Infection with abalone herpes-like virus proposed for adoption at the 78th General Session in May 2010 is presented at Annex XIX.

EU position

The EU supports the adoption of the new Chapter.

2.19. Necrotising hepatopancreatitis (Ch 9.X.)

The Aquatic Animals Commission considered Member comments and made relevant amendments. The chapter was also amended to include generic changes proposed for Articles 9.X.3, 9.X.8., 9.X.9. and 9.X.11.

The Aquatic Animals Commission proposed that aquatic animal products listed under Articles X.X.3 and X.X.11 be 'under study'. The Aquatic Animals Commission requested the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals assess products that would be eligible for those articles when it meets later this year.

The new Chapter 9.X. Necrotising hepatopancreatitis proposed for adoption at the 78th General Session in May 2010 is presented at Annex XX.

EU position

The EU supports the adoption of the new Chapter.

2.20. Disinfection of salmonid eggs – (Article 10.4.X., Article 10.5.X. and Article 10.9.X.)

The Aquatic Animals Commission reviewed the recommendations of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals in response to Member comments on amendments to new Articles on disinfection of salmonid eggs – (Article 10.4.X., Article 10.5.X. and Article 10.9.X.) and agreed with the proposed amendments. (Refer to the *ad hoc* Group Report in Annex XXXII).

The Aquatic Animals Commission agreed with the advice of the *ad hoc* Group to maintain the measures additional to disinfection, for the importation of eggs from an infected country, zone or compartment.

The *ad hoc* Group identified the following prerequisites for trade in disinfected eggs from an infected country, zone or compartment: (i) there is no true vertical transmission of the disease and (ii) the disinfection protocol is effective in reducing the risk of egg surface associated transmission of the disease.

The *ad hoc* Group considered that the following diseases do not exhibit true vertical transmission: IHN, VHS and ISA. The *ad hoc* Group noted that egg disinfection is a mitigation measure against egg surface associated transmission but may not always be effective, particularly where eggs have been exposed to high levels of virus or where water quality is variable. The *ad hoc* Group recommended maintaining point 1 of the draft new articles on trade measures for disinfected salmonid eggs requesting that an assessment of the risk be conducted prior to importation.

The new Articles on disinfection of salmonid eggs (Article 10.4.X., Article 10.5.X. and Article 10.9.X.) proposed for adoption at the 78th General Session in May 2010 is presented at Annex XXI.

EU position

The EU can only support the adoption of the Articles, if point 2 a) is amended to read as follows: the *eggs* should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* (under study) ~~or those~~ specified by the *Competent Authority* of the *importing* country; and

Rationale:
As previously highlighted by the *ad hoc* Group on Safety of Products derived from Aquatic Animals, a prerequisite for trade in disinfected eggs from an infected country, zone or compartment is that the disinfection protocol is effective in reducing the risk of egg surface associated transmission of disease. It is the opinion of the EU that Chapter 1.1.3 of the Aquatic Manual needs further elaboration before it can be regarded as an effective disinfection protocol. As no revised version of that Chapter is presented for adoption this year, the EU proposes that the part of the Article referring to Chapter 1.1.3 of the Aquatic Manual is put under study. As long as that reference is under study, the importing country should lay down the applicable disinfection protocol.

In addition the EU would request the AAC to consider adding a new point 4 at the end of each of the Articles:

The OIE Members may wish to consider internal measures, such as renewed disinfection of the eggs upon arrival in the importing country.

Furthermore, the EU would support that Articles on egg disinfection for all listed diseases which do not exhibit true vertical transmission are developed. In the further development of this article the EU would encourage the AAC to explore whether the risk assessment referred to in point 1 of the Articles could be replaced by a description of disease specific additional risk mitigation measures to be taken by the exporting country to ensure the safe trade in disinfected eggs.

2.21. Slaughter of farmed fish for human consumption (Ch 7.3.)

The Aquatic Animals Commission considered Member comments and made relevant amendments as follows:

The Aquatic Animals Commission looked at the definition of slaughter in the *Terrestrial Code* and did not adopt this definition because it generally does not apply to aquatic animal species. As the term was not amenable to definition in the *Aquatic Code*, references to slaughter were amended to read 'stunning and killing' throughout the chapter.

The Commission did not agree with the proposal from a Member to make specific provisions for small aquaculture establishments because it considered that appropriate methods were already addressed in Article 7.3.6.

The Aquatic Animals Commission noted Member comments about point 4 in Article 7.3.6. 'Other stunning and killing methods' but did not agree to delete the text because these methods are used in practice and in many cases there are no alternative methods. The Aquatic Animals Commission did not agree with a Member's proposal to add the text in point 4 in Article 7.3.6. to the Table in Article 7.3.8. because there is a lack of scientific information relevant to the methods described in point 4. The Aquatic Animals Commission will keep this matter under review and encouraged Members to submit relevant scientific information to assist future deliberations on this matter.

The Aquatic Animals Commission noted that the development of the chapter on humane killing of fish for disease control purposes is on the Aquatic Animals Commission work plan.

The new Chapter 7.3. Welfare Aspects of Stunning and Slaughter of Farmed Fish for Human Consumption proposed for adoption at the 78th General Session in May 2010 is presented at Annex XXII.

EU position

The EU welcomes the work carried out on the Draft Chapter on the Welfare Aspects of Stunning and Killing of Farmed Fish for Human Consumption and can support the adoption of the Chapter. The EU thanks the OIE for having taken into account a number of comments previously submitted.

Moreover, the EU wishes to encourage OIE to develop as soon as possible also the Draft Chapter on Humane Killing of Fish for Disease Control Purposes, as indicated on the Aquatic Animals Commission work plan and in consistency with the Terrestrial Code.

Specific EU comments are provided in the Annex XXII for further development of the Chapter 7.3.

2.22. Introduction to the recommendations for controlling antimicrobial resistance (Ch 6.1.)

The Aquatic Animals Commission considered Member comments and comments of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals, and made relevant amendments.

In response to a Member's comment regarding the need to make specific reference to the environment in Ch 6.1. the Aquatic Animals Commission advised that this is covered in the proposed new Chapter Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (see Item 3.1.)

The new Chapter 6.1. Introduction to the Recommendations for Controlling Antimicrobial Resistance proposed for adoption at the 78th General Session in May 2010 is presented at Annex XXIII.

EU positions

The EU supports the adoption of this new Chapter.

The EU strongly encourages the OIE to continue its collaboration with the Codex Alimentarius Commission in the field of antimicrobal resistance. It reiterates its former comment regarding the last sentence of the third paragraph that should read: "Arising from its mandate for the protection of animal health and food safety, and in synergy with activities of the Codex Alimentarius Commission, the OIE developed these chapters to provide guidance to Members in regard to risks in the animal sector."

2.23. Recommendations for safe transport of aquatic animals and aquatic animal products (Chapter 5.4.)

The Aquatic Animals Commission reviewed the title of Chapter 5.4. and proposed an amendment to clarify the contents of this chapter and ensure a clear difference between this chapter and Chapter 7.2. Welfare of farmed fish during transport.

The revised text Ch 5.4. Control of Aquatic Animal Health Risks Associated with Transport of Aquatic Animals proposed for adoption at the 78th General Session in May 2010 is presented at Annex XXIV.

EU position

The EU supports the adoption of the modified Chapter.

2.24. Handling and disposal of carcasses and wastes of aquatic animals (Ch X.X)

The Aquatic Animals Commission reviewed the recommendations of the *ad hoc* Group on Disposal of Aquatic Animals in response to Member comments on amendments in the proposed Chapter X.X. Handling and Disposal of Carcasses and Wastes of Aquatic Animals and agreed with the proposed amendments.

The Aquatic Animals Commission noted that the key amendments made to the chapter were: amendment of the title to more accurately reflect the syntax of the chapter; removal of duplication; amendment of the order of articles to provide a more logical flow; amendment of the Introduction, clarification of the Scope; deletion of definitions that were redundant; consolidation and the addition of new text on mass mortality events. Although there have been considerable changes made to the

overall layout of the chapter, the Commission noted that the technical content of the chapter was largely unchanged.

The new Chapter Handling, Disposal and Treatment of Aquatic Animal Waste (Ch X.X) proposed for adoption at the 78th General Session in May 2010 is presented at Annex XXV.

EU position

The EU supports the adoption of the new Chapter.

3. OIE *Aquatic Animal Health Code* – proposed new articles and chapters

3.1. Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Ch 6.2.)

The Aquatic Animals Commission reviewed the draft chapter on Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine, developed by the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals and supported the approach taken.

The new draft Chapter 6.2. Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine is presented at Annex XXIX for Member comment.

4. Update relevant activities of the OIE

The Aquatic Animals Commission reviewed a draft 'Agreement on Confidentiality and Impartiality' destined for use by all OIE Commissions, working groups and *ad hoc* Groups and recognised the need for this approach and accepted the document in principle.

Dr Kahn informed the Commission of the very productive work of an *ad hoc* Group that has completed a review and produced the manuscript for a second edition of the OIE Import Risk Analysis Handbook Volume 1 that will be published in 2010.

5. Cooperation with FAO

The Aquatic Animals Commission noted the report provided by FAO attached at Annex XXXV

6. OIE Conferences and Meetings

Members of the Aquatic Animals Commission or other OIE representatives attended the following OIE conferences and meetings and delivered a presentation on the work of the Aquatic Animals Commission:

- 10th Conference of the OIE Regional Commission for the Middle East (25–29 October 2009, Doha, Qatar).
- 26th Conference of the OIE Regional Commission for Asia, the Far East and Oceania (16–21 November 2009, Shanghai, People's Republic of China).
- FAO/OIE Aquatic Biosecurity Framework for Southern Africa: A Scoping Meeting of Regional Fisheries and Veterinary Authorities (13–14 October 2009, Namibia).
- 4th Meeting of the Inter-American Committee of the OIE on Aquatic Animal Health (Costa Rica, December, 2009)
- 8th Annual General Meeting of NACA Regional Advisory Group on Aquatic Animal Health (Bangkok, December 2009)

7. Upcoming OIE Conferences and Meetings

Members of the Aquatic Animals Commission or other OIE representatives will attend the following OIE conferences and meetings and deliver a presentation on the work of the Aquatic Animals Commission:

– 24th Conference of the OIE Regional Commission for Europe (Kazakhstan 20-24 September 2010);

– 20th Conference of the OIE Regional Commission for the Americas (Uruguay, 16-19 November 2010);

– Second International Conference of OIE Reference Laboratories and Collaborating Centres (21–23 June 2010, Paris, France).

– International Symposium for ISA (13-15 September 2010, Norway)

– Primera Conferencia Chilena de Bioseguridad (22-23 March 2010, Chile).

8. OIE Regional aquatic animal focal points training workshops:

Members of the Aquatic Animals Commission will attend and deliver presentations at the following OIE regional aquatic animal focal points training workshops:

Europe – Dubrovnik, Croatia: 21-23 April 2010

Middle East – Umm el Quwain, UAE: 27-29 Sept 2010

Africa – Namibia: 16-18 June 2010

Americas – Roatan, Honduras: 23-25 November 2010

Far East, Asia Pacific: 2011

9. Second Global Conference on Aquatic Animal Health: 'Contribution of Aquatic Animal Health to Global Food Security'

All members of the Aquatic Animals Commission indicated that they would be happy to participate in the scientific committee and look forward to receive further information on this conference.

10. *Manual of Diagnostic Tests for Aquatic Animals, seventh edition 2012*

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

10.1. References to non-susceptible species in mollusc chapters

As recorded in the report of the meeting of the Aquatic Animals Commission held in October 2009, the Commission agreed with the recommendation of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals that the reference to non-susceptible species in Article X.X.3. point 1c) of the *Aquatic Code* chapters on Infection with *Bonamia exitiosa*, *Bonamia ostreae*, and *Marteilia refringens* be moved to the relevant chapters of the OIE Manual of Diagnostic Tests for Aquatic Animals (*Aquatic Manual*).

The OIE designated experts on these diseases reviewed the list of non-susceptible species and clarified where scientific information substantiated evidence of non-susceptibility existed. Those species could be retained as non-susceptible species to the disease in question in the Aquatic Manual chapter.

It was found that no scientific literature documents the non-susceptibility of: *Crassostrea gigas*, *C. virginica*, and *Saccostrea glomerata* for *B. exitiosa*; *C. virginica* for *B. ostreae*; and *C. gigas* for *M. refringens*.

The revised text in Chapter 2.4.3. in the *Aquatic Manual* proposed for adoption at the 78th General Session in May 2010 is presented at Annex XXVI.

10.2. Guidance document on considering species as susceptible to diseases

The Aquatic Animals Commission reviewed Member comments and made a minor modification to the document. The next step is to forward the document to the authors of the disease chapters in the *Aquatic Manual* for review. The purpose of the document is for guidance for authors.

10.3. Review of the two new chapters on amphibian diseases

The two chapters on diseases of amphibians: infection with *Batrachochytrium dendrobatidis* and infection with ranavirus, were not received on time for review by the Commission.

10.4. Review of the new chapter on Infection with Abalone Herpes-like Virus

The Aquatic Animals Commission reviewed the draft chapter on Infection with abalone herpes-like virus and agreed that they should be proposed for adoption.

The new *Aquatic Manual* chapter Infection with Abalone Herpes-like Virus proposed for adoption at the 78th General Session in May 2010 is presented at Annex XXVII.

If adopted, these new chapters will be added to the web version of the *Aquatic Manual*, immediately after the 78th General Session.

10.5. Review of amended disease card on infection with Abalone Herpes-like Virus

The Commission noted that there is now a draft *Aquatic Manual* chapter on Infection with Abalone Herpes-like Virus (see item 11.4 below). As the card was out of date the Aquatic Animals Commission decided to remove it from the Commission's web pages.

10.6. Review of author and reviewer lists

The Commission reviewed and updated the lists of authors and reviewers for the next edition of the *Aquatic Manual*. The authors will be invited to update their chapters after the next meeting of the Commission in October this year. The updated chapters will then be sent to reviewers and Members for comments.

10.7. Review of the template for disease-specific chapters

The *ad hoc* Group on Aquatic Surveillance had undertaken to amend the template for disease-specific chapters in the *Aquatic Manual*. The Commission requested that this be completed in time for review at its meeting in February 2011.

11. OIE Reference Laboratories and Collaborating Centres

11.1. Comment from Chile

The Commission noted a comment from Chile regarding the rights and obligations included in the Mandates and Internal Rules for OIE Reference Laboratories and Collaborating Centres. The Commission agreed that although it is difficult to properly assess the performance of an OIE Reference Laboratory or Collaborating Centre, it was not in a position to discuss or address the issue at this meeting. It proposed that the topic be included in items for discussion at the Second Global Conference of OIE Reference Laboratories and Collaborating Centres, to be held in June 2010.

11.2. Review of annual reports

Reports had been received from all but one 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.

The Commission noted significant differences in the nature of the information provided under different headings, the amount of content and the style. For example some experts provided simple bullet points under each heading while others wrote lengthy paragraphs. The Aquatic Animals Commission proposed that the experts be given an example report illustrating what the OIE and the Commission would like to receive from its experts in their annual reports and requested Ms Linnane to undertake this action.

11.3. Updating the list of OIE Reference Laboratories and Collaborating Centres

11.3.1. Joint application for Collaborating Centre status: Collaborating Centre for Aquatic Epidemiology and Risk Assessment

EU position

The EU supports the approval of the Atlantic Veterinary College, Centre for Aquatic Health Science, University of Prince Edward Island, Canada and The National Veterinary Institute, Department of Epidemiology, Oslo, Norway as an OIE Collaborating Centre for Epidemiology and Risk Assessment of Aquatic Animal Diseases and the new OIE reference laboratory for Abalone Herpes-like Virus.

At its last meeting, the Commission had received an application from the Atlantic Veterinary College (AVC), Centre for Aquatic Health Science, University of Prince Edward Island, Canada for an OIE Collaborating Centre for Aquatic Epidemiology and Evidence-Based Health Management, and a second application from the National Veterinary Institute, Department for Epidemiology, Sentrum, Norway for a Collaborating Centre for Risk Assessment, Spatial Modelling and Control of Diseases in Farmed Fish. The Commission requested clarification of certain aspects of these two applications and suggested that a joint collaborating centre may be more appropriate.

The Commission reviewed the revised proposal and was satisfied that all supplementary information had been provided. The two institutes have agreed to a joint application for an OIE Collaborating Centre for Aquatic Epidemiology and Risk Assessment. The Commission recommended its approval. The two institutions will be equal partners in the Collaborating Centre. The Aquatic Animals Commission recommended that the Collaborating Centre be titled 'OIE Collaborating Centre for Epidemiology and Risk Assessment of Aquatic Animal Diseases'.

Contact details that will appear on the OIE website are provided in an Annex XXVIII

The Collaborating Centre will be proposed for adoption at the 78th General Session in May.

11.3.2. Application for a Reference Laboratory for Infection with Abalone Herpes-like Virus in Chinese Taipei

An application was received from Chinese Taipei for approval as an OIE Reference Laboratory for Infection with Abalone Herpes-like Virus. The Commission reviewed the application and recommended its approval.

Contact details that will appear on the OIE website are provided in an Annex XXVIII.

The Reference Laboratory will be proposed for adoption at the 78th General Session in May 2010.

11.3.3. Expert at the OIE Reference Laboratory for Infection with *Mikrocytos mackini*

The Commission had been informed that the OIE Designated Expert at the OIE Reference Laboratory for Infection with *Mikrocytos mackini* at the Pacific Biological Station, Fisheries and Oceans Canada had retired. The Laboratory will be temporarily removed from the OIE list until a suitably qualified expert can be appointed.

11.4. Laboratory Twinning Programme

The Commission reviewed several project proposals and provided advice on relevant technical components. The Aquatic Animals Commission welcomed these applications, which are the first for aquatic animal diseases, and looked forward to developments in this area.

The Aquatic Animals Commission encouraged Members to consider opportunities for future laboratory twinning projects.

12. Any other business

12.1. Zoonotic issues in aquatic animals

Dr Daniel Chaisemartin joined the Aquatic Animals Commission for this agenda item. Dr Olga Haenen made a presentation on this issue. The Commission noted that this is potentially an important topic for the OIE and decided to prepare a discussion paper for consideration at the Commission's October 2010 meeting.

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

The Aquatic Animals Commission reviewed and updated their work plan, which is provided at Annex XXXVI for Members' information.

13. Date of the next meeting

11-15 October 2010.

.../Annexes

Annex I

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 22–26 February 2010

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Annex I (contd)

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Annex II (contd)

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 22–26 February 2010

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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

1.2. Report of the *ad hoc* Group on Disposal of Aquatic Animal Waste

1.3. Report of the *ad hoc* Group on Safety of Commodities Derived from Aquatic Animals

1.4. Report of the *ad hoc* Group on Crustacean Diseases

1.5. Report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals

2. OIE *Aquatic Animal Health Code* – Member comments

2.1. General comments

2.2. Glossary

2.3. Diseases listed by the OIE (Chapter 1.3.)

2.4. Example Articles X.X.3., X.X.9. and X.X.12.

2.5. Criteria to assess the safety of aquatic animal commodities (Chapter 5.3.)

2.6. Amended text for epizootic haematopoietic necrosis (Articles 10.1.3., 10.1.9. and 10.1.12.), Taura syndrome (Articles 9.4.3., 9.4.9. and 9.4.11.) and infection with B. ostreae (Articles 11.2.3., 11.2.9. and 11.2.11.)

2.7. Measures concerning international transport of aquatic animal disease agents and pathological material (Chapter 5.9.)

2.8. Import risk analysis (Chapter 2.2.)

2.9. Quality and evaluation of Competent Authorities (Chapter 3.1.)

2.10. Zoning and compartmentalisation (Chapter 4.1.)

2.11. Application of compartmentalisation (Chapter 4.X.)

2.12. Control of aquatic animal health hazards in aquatic animal feed (Chapter 4.5.)

2.13. General obligations related to certification (Chapter 5.1.)

2.14. Certification procedures (Chapter 5.2.)

2.15. Model international aquatic animal health certificates (Chapter 5.10.)

2.16. Welfare of farmed fish during transport (Chapter 7.2.)

2.17. Article X.X.8. for inclusion in all disease specific chapters

2.18. Infection with abalone herpes-like virus (Chapter 11.X.)

2.19. Necrotising hepatopancreatitis (Chapter 9.X.)

Annex II (contd)

2.20. Disinfection of salmonid eggs – (Article 10.4.X., Article 10.5.X. and Article 10.9.X.)

2.21. Slaughter of farmed fish for human consumption (Chapter 7.3.)

2.22. Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.1.)

2.23. Recommendations for safe transport of aquatic animals and aquatic animal products (Chapter 5.4.)

2.24. Handling and disposal of carcasses and wastes of aquatic animals (Chapter X.X)

3. OIE *Aquatic Animal Health Code* – proposed new articles and chapters

3.1. Draft Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (Chapter 6.2.)

4. Update relevant activities of the OIE

5. Cooperation with FAO

6. OIE Conferences and Meetings

7. Upcoming OIE Conferences and Meetings

8. OIE Regional aquatic animal focal points training workshops:

9. Second Global Conference on Aquatic Animal Health: 'Contribution of Aquatic Animal Health to Global Food Security'

10. *Manual of Diagnostic Tests for Aquatic Animals, seventh edition 2012*

10.1. References to non-susceptible species in mollusc chapters

10.2. Guidance document on considering species as susceptible to diseases

10.3. Review of the two new chapters on amphibian diseases

10.4. Review of the new chapter on Infection with abalone herpes-like virus

10.5. Review of amended disease card on infection with abalone herpes-like virus

10.6. Review of author and reviewer lists

10.7. Review of the template for disease-specific chapters

11. OIE Reference Laboratories and Collaborating Centres

11.1. Comment from Chile

11.2. Review of annual reports

11.3. Updating the list of OIE Reference Laboratories and Collaborating Centres

11.3.1. Joint application for Collaborating Centre status: Collaborating Centre for Aquatic Epidemiology and Risk Assessment

11.3.2. Application for a Reference Laboratory for Infection with abalone herpes-like virus in Chinese Taipei

11.3.3. Expert at the OIE Reference Laboratory for Infection with *Mikrocytos mackini*

11.4. Laboratory Twinning Programme

12. Any other business

12.1. Zoonotic issues in aquatic animals

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

13. Date of the next meeting

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Annex III

GLOSSARY

EU positions

The EU can support the adoption of the modified Glossary

Aquatic Animal Health Services

means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the *Aquatic Code* in the territory. The *Aquatic Animal Health Services* are under the overall control and direction of the *Competent Authority*. Private sector organisations, veterinarians, aquatic animal health professionals or veterinary paraprofessionals are normally accredited or approved by the *Competent Authority* to deliver the delegated functions.

~~***Buffer zone***~~

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

Protection zone

means a *zone* established to protect the health status of *aquatic animals* in a free country or *free zone*, from those in a country or *zone* of a different *aquatic animal health status*, using measures based on the epidemiology of the *disease* under consideration to prevent spread of the ~~causative~~ ~~pathogenic~~ *disease agent* into a free country or *free zone*. These measures may include, but are not limited to, vaccination, movement control and an intensified degree of *surveillance.*

~~***Central Bureau***~~***Headquarters***

means the Permanent Secretariat of the World Organisation for Animal Health ~~which headquarters are~~ located at:

12, rue de Prony, 75017 Paris, France
Telephone: 33-(0)1 44 15 18 88
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Competent Authority

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

means the *Veterinary Authority* or other Governmental Authority of a~~n OIE~~ Member having the responsibility and competence for ensuring or supervising the implementation of aquatic animal health and *welfare* measures, international health certification and other standards and recommendations in the *Aquatic Code* in the whole territory.

Early detection system

means an efficient system for ensuring the rapid recognition of signs that are suspicious of a *listed*

disease, or an *emerging disease* situation, or unexplained mortality, in *aquatic animals* in an *aquaculture establishment* or in the wild, and the rapid communication of the event to the *Competent Authority*, with the aim of activating diagnostic investigation with minimal delay.

Annex III (contd)

Such a system will include the following characteristics:

a) broad awareness, e.g. among the personnel employed at *aquaculture establishments* or involved in processing, of the characteristic signs of the *listed diseases* and *emerging diseases*;

b) *veterinarians* or *aquatic animal* health ~~specialists~~ professionals trained in recognising and reporting suspicion~~s~~ of *disease* occurrence;

c) ability of the *Competent Authority* to undertake rapid and effective *disease* investigation based on a national chain of command;

d) access by the *Competent Authority* to laboratories with the facilities for diagnosing and differentiating *listed diseases* and *emerging diseases*~~.~~;

e) the legal obligation of private *veterinarians* or *aquatic animal* health professionals to report suspicions of *disease* occurrence to the *Veterinary Authority* or other *Competent Authority*.

Emerging disease

~~means a newly recognised serious *disease*, the cause of which may or may not yet be established, that has the potential to be spread within and between populations, for example by way of trade in *aquatic animals* and/or *aquatic animal products*.~~

means a newly recognised *infection* resulting from the evolution or change of an existing pathogenic agent, a known *infection* spreading to a new geographic area or population, or a previously unrecognised pathogenic agent or *disease* diagnosed for the first time and which has a significant impact on *aquatic animal* or public health.

~~***Feed additives***~~

~~means any ingredient intentionally added in micro-amounts not normally consumed as *feed* by itself, whether or not it has nutritional value or other effect on the animal, which affects the characteristics of *feed* or of the animal products. Micro-organisms, enzymes, acidity regulators, trace elements, vitamins, substances used to attract *aquatic animals* to feed and promote *feed* intake, pigments, synthetic binders, synthetic amino acids, antioxidants and other products fall within the scope of this definition, depending on the purpose of use and method of administration. This excludes veterinary drugs.~~

~~means any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value or other effect on the *animal*, which affects the characteristics of feed of the *animal* products. Microorganisms, enzymes, pH regulators, trace elements, vitamins and other products fall within the scope of this definition depending on the purpose of use and method of administration. This excludes veterinary drugs.~~

Hazard

~~means any pathogen that could produce adverse consequences on the importation of a *commodity*.~~

means a biological, chemical or physical agent in, or a condition of, an *aquatic animal* or *aquatic animal product* with the potential to cause an adverse effect on *aquatic animal* health or public health.

Infected zone

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

~~*protection zone.*~~

International aquatic animal health certificate

~~means a certificate issued by a member of the *personnel of the Competent Authority* of the *exporting country*, certifying the state of health of the *aquatic animals*, and a declaration that the *aquatic animals* originate from a source subjected to official health *surveillance* according to the procedures described in the *Aquatic Manual*.~~

means a certificate, issued in conformity with the provisions of Chapter 5.10., describing the *aquatic animal* health and/or public health requirements ~~which~~ that ~~must~~ should be ~~are~~ fulfilled prior to export of the *aquatic animal* ~~by the exported~~ *commodity~~ies~~*.

Notification – Aquatic Code

means the procedure by which:

1. the *Veterinary Authority* informs the *Central Bureau*,

2. the *Central Bureau* informs *Veterinary Authorities* of Members

of the occurrence ~~confirmation~~ of a *disease* ~~*outbreak*~~, according to the provisions of Section 1. of the *Aquatic Code*.

Pathological material

~~means tissues, organs, fluids, etc., from *aquatic animals*, or strains of infectious organisms (which could be identified as an isolate or biovar) to be sent to an *aquatic animal disease* laboratory or to a reference laboratory recognised by the OIE, the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the European Union (EU), etc.~~

means samples obtained from live or dead *aquatic animals*, containing or suspected of containing ~~infectious or parasitic~~ *disease agents*, to be sent to a laboratory.

~~***Personnel of the Competent Authority***~~

~~means any competent personnel working within the body of, or designated by, the *Competent Authority*.~~

~~***Slaughtering***~~

~~means the killing and bleeding of fish.~~

Susceptible species

means a species of *aquatic animal* in which *infection* has been demonstrated by natural *cases* or by experimental exposures to the *disease agent* that mimics the natural pathways for *infection*. Each *disease* chapter in the *Aquatic Code* and *Aquatic Manual* contains a list of currently known *susceptible species*.

~~***Veterinary Services***~~

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

~~means the governmental and non-governmental organisations that implement animal health and *welfare* measures and other standards and recommendations in the OIE *Codes* in the territory. The *Veterinary Services* are under the overall control and direction of the *Veterinary Authority*. Private sector organisations, *veterinarians*, veterinary paraprofessionals or aquatic animal professionals are normally accredited or approved by the *Veterinary Authority* to deliver the delegated functions.~~

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— text deleted

Annex IV

CHAPTER 1.3.

DISEASES LISTED BY THE OIE

EU position

The EU supports the adoption of the modified Chapter

Preamble: The following *diseases* are listed by the OIE according to the criteria for listing an *aquatic animal disease* (see Article 1.2.1.) or criteria for listing an *emerging aquatic animal disease* (see Article 1.2.2.).

In case of modifications of this list of *aquatic animal diseases* adopted by the General Assembly, the new list comes into force on 1 January of the following year.

Article 1.3.1.

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

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

Article 1.3.2.

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

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*
- Infection with abalone herpes-like virus.

Article 1.3.3.

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

- Taura syndrome
- White spot disease
- Yellow head disease
- Infectious hypodermal and haematopoietic necrosis
- Crayfish plague (*Aphanomyces astaci*)

- Necrotising hepatopancreatitis ‡

- Infectious myonecrosis

- White tail disease

- ~~Milky haemolymph disease of spiny lobsters (*Panulirus* spp.) ‡~~.

Annex IV (contd)

Article 1.3.4.

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

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

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— text deleted

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

Annex V

AN EXAMPLE (DISEASE X) TO BE APPLIED ACROSS ALL DISEASE CHAPTERS (SECTIONS 8, 9, 10 AND 11)

EU position

The EU agrees with the proposed text.

Article X.X.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose ~~regardless of the Disease X status of the~~ from a ~~exporting~~ country, zone or compartment not declared free from Disease X

1. *Competent Authorities* should not require any Disease X related conditions, regardless of the Disease X status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article X.X.2. intended for any purpose and complying with Article 5.3.1.:

   [i) aquatic animal product(s).*] (under study)

2. When authorising the importation or transit of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article X.X.2., other than those referred to in point 1 of Article X.X.3., *Competent Authorities* should require the conditions prescribed in Articles X.X.7. to X.X.12. relevant to the Disease X status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of ~~*a commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of Disease X of~~rom~~ a species not covered in Article X.X.2. but which could reasonably be expected to pose a risk of transmission for Disease X, *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 X.X.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 Disease X

When importing, for processing for human consumption, ~~live~~ *aquatic animals* and *aquatic animal products* of the species referred to in Article X.X.2. from a country, *zone* or *compartment* not declared free from Disease X, 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* or containment facilities until ~~for~~ processing into one of the products referred to in point 1 of Article X.X.3., or products described in point 1 of Article X.X.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 Disease agent X or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* 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.

[…]

Annex V (contd)

Article X.X.12. (fish chapters) /Article X.X.11. (mollusc and crustacean chapters)

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Disease X

1. *Competent Authorities* should not require any Disease X related conditions, regardless of the Disease X status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   [i) commodity (s)*] (under study)

   For these *commodities* 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.

2. When importing ~~*live*~~ *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article X.X.2. from a country, *zone* or *compartment* not declared free from Disease X, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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— text deleted

* As currently listed in the *Aquatic Code* for each disease specific chapter. This list is considered under study until specific assessments have been completed and adopted

Annex VI

CHAPTER 5.3.

CRITERIA TO ASSESS THE SAFETY OF AQUATIC ANIMAL COMMODITIES

EU position

The EU agrees with the proposed text.

In the context of this chapter the word safety is applied only to animal health considerations for OIE listed *diseases.*

Article 5.3.1.

Criteria to assess the safety of aquatic animals and aquatic animal products for any purpose ~~commodities irrespective regardless of country~~ from a country, zone or compartment not declared free from disease X ~~status~~

In all *disease* chapters, point 1~~a)~~ of Article X.X.3. lists ~~*commodities*~~ *aquatic animals* and *aquatic animal products* that can be traded for any purpose ~~irrespective regardless of country~~ from a country, *zone* or *compartment* not declared free from disease X ~~status~~. The criteria for inclusion of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* in point 1~~a)~~ of Article X.X.3. are based on the absence of the *disease agent* in the traded ~~*commodity*~~ *aquatic animals* and *aquatic animal products* or inactivation of the *disease agent* by treatment or processing.

The assessment of the safety of the ~~*commodity*~~ *aquatic animals* and *aquatic animal product* 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*~~ *aquatic animal product* do not jeopardise the safety of the traded ~~*commodity*~~ *aquatic animal product*.

For an ~~*commodity*~~ *aquatic animal* or *aquatic animal product* to be considered safe for *international trade* under the provisions of ~~point 1a) of~~ Article X.X.3., it should comply with the following criteria:

1. Absence of *disease agent* in the traded ~~*commodity*~~ *aquatic animal* or *aquatic animal product*:

   a) There is strong evidence that the *disease agent* is not present in the tissues from which the ~~*commodity*~~ *aquatic animal* or *aquatic animal product* is derived.

   AND

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

OR

2. Even if the *disease agent* is present in, or contaminates the tissues from which the ~~*commodity*~~ *aquatic animal* or *aquatic animal product* is derived, the treatment or processing to produce the ~~*commodity*~~ *aquatic animal* or *aquatic animal product* to be traded inactivates the *disease agent*:

Annex VI (contd)

a) physical (e.g. temperature, drying, smoking);

AND/OR

b) chemical (e.g. iodine, pH, salt, smoke);

AND/OR

c) biological (e.g. fermentation).

Article 5.3.2.

Criteria to assess the safety of aquatic animals or ~~of~~ aquatic animal products ~~destined~~ for retail trade for human consumption from a country, zone or compartment not declared free of a ~~irrespective of country~~ disease ~~status~~

In all *disease* chapters, point 1~~b)~~ of Article X.X.12~~3~~. (fish disease chapters) and; Article X.X.X.11. (mollusc and crustacean disease chapters) lists *aquatic animals* or *aquatic animal products* for retail trade ~~destined~~ for human consumption. The criteria for inclusion of *aquatic animals* or *aquatic animal products* in point 1~~b)~~ of Article X.X.12~~3~~. (fish disease chapters) and; Article X.X.X.11. (mollusc and crustacean disease chapters) include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely ~~quantity~~ presence of viable *disease agent* in the waste.

For the purpose of this criterion retail means the selling or provision of ~~live~~ *aquatic animals* or *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:

(i) the ~~live~~ *aquatic animals* or *aquatic animal products* ~~is~~ are used for human consumption only;

ii) waste may not always be handled in an appropriate manner that mitigates the introduction of the *disease agent*. The level of risk is related to the waste disposal practices in each Member's country or territory;

(iii) 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)~~

(iv) ~~that~~ any other steps in the treatment, processing and subsequent handling of the ~~live~~ *aquatic animals* or *aquatic animal products* prior to importation do not jeopardise the safety of the traded ~~live~~ *aquatic animals* or *aquatic animal products*.

For ~~live~~ *aquatic animals* or *aquatic animal products* to be considered ~~safe~~ for *international trade* under the provisions of point 1~~b)~~ of Article X.X.12~~3~~. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters), it should comply with the following criteria:

1. the *aquatic animals* or *aquatic animal product* is prepared and packaged for retail trade for human consumption; AND

EITHER

2. it includes only a small amount of waste tissues generated by the consumer;

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 generated by the consumer~~;~~.

   ~~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);~~

         ~~OR~~

      ~~ii) chemical (e.g. pH, salt, smoke);~~

         ~~OR~~

      ~~iii) biological (e.g. fermentation).~~

- - - - - - - - - - - - - - -

— text deleted

Annex VII (A)

CHAPTER 10.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

EU position

The EU agrees with the proposed text.

[…]

Article 10.1.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a exporting country, zone or compartment not declared free from epizootic haematopoietic necrosis

1. *Competent Authorities* should not require any EHN related conditions, regardless of the EHN status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.1.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

   ii) pasteurised fish products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent which has been demonstrated to inactivate EHNV;

   iii) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or equivalent);

   iv) fish skin leather;

   v) fish oil; and

   vi) fish meal.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.1.2., other than those referred to in point 1 of Article 10.1.3., *Competent Authorities* should require the conditions prescribed in Articles 10.1.7. to 10.1.12. relevant to the EHN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of EHN from a species not covered in Article 10.1.2. but which could reasonably be expected to pose a risk of transmission for EHN, *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 10.1.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

When importing, for processing for human consumption, *aquatic animals* and *aquatic animal products* of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Annex VII (A) (contd)

1. the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.1.3., or products described in point 1 of Article 10.1.12., 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 EHNV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

[…]

Article 10.1.12.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

1. *Competent Authorities* should not require any EHV related conditions, regardless of the EHV status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) fillets or steaks (chilled or frozen).

   For these *commodities* 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.

2. When importing *aquatic animals* and *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation *measures*.

— text deleted

CHAPTER 9.4.

TAURA SYNDROME

EU position

The EU agrees with the proposed text.

[…]

Article 9.4.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from Taura Syndrome

1. *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 9.2.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

   ii) cooked crustacean products that have been subjected to heat treatment at 70°C for at least 30 minutes or to any equivalent treatment which has been demonstrated to inactivate TSV;

   iii) pasteurised crustacean products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent.

   iv) crustacean oil;

   v) crustacean meal; and

   vi) chemically extracted chitin.

2. When authorising the importation or transit of the *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.4.2., other than those listed in point 1 of Article 9.4.3., *Competent Authorities* should require the conditions prescribed in Articles 9.4.7. to 9.4.11. relevant to the TS status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of a *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of TS from a species not covered in Article 9.4.2. but which could reasonably be expected to pose a risk of transmission for TSV, *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 9.4.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from Taura syndrome

When importing, for processing for human consumption, *aquatic animals* and *aquatic animal products* of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Annex VII (A) (contd)

1. the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.4.3., or products described in point 1 of Article 9.4.11., or other products authorised by the *Competent Authority*; and

2. all effluent and waste materials from the processing are treated in a manner that ensures inactivation of TSV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

[…]

Article 9.4.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Taura syndrome

1. *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) frozen, peeled shrimp (shell off, head off).

   For these *commodities* 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.

2. When importing *aquatic animals or aquatic animal products,* other than those referred to in point 1 above, of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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— text deleted

CHAPTER 11.2.

INFECTION WITH *BONAMIA OSTREAE*

EU position

The EU agrees with the proposed text.

[…]

Article 11.2.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from *B. ostreae*

1. *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 11.2.2. intended for any purpose and complying with Article 5.3.1.:

   i) frozen oyster meat

   ii) frozen half-shell oysters

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.2.2., other than those referred to in point 1 of Article 11.2.3., *Competent Authorities* should require the conditions prescribed in Articles 11.2.7. to 11.2.11. relevant to the *B. ostreae* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of infection with *B. ostreae* from a species not covered in Article 11.2.2. but which could reasonably be expected to pose a risk of transmission for *B. ostreae*, *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 11.2.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from *B. ostreae*

When importing, for processing for human consumption, *aquatic animals* and *aquatic animal products* of the species referred to in Article 11.2.2. from a country, *zone* or *compartment* not declared free from *B. ostreae*, 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* or containment facilities until processing into one of the products referred to in point 1 of Article 11.2.3., or products described in point 1 of Article 11.2.11., 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 *B. ostreae* or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

Annex VII (A) (contd)

[…]

Article 11.2.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from *B. ostreae*

1. *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) chilled oyster meat;

   ii) chilled half-shell oysters.

   For these *commodities* 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.

2. When importing *aquatic animals or aquatic animal products,* other than those referred to in point 1 above, of the species referred to in Article 11.2.2. from a country, *zone or compartment* not declared free from *B. ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk mitigation* measures.

— text deleted

Annex VII (B)

CHAPTER 10.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

EU position

The EU agrees with the proposed text.

[…]

Article 10.1.3.

~~Commodities~~ Importation or transit of aquatic animals and aquatic animal products for any purpose ~~regardless of the EHN status of the~~ from a exporting country, zone or compartment not declared free from EHN

1. ~~When authorising the importation or transit of the following *commodities*, the~~ *Competent Authorities* should not require any EHN related conditions, regardless of the EHN status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.1.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

   ii) pasteurised fish products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent which has been demonstrated to inactivate EHNV;

   iii) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or equivalent);

   iv) fish skin leather;

   v) fish oil; and

   vi) fish meal.

   ~~a) From the species referred to in Article 10.1.2. intended for any purpose:~~

      ~~i) *commodities* treated in a manner that inactivates the *disease agent* e.g. fish skin leather made from fish skin,;~~

      ~~ii) pasteurised products and some ready-to-eat meals; and~~

      ~~iii) fish oil; and~~

      ~~iv) fish *meal* intended for use in *feed*;~~

      ~~ii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.~~

Annex VII (B) (contd)

~~b) The following *commodities* destined for human consumption from the species referred to in Article 10.1.2. 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), OIE 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.~~

2. When authorising the importation or transit of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.1.2., other than those referred to in point 1 of Article 10.1.3., ~~the~~ *Competent Authorities* should require the conditions prescribed in Articles 10.1.7. to 10.1.12. relevant to the EHN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation~~/~~ or transit of ~~a *commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of EHN ~~of a live *commodity*~~ from a species not covered in Article 10.1.2. but which could reasonably be expected to pose a risk of transmission ~~be a potential mechanical vector~~ for EHN, ~~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 10.1.9.

Importation of ~~live~~ aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

When importing, for processing for human consumption, ~~live~~ *aquatic animals* and *aquatic animal products* of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment ~~be~~ is delivered directly to and held in *quarantine* or containment facilities until ~~for slaughter and~~ processing into one of the products referred to in point 1 of Article 10.1.3., or products described in point 1 of Article 10.1.12., 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 EHNV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* ~~OIE~~ Members may wish to consider introducing internal measures to address the *risks* associated with the *commodity* ~~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 10.1.3.~~

[…]

Article 10.1.12.

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

1. *Competent Authorities* should not require any EHV related conditions, regardless of the EHV status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   ~~i)~~ ~~*eviscerated fish* (chilled or frozen);~~

   ~~ii)~~ fillets or steaks ~~cutlets~~ (chilled or frozen)~~; and~~

   ~~iii)~~ ~~artificially dried *eviscerated fish* (including air dried, flame dried and sun dried).~~

   For these *commodities* 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.

2. When importing ~~live~~ *aquatic animals* and *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

2. ~~1. the direct delivery into and holding of the consignment in facilities for processing to one of the~~ products referred to in point 1 of Article 10.1.3. or other products authorised by the Competent Authority;

~~3.~~ 2. the ~~treatment of all effluent and waste material in a manner that ensures inactivation of EHNV.~~

~~This Article does not apply to *commodities* referred to in point 1 of Article 10.1.3.~~

- - - - - - - - - - - - - - -

— text deleted

CHAPTER 9.4.

TAURA SYNDROME

EU position

The EU agrees with the proposed text.

[…]

Article 9.4.3.

~~Commodities~~ Importation or transit of aquatic animals and aquatic animal products for any purpose ~~regardless of the Taura Syndrome status of the~~ from a ~~exporting~~ country, zone or compartment not declared free from Taura Syndrome

1. ~~When authorising the importation or transit of the following *commodities*, the~~ *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article 9.2.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

   ii) cooked crustacean products that have been subjected to heat treatment at 70°C for at least 30 minutes or to any equivalent treatment which has been demonstrated to inactivate TSV;

   iii) pasteurised crustacean products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent;

   iv) crustacean oil;

   v) crustacean meal; and

   vi) chemically extracted chitin.

   ~~a) For the species referred to in Article 9.4.2. intended for any purpose:~~

      ~~i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled cooked products~~

      ~~ii) canned products; or pasteurised products and some ready-to-eat meals; and~~

      ~~iii) crustacean oil; and~~

      ~~iv) crustacean *meal* intended for use in *feed*;~~

      ~~iiv) chemically extracted chitin.~~

~~iii) crustacean products made non infectious through processing as dry *feed* (e.g. pelleted or extruded *feed*);~~

Annex VII (B) (contd)

~~iv) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.~~

~~b) [The following products destined for human consumption from species referred to in Article 9.4.2. which have been prepared and packaged for direct retail trade:] (under study)~~

2. When authorising the importation or transit of the ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.4.2., other than those listed in point 1 of Article 9.4.3., ~~the~~ *Competent Authorities* should require the conditions prescribed in Articles 9.4.7. to 9.4.11. relevant to the TS status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation~~/~~ or transit of a ~~*commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of TS ~~of a *commodity* of~~ from a species not covered in Article 9.4.2. but which could reasonably be expected to pose a risk of transmission ~~be a potential mechanical vector~~ for TSV, ~~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 9.4.9.

Importation of ~~live~~ aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from Taura syndrome

When importing, for processing for human consumption, ~~live~~ *aquatic animals* and *aquatic animal products* of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment ~~be~~ is delivered directly to and held in *quarantine* or containment facilities ~~isolation until~~ until ~~for~~ processing ~~and/or consumption;~~ into one of the products referred to in point 1 of Article 9.4.3., or products described in point 1 of Article 9.4.11., or other products authorised by the *Competent Authority*; and

2. all effluent~~, dead *aquatic animals*~~ and waste materials ~~s~~ from the processing ~~be~~ are treated in a manner that ensures inactivation of TSV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* ~~OIE~~ Members may wish to consider introducing internal measures to address the *risks* associated with the ~~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 9.4.3.~~

[…]

Article 9.4.11.

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Taura syndrome

1. *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

~~[~~i) frozen, peeled shrimp (shell off, head off)~~] (under study)~~.

For these *commodities* 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.

2. When importing ~~*live*~~ *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, 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 9.4.3.~~

- - - - - - - - - - - - - - -

— text deleted

CHAPTER 11.2.

INFECTION WITH *BONAMIA OSTREAE*

EU position

The EU agrees with the proposed text.

[…]

Article 11.2.3.

~~Commodities~~ Importation or transit of ~~live~~ aquatic animals and aquatic animal products for any purpose ~~regardless of the *B. ostreae* status of the~~ from a ~~exporting~~ country, zone or compartment not declared free from *B. ostreae*

1. ~~When authorising the importation or transit of the following *commodities*, the~~ *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article 11.2.2. intended for any purpose and complying with Article 5.3.1.~~:~~

   i) frozen oyster meat;

   ii) frozen half-shell oysters.

   ~~a) From the species referred to in Article 11.2.2. intended for any purpose:~~

   ~~i) *commodities* treated in a manner that inactivates the *disease agent* e.g.canned or~~

   ~~ii) pasteurised 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 11.2.2. which have been prepared and packaged for direct retail trade:~~

      ~~i) off the shell (chilled or frozen);~~

      ~~ii) half-shell (chilled).~~

   ~~c) All *commodities* from *Crasso straggas*, *C. virginica*, *Rudit apesdecussa tus*, *R. philippin arum* , *Mytilusgallo provincialis* and *M.edulis*, including the live *aquatic animal.*~~

~~For the *commodities* referred to in point 1b), OIE 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.~~

2. When authorising the importation or transit of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.~~1~~.2.2., other than those referred to in point 1 of Article 11.2.3., ~~the~~ *Competent Authorities* should require the conditions prescribed in Articles 11.2.7. to 11.2.11. relevant to the *B. ostreae* status of the *exporting country*, *zone* or *compartment*.

Annex VII (B) (contd)

3. When considering the importation~~/~~ or transit of ~~a *commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of infection with *B. ostreae* ~~of a *commodity*~~ from ~~bivalve~~ a species not covered in Article 11.2.2. ~~or in point 1c) of Article 11.2.3.~~ but which could reasonably be expected to pose a risk of transmission ~~be a potential mechanical vector~~ for *B. ostreae*, ~~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 11.2.9.

Importation of ~~live~~ aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from *B. ostreae*

When importing, for processing for human consumption, ~~live~~ *aquatic animals* and *aquatic animal products* of the species referred to in Article 11.2.2. from a country, *zone* or *compartment* not declared free from *B. ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment ~~be~~ is delivered directly to and held in *quarantine* or containment facilities ~~until~~ ~~for~~ until processing ~~and/or consumption~~ into one of the products referred to in point 1 of Article 11.2.3., or products described in point 1 of Article 11.2.11., 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 *B. ostreae* or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

~~This Article does not apply to *commodities* referred to in point 1 of Article 10.1.3.~~

[…]

Article 11.2.11.

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from *B. ostreae*

1. *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) ~~off the shell~~ chilled oyster meat ~~(chilled or frozen)~~;

   ii) chilled half-shell oysters ~~(chilled or frozen).~~

   For these *commodities* 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.

2. When importing ~~*live*~~ *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the *species* referred to in Article 11.2.2. from a country, *zone or compartment* not declared free from *B. ostreae*, 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 10.1.3.~~

— text deleted

Annex VIII

CHAPTER 5.9.

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

EU position

The EU agrees with the proposed text.

Article 5.9.1.

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 5.9.2.

[…]

— text deleted

Annex IX

CHAPTER 2.2.

IMPORT RISK ANALYSIS

EU position

The EU agrees with the proposed text.

[…]

Article 2.2.3.

Principles of risk assessment

1. *Risk assessment* should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. *Risk assessment* ~~must~~ should be able to accommodate the variety of animal *commodities*, the multiple *hazards* that may be identified with an importation and the specificity of each *disease*, detection and *surveillance* systems, exposure scenarios and types and amounts of data and information.

2. Both *qualitative risk assessment* and *quantitative risk assessment* methods are valid. ~~Although quantitative assessment is recognised as being able to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited.~~

[…]

— text deleted

Annex X

CHAPTER 3.1.

QUALITY OF ~~COMPETENT AUTHORITIES~~ AQUATIC ANIMAL HEALTH SERVICES

EU position

The EU supports the adoption of the modified chapter.

However, in the first paragraph of Article 3.1.5, Competent Authorities should be replaced by Aquatic Animal Health Services at the end of the sentence, in the interest of consistency in wording. This paragraph should read:

The OIE has established procedures for the evaluation of ~~*Competent Authorities*~~ *Aquatic Animal Health Services* of Members. Members can make a request to the OIE for an evaluation of their ~~***Competent Authorities***~~ ***Aquatic Animal Health Services***

Article 3.1.1.

~~The quality of *Competent Authorities*~~ *Aquatic Animal Health Services* of OIE Members ~~depends on multiple factors that include~~ need to embody the fundamental principles of an ethical, organisational, legislative, regulatory and technical nature. ~~*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 a Member's ~~the *Competent Authority*~~ *Aquatic Animal Health Service* ~~of an OIE Member Country or Territory (Member)~~ is important ~~to~~ in the establishment and maintenance of confidence in its ~~*international*~~ *aquatic animal health status and international health certificates* ~~by *Competent Authorities* of other Members~~.

These fundamental principles are presented in Article 3.1.2. Other factors ~~affecting the quality of *Competent Authorities*~~ to consider when evaluating *Aquatic Animal Health Services* are described in the *Aquatic Code* (*notification*, principles of certification, etc.).

The ~~quality~~ ability of ~~*Competent Authorities*~~ *Aquatic Animal Health Services* to deliver, monitor and control *aquatic animal diseases* based on Members' ~~including~~ aquatic animal health legislation and regulations, can be measured through an evaluation or audit whose~~, the~~ general principles ~~of which~~ are described in Article 3.1.3. and in Article 3.1.4.

A procedure for evaluating ~~*Competent Authorities*~~ *Aquatic Animal Health Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

Article 3.1.2.

Fundamental principles of quality

~~*Competent Authorities*~~ *Aquatic Animal Health Services* should comply with the following principles to ensure the quality of their activities:

1. Professional judgement

~~The personnel of~~ ~~*Competent Authorities*~~ *Aquatic Animal Health Services* should ensure that personnel 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 Authority*~~ *Aquatic Animal Health Service* personnel are free from any commercial, financial, hierarchical, political or other pressures which may inappropriately influence ~~might affect~~ their judgement or decisions.

Annex X (contd)

3. Impartiality

~~Competent Authorities~~ *Aquatic Animal Health Services* 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.

4. Integrity

~~Competent Authorities~~ *Aquatic Animal Health Services* are responsible for ensuring ~~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

~~Competent Authorities~~ *Aquatic Animal Health Services* should conduct themselves, ~~at all times act~~ in an objective, transparent and non-discriminatory manner.

6. Aquatic animal health legislation and regulations

Aquatic animal health legislation and regulations ~~is~~ are a fundamental element ~~of quality~~ that ~~as it~~ supports good governance and provides the legal framework for all key activities of the ~~*Competent Authority*~~ *Aquatic Animal Health Service.*

Legislation and regulations should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, ~~it~~ they should define and document the responsibilities and structure of the organisations in charge of traceability and ~~the animal identification system,~~ 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* when they are in charge of veterinary public health activities.~~

~~6~~7. General organisation

~~Competent Authorities~~ *Aquatic Animal Health Services* ~~must~~ should be able to demonstrate by means of an appropriate legislation and regulations ~~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. ~~The regulatory framework should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, 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* when they are in charge of veterinary public health activities.~~

~~Competent Authorities~~ *Aquatic Animal Health Services* should have at their disposal effective systems for *aquatic animal disease surveillance*, *diagnosis* and *notification* of disease problems 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.

~~*Competent Authorities*~~ *Aquatic Animal Health Services* 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 Authority*~~ *Aquatic Animal Health Services* 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~~8. Quality policy

~~*Competent Authorities*~~ *Aquatic Animal Health Services* 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 a suitable reference system, which should be used if a Member chooses to adopt a quality system.

~~8~~9. Procedures and standards

~~*Competent Authorities*~~ *Aquatic Animal Health Services* 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 pathogens in *aquatic animal* products.

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

Annex X (contd)

~~9~~10. Information, complaints and appeals

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

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

~~10~~11. Documentation

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

~~11~~12. Self-evaluation

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

A procedure for evaluating ~~*Competent Authorities*~~ *Aquatic Animal Health Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

~~12~~13. Communication

~~*Competent Authorities*~~ *Aquatic Animal Health Services* should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.

~~13~~14. Human and financial resources

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

Article 3.1.3.

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 Authority*~~ *Aquatic Animal Health Services* where the initiating Member is an actual or a prospective importer of *aquatic animal 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 Authority*~~ *Aquatic Animal Health Services* 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 3.1.4.

A Member which intends to conduct an evaluation of another Member's ~~*Competent Authority*~~ *Aquatic Animal Health Services* should 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 Authority*~~ *Aquatic Animal Health Services* by another Member, and following bilateral agreement of the evaluation process and criteria, a Member should expeditiously provide the 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 3.1.1. and in Article 3.1.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 3.1.1., prevailing in the countries concerned.

The outcome of an 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 which 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 ~~*Competent Authorities*~~ *Aquatic Animal Health Services*, the matter should be dealt with having regard to the procedures set out in Article 3.1.3.

Article 3.1.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of ~~*Competent Authorities*~~ *Aquatic Animal Health Services* of Members. Members can make a request to the OIE for an evaluation of their *Competent Authority*.

The World Assembly of OIE Delegates 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*~~ *Aquatic Animal Health Services* of the Member using the OIE PVS *Tool*: Application to Aquatic Animal Health Services (~~*for the Evaluation of Performance of Veterinary Services* (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*~~ *Aquatic Animal Health Services* 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.

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Annex XI

CHAPTER 4.1.

ZONING AND COMPARTMENTALISATION

EU position

The EU agrees with the proposed amendments

Article 4.1.1.

Introduction

Given the difficulty of establishing and maintaining freedom from a particular *disease* for an entire country especially for *diseases* whose entry is difficult to control, there may be benefits to one or more Members in establishing and maintaining a *subpopulation* with a distinct aquatic animal health status. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management practices.

Zoning and compartmentalisation are procedures implemented by a country under the provisions of this chapter to define *subpopulations* of distinct aquatic animal health status for the purpose of *disease* control or *international trade*. Compartmentalisation applies to a *subpopulation* when management practices related to biosecurity are the defining factors, while zoning applies when a *subpopulation* is defined on a geographical basis. In practice, spatial considerations and good management play important roles in the application of both concepts.

This chapter is to assist OIE Members wishing to establish and maintain different *subpopulations*, using the principles of compartmentalisation and zoning. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks* of *disease*.

Before trade in *aquatic animals* or *aquatic animal products* may occur, an *importing country* needs to be satisfied that its *aquatic animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its *territory*.

In addition to contributing to the safety of *international trade*, zoning and compartmentalisation may assist *disease* control or eradication within Members. Zoning may encourage the more efficient use of resources, and compartmentalisation may allow the functional separation of a *subpopulation* from other domestic or wild *aquatic animals* through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following an *outbreak* of *disease*, compartmentalisation may allow a Member be able to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the resumption of trade.

Zoning and compartmentalisation may not be applicable to all *diseases*, but separate requirements will be developed for each *disease* for which the application of zoning or compartmentalisation is considered appropriate.

To regain the status of a *free zone* or *free compartment* following an *outbreak* of *disease*, Members should follow the recommendations in the relevant *disease* chapter in the *Aquatic Code*.

Annex XI (contd)

Article 4.1.2.

General considerations

The *Competent Authority* of an *exporting country* that is establishing a *zone* or *compartment* for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Aquatic Code*, including those on *surveillance*, and the identification and traceability of *aquatic animals*. The *Competent Authority* of an *exporting country* should be able to explain to the *Competent Authority* of an *importing country* the basis for its claim of a distinct *aquatic animal health status* for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, *risk* of introduction and establishment of *disease*, and applicable biosecurity measures. The *exporting country* should be able to demonstrate, through detailed documentation supplied to the *importing country*, published through official channels, that it has implemented the recommendations in the *Aquatic Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Aquatic Code* are applied, and the *Competent Authority* of the *exporting country* certifies that this is the case. Note that an *importing country* may adopt a higher level of protection where it is scientifically justified and the obligations referred to in Article 2.1.2. are met. Article 4.1.4. is also relevant.

Where countries share a *zone* or *compartment*, the *Competent Authority* of each country should collaborate to define and fulfil their respective responsibilities.

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources and the technical capability of the *Competent Authority* (and of the relevant industry, in the case of a *compartment*) including on *disease surveillance* and *diagnosis*.

Article 4.1.3.

Principles for defining a zone or compartment, including protection zones

In conjunction with the above considerations and the definitions of *zone* and *compartment*, the following principles should apply when Members define a *zone* or *compartment*:

1. The extent of a *zone* should be established by the *Competent Authority* on the basis of the definition of *zone* and made public through official channels.

2. A protection zone may be established to preserve the health status of *aquatic animals* in a free country or *zone*, from adjacent countries or *zones* of different aquatic animal health status. Measures should be implemented based on the epidemiology of the *disease* under consideration to prevent introduction of the pathogenic agent. These measures should include intensified movement control and *surveillance* and may ~~also~~ include vaccination, ~~special identification,~~ raised awareness or other measures.

   The application of these measures can be in the entire *free zone* or in a defined area within and/or outside the *free zone*.

~~2~~3. The factors defining a *compartment* should be established by the *Competent Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.

~~3~~4. *Aquatic animals* belonging to such *subpopulations* need to be recognizable as such through a clear epidemiological separation from other *aquatic animals* and all things presenting a *disease risk*.

~~4~~5. For a *zone* or *compartment*, the *Competent Authority* should document in detail the measures taken to ensure the identification of the *subpopulation*, for example by means of registration of all the *aquaculture establishments* located in such a *zone* or *compartment* and the establishment and maintenance of its *aquatic animal health status* through a *biosecurity plan*. The measures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, the *aquatic animal health status* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *aquatic animals*, and commercial management and husbandry practices), and *surveillance*.

~~5~~6. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant enterprise/industry and the *Competent Authority*, and their respective responsibilities, including the procedures for oversight of the operation of the *compartment* by the *Competent Authority*.

~~6~~7. For a *compartment*, the *biosecurity plan* should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted and the management practices are adequate to meet the definition of the *compartment*. In addition to information on *aquatic animal* movements, the *biosecurity plan* should include production and stock records, *feed* sources, traceability, *surveillance* results, visitor logbook, morbidity and mortality history, medications, vaccinations, water supply and effluent treatments, documentation of training and any other criteria necessary for evaluation of *risk* mitigation. The information required may vary according to the *aquatic animal* species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the *risks* are regularly re-assessed and the measures adjusted accordingly.

~~7~~8. Thus defined, the *zones* and *compartments* constitute the relevant *subpopulations* for the application of the recommendations in Section 8. to Section 11. of the *Aquatic Code*.

Article 4.1.4.

Sequence of steps to be taken in establishing a zone ~~or a compartment and~~ having it recognised for international trade purposes

There is no single sequence of steps which should be followed in establishing a *zone* ~~or a *compartment*~~. The steps that the *Competent Authority* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. For zoning

   a) The *exporting country* identifies a geographical area, which it considers to contain an *aquatic animal subpopulation* with a distinct aquatic animal health status with respect to a specific *disease*/specific *diseases*, based on *surveillance*.

   b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its *territory*, in accordance with the recommendations in the *Aquatic Code*.

   c) The *exporting country* provides the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separated *zone* for *international trade* purposes.

Annex XI (contd)

d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:

i) an evaluation of the *exporting country*'s *Competent Authority*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and

iv) other relevant OIE standards.

e) The *importing country* notifies the *exporting country* of the result of its determination and the underlying reasons, within a reasonable period of time, being either:

i) recognition of the *zone*;

ii) request for further information; or

iii) rejection of the area as a *zone* for *international trade* purposes.

f) an attempt should be made to resolve any differences over the recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism).

g) The *importing country* and the *exporting country* should enter into a formal agreement recognising the *zone*.

2. For compartmentalisation

Refer to Chapter 4.X.

~~a) Based on discussions with the relevant enterprise/industry, the *exporting country* identifies a *compartment* of one or more *aquaculture establishments* or other premises that operate under common management practices related to biosecurity, and which contains an identifiable *aquatic animal subpopulation* with a distinct aquatic animal health status with respect to a specific *disease*/specific *diseases*; the *exporting country* describes how this status is maintained through a partnership between the relevant enterprise/industry and the *Competent Authority* of the *exporting country*.~~

~~b) The *exporting country* examines the *compartment*'s *biosecurity plan* and confirms through an audit that:~~

~~i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and~~

~~ii) the *surveillance* programme in place is appropriate to verify the status of such *aquaculture establishment(s)* with respect to such *disease(s)*.~~

~~c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Aquatic Code*.~~

~~d) The *exporting country* provides the above information to the *importing country*, with an explanation of why such an enterprise can be treated as an epidemiologically separated *compartment* for *international trade* purposes.~~

e) The *importing country* determines whether it accepts such an enterprise as a *compartment* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:

i) an evaluation of the *exporting country*'s *Competent Authority*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and

iv) ther relevant OIE standards.

f) The *importing country* notifies the *exporting country* of the result of its examination and the underlying reasons, within a reasonable period of time, being either:

i) recognition of the *compartment*;

ii) request for further information; or

iii) rejection of such an enterprise as a *compartment* for *international trade* purposes.

g) An attempt should be made to resolve any differences over the recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism).

h) The *importing country* and the *exporting country* should enter into a formal agreement recognising the *compartment*.

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Annex XII

CHAPTER 4.X.

APPLICATION OF COMPARTMENTALISATION

EU position

The EU would agree with the proposed amendments.

Article 4.X.1.

Introduction and objectives

The recommendations in this Chapter provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 4.1. with the objective to facilitate trade in *aquatic animals* and products of *aquatic animal* origin and as a tool for *disease* management.

Establishing and maintaining a disease free-status throughout the country should be the ~~final~~ ultimate goal for OIE Members. However, establishing and maintaining a *disease*-free status for an entire country may be difficult, especially in the case of *diseases* that exist in wild *aquatic animal* species or can easily cross international boundaries. For many *diseases*, OIE Members have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based ~~of~~ on management ~~practices~~ and biosecurity practices. However, spatial considerations and good management practices play a role in the application of both concepts.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of *subpopulations*.

For example, an *aquaculture establishment* in an infected country or *zone* might have biosecurity measures and management practices that result in negligible *risk* from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease*-specific separation between *subpopulations*.

In *disease*-free countries or *zones*, it is preferable that *compartments* ~~preferably should be~~ are defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* ~~must~~ should be under the responsibility of the *Veterinary Authority* or other *Competent Authority* in the country. For the purposes of this Chapter, compliance by the Members with Chapters 1.1. and 3.1. is an essential prerequisite.

Article 4.X.2.

Principles for defining a compartment

A *compartment* may be established with respect ~~of~~ to a specific *disease* or *diseases*. A *compartment* ~~must~~ should be clearly defined.~~,~~ This should indicate~~ing~~, *inter alia*, the location of all its components including *establishments,* as well as related functional units (such as brood stock facilities, hatcheries, nurseries, grow-out facilities, slaughterhouses, processing plants etc.).~~,~~ It should also describe their interrelationships and their contribution to an epidemiological separation between the *aquatic animals* in a *compartment* and *subpopulations* elsewhere with a different health status. The definition of *compartment* ~~may revolve around~~ should encompass *disease* specific epidemiological factors, the *aquatic animal* species in the *compartment*, production systems, biosecurity practices infrastructural factors and *surveillance*.

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Article 4.X.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* ~~must~~ should provide to the *Competent Authority* documented evidence on the following:

1. Physical or spatial factors that affect the status of biosecurity in a compartment

   While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and *surveillance* measures:

   a) disease status in adjacent areas and in areas epidemiologically linked to the *compartment*;

   b) location, disease status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:

      i) *aquatic animal* populations with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;

      ii) slaughterhouses or processing plants;

      iii) exhibitions, 'put and take' fisheries, fish markets, restaurants with live fish and other points of *aquatic animal* concentration.

2. Infrastructural factors

   Structural aspects of an establishment or ~~of the~~ *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

   a) water supply;

   b) effective means of physical separation;

   c) facilities for people entry including access control;

   d) vehicle and vessel access including washing and disinfection procedures;

   e) unloading and loading facilities;

   f) isolation facilities for introduced *aquatic animals*;

   g) facilities for the introduction of material and equipment;

   h) infrastructure to store feed and veterinary products;

   i) disposal of ~~carcasses~~ *aquatic animal* waste;

   j) measures to prevent exposure to fomites, ~~living~~ mechanical or biological vectors;

   k) feed supply/source.

3. Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

a) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including *aquatic animal* movements, wild aquatic animals, potential vectors, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;

b) the critical control points for each pathway;

c) measures to mitigate exposure for each critical control point;

d) standard operating procedures including:

   i) implementation, maintenance, monitoring of compliance with the risk mitigation measures,

   ii) application of corrective actions,

   iii) verification of the process,

   iv) record keeping;

e) contingency plan in the event of a change in the level of exposure;

f) reporting procedures to the *Veterinary Authority* or other *Competent Authority*;

g) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;

h) the *surveillance* programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the *biosecurity* plan in accordance with the level of *risk* for each identified pathway. This evidence should be structured in line with the principles of Hazard Analysis and Critical Control Point (HACCP). The biosecurity risk of all operations of the *compartment* should be ~~regularly~~ re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the disease agent into the *compartment*.

4. Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid *traceability* system. Although individual identification of *aquatic animals* may not be feasible, the *Veterinary Authority* or other *Competent Authority* should provide sufficient assurance of *traceability* in such a way that their history and movements can be documented and audited.

All *aquatic animal* movements into and out of the *compartment* should be recorded at the *compartment* level, and when needed, based on a *risk assessment*, ~~certified~~ approved by the *Veterinary Authority* or other *Competent Authority*. Movements within the *compartment* need not be certified but should be recorded and documented at the *compartment* level.

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Article 4.X.4.

Documentation

Documentation ~~must~~ should provide clear evidence that the biosecurity, *surveillance*, *traceability* and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include production unit records (e.g. cage, pond), feed sources, laboratory tests, ~~death~~ mortality records, ~~the~~ visitor logbook, morbidity history, water supply and effluent treatments medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Aquatic Code* Chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary Authority* or other *Competent Authority* a baseline *aquatic animal* health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current *aquatic animal health status* of the *compartment*.

Vaccination records including the *aquatic animal* groups vaccinated, type of vaccine and frequency of administration ~~must~~ should be available to enable interpretation of *surveillance* data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information ~~must~~ should be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary Authority* or other *Competent Authority*.

Article 4.X.5.

Surveillance for the disease agent or disease

The *surveillance* system should comply with Chapter 1.4. on Surveillance and the specific recommendations for *surveillance* for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased *risk* of exposure to the agent for which the *compartment* has been defined, the ~~detection level~~ sensitivity of the internal and external *surveillance* system should be reviewed, documented and, where necessary, ~~raised~~ increased. At the same time, biosecurity measures in place should be reassessed and increased if necessary.

1. Internal surveillance

   Surveillance should involve the collection and analysis of *disease/infection* data so that the *Veterinary Authority* or other *Competent Authority* can certify that the animal *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A *surveillance* system that is able to ensure early detection in the event that the agent enters a *subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different *surveillance* strategies may be applied to achieve the desired confidence in *disease* freedom.

2. External surveillance

   The biosecurity measures applied in a *compartment* ~~must~~ should be appropriate to the level of exposure of the *compartment*. External *surveillance* will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of ~~active~~ targeted and passive *surveillance* is necessary to achieve the goals described above. Based on the recommendations of Chapter 1.4., targeted *surveillance* based on an assessment of *risk* factors may be the most efficient *surveillance* approach. Targeted *surveillance* should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 4.X.6.

Diagnostic capabilities and procedures

Officially-designated laboratory facilities should be available for sample testing. All laboratory tests and procedures should comply with the recommendations of the *Aquatic Manual* ~~*laboratory*~~ for the specific *disease*. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary Authority* or other *Competent Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 4.X.7.

Emergency response and notification

Early detection, diagnosis, ~~and~~ notification of *disease* and rapid response are critical to minimise the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, the free status of the *compartment* should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.

In case of the detection ~~an occurrence~~ of any ~~infectious~~ *disease* not present according to the baseline animal health report of the *compartment* referred to in Article 4.2.4., the management of the *compartment* should notify the *Veterinary Authority* or other *Competent Authority*, and initiate a review to determine whether there has been a breach in the biosecurity measures and notify the *Veterinary Authority* or other *Competent Authority*. If a significant breach in biosecurity, even in the absence of *outbreak*, is detected, export certification as a free *compartment* should be suspended. Disease free status of the *compartment* may only be reinstated after the *compartment* has adopted the necessary measures to re-establish the original biosecurity level and the *Veterinary Authority* or other *Competent Authority* re-approves the status of the *compartment*.

In the event of a *compartment* being at risk from a change, in the surrounding area, in the disease situation for which the *compartment* was defined, the *Veterinary Authority* should re-evaluate without delay the status of the *compartment* and consider whether any additional biosecurity measures are needed to ensure that the integrity of the *compartment* is maintained.

Article 4.X.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Veterinary Services*, including laboratories, ~~must~~ should be clearly documented in accordance with the Chapter on the Evaluation of *Veterinary Services* of the *Aquatic Code*, to provide confidence in the integrity of the *compartment*.

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The *Veterinary Authority* or other *Competent Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary Authority* or other *Competent Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this Chapter and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.

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Annex XIII

CHAPTER 4.5.

CONTROL OF HAZARDS ~~OF AQUATIC ANIMAL HEALTH HAZARDS AND PUBLIC HEALTH IMPORTANCE~~ IN AQUATIC ANIMAL FEEDS

EU position

The EU supports the adoption of the revised chapter.

However, the EU wishes the AAC to take the following comment into account in future revisions of this chapter:

In Article 4.5.8 the point 1 b) and point 1 c) the possible risk mitigating measures referred to are formulated quite differently. For instance, whereas point 1 b) i) refers to "disease free country, free zone or free compartment", point 1 c) refers to "sourcing fish only from stocks where there is no evidence of infection with any of the OIE diseases". The question is whether the wording of these two points could be better harmonised.

Article 4.5.1.

Introduction

One of the key objectives of the *Aquatic Code* is to help OIE Members trade safely in *aquatic animals* and *aquatic animal products* by developing relevant *aquatic animal* health measures. These recommendations address *aquatic animal* health hazards in *aquatic animal feed*. A key objective is to prevent the spread, via *aquatic animal feed*, of *diseases* from an infected country, *zone* or *compartment* to a *free country*, a *free zone* or a *free compartment*.

~~These recommendations do not address food safety issues in detail as this is not within the mandate of the *Aquatic Code*.~~

These recommendations should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code* ~~(under study)~~. The Food and Agriculture Organization of the United Nations (FAO) has published recommendations relevant to terrestrial and *aquatic animal feed* (Technical Guidelines for Responsible Fisheries – Aquaculture Development: 1. Good aquaculture feed manufacturing practice. FAO 2001; Draft Good Practices for the Animal Feed Industry – Implementing the Codex Alimentarius' Code of Practice on Good Animal Feeding, IFIF/FAO [In preparation]) and there is a Codex Alimentarius Commission (CAC) standard (Code of Practice on Good Animal Feeding [CAC/RCP 54-2004]). OIE Members are encouraged to consult these publications.

Key considerations relevant to *aquatic animal feed* are as follows:

1. Concentration of *aquaculture establishments* heightens the *risk* of *disease* transmission, whether the pathogen enters the culture system via *feed* or other means.

2. For many *aquatic animal* species, predation (including cannibalism) is their natural way of feeding in their natural habitat.

3. Historically, animal proteins used in *feed* were mainly sourced from the marine environment, due to the nutritional needs of *aquatic animals* and for reasons of economy. This practice increases the *risk* of *disease* transmission, especially when *aquatic animals* are fed live or whole *aquatic animals* of the same or related species. There are many examples of this type of practice, e.g. early stage crustaceans fed on Artemia species and *aquaculture* tuna fed on whole wild caught fish.

4. The usage of *feed* in moist form (moisture content equal to or greater than 70%), semi-moist form (moisture content between 15 and 70%), and dry form (a moisture content equal to or less than 15%) implies different levels of *risk* due to the processing applied to the *feed*.

5. With the increasing number of species being farmed (especially marine finfish), the use of *live feed* and moist feed has increased. It is likely that these industries will in future use formulated *feed* as appropriate technologies are developed.

Annex XIII (contd)

6. Hazards may be transmitted from *feed* to *aquatic animals* via direct or indirect means. Direct transmission occurs when the cultured species consumes *feed* containing a pathogenic agent (e.g. shrimp larvae consuming rotifer ~~infected~~ contaminated with white spot syndrome virus) while indirect transmission refers to pathogens in *feed* entering the aquatic environment or infecting non target species, and thereby establishing a mechanism for indirect *infection* of the species of commercial interest. Pathogens that are less host-specific (e.g. white spot syndrome virus, *Vibrio* species) present a greater *risk* of indirect transmission as they can establish reservoirs of *infection* in multiple species.

7. As new species become the subject of *aquaculture*, new pathogens emerge in association with these hosts. The expression of *disease* may be facilitated by culturing species under intensive and novel conditions. Also, it is necessary to conduct research and develop new *feed* (and *feed ingredients*) that are appropriate to the species and its culture system. As more and more *aquatic animal* species are being cultured, it is difficult to make recommendations for all *disease agent*/host species combinations.

Article 4.5.2.

Scope

These recommendations document *risk* mitigation measures, including traceability and certification, to deal with *aquatic animal* health *risks* associated with trade in *aquatic animal feed* and *feed ingredients*. They recommend the control of hazards through adherence to recommended practices during the production (harvest, handling, storage, processing and distribution) and use of both commercial and on-farm produced *feed* (and *feed ingredients*) for *aquatic animals*. Hazards include pathogens that cause *OIE-listed diseases* and other agents that cause an adverse effect on animal and/or public health. While *aquatic animals* grown for food are the main focus, the same principles apply to *feed* for *aquatic animals* used for other purposes.

Article 4.5.3.

~~**Definitions**~~

~~**Hazard**~~

~~means a biological, chemical or physical agent in a *feed* or a *feed ingredient* with the potential to cause an adverse effect on animal or public health.~~

Article 4.5.4.

General principles

1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory requirements related to animal *feed*, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties, including requirements to provide information and assistance. Refer to Chapter 3.1. of the *Aquatic Code*.

It is a particular responsibility of the *Competent Authority* to set and enforce the regulatory requirements pertaining to the use of veterinary drugs, *aquatic animal disease* control and the food safety aspects that relate to the management of live *aquatic animals* on farm.

Those involved in the production and use of animal *feed* and *feed ingredients* have the responsibility to ensure that these products meet regulatory requirements. All personnel involved in the harvest, manufacture, storage and handling of *feed* and *feed ingredients* should be adequately trained and aware of their role and responsibility in preventing the spread of hazards. Appropriate *contingency plans* should be developed in case of a *feed*-borne *outbreak* of *disease*. Equipment for producing, storing and transporting *feed* should be kept clean and maintained in good working order.

Private veterinarians and others (e.g. laboratories) providing specialist services to producers and to the *feed* industry may be required to meet specific regulatory requirements pertaining to the services they provide (e.g. *disease* reporting, quality standards, transparency).

2. Regulatory standards for feed safety

All *feed* and *feed ingredients* should meet regulatory standards for *feed* safety. ~~In defining limits and tolerances for hazards, s~~ Scientific evidence~~, I~~including ~~defining limits and tolerances for hazards, scientific evidence, including~~ the sensitivity of analytical methods, and on the characterisation of *risks*, should be taken into account in defining limits and tolerances for hazards.

3. Risk analysis

Internationally accepted principles and practices for *risk analysis* (see Section 2. of the *Aquatic Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

A generic *risk analysis* framework should be applied to provide a systematic and consistent process for managing hazards.

4. Good practices

Where national guidelines exist, good *aquaculture* practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them or adopt suitable international standards or recommendations.

Where appropriate, Hazard Analysis and Critical Control Point (HACCP; as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene [CAC/RCP 1-1969]) principles should be followed to control hazards that may occur in *feed*.

5. Relationship between prions and aquatic animal species

Scientific knowledge is lacking on the relationship between prions and *aquatic animal* species. There is no evidence to suggest that the use of terrestrial animal by-products as ingredients in *aquatic animal feed* as currently practiced in *aquaculture* gives rise to *risks* in respect of prion diseases. More scientific information is desirable to enable *aquaculture* industries to utilise more terrestrial animal by-products as a means of reducing dependency on aquatic protein and lipid sources.

6. Bioaccumulation

Heavy metals, dioxins and polychlorinated biphenyls (PCB) persist in ~~fatty~~ certain tissues and therefore tend to *accumulate* through the food chain.

Annex XIII (contd)

7. Geographic and environmental considerations

Aquatic and terrestrial harvest areas for *feed* should not be located in proximity to sources of animal health or food safety hazards. Where this cannot be avoided, preventive measures should be *applied* to control *risk*. The same recommendations apply for the processing of *feed* and the location of *aquaculture establishments*.

Aquatic animal health *considerations* include factors such as disease status, location of quarantined premises, existence of processing plants without proper biosecurity measures and the existence of *zones/compartments* of specified health status.

Public health considerations include factors such as industrial operations and waste treatment plants that generate pollutants and other hazardous products. The potential accumulation of pollutants in the *food* chain through *feed* needs to be considered.

8. Zoning and compartmentalisation

Feed is an important components of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 4.1. of the *Aquatic Code*.

9. Sampling and analysis

Sampling and analytical protocols for *feed* should be based on scientific principles and procedures, and OIE standards where applicable.

10. Labelling

Labelling should be clear and informative on how the *feed* and *feed ingredients* should be handled, stored and used and should comply with regulatory requirements. Labelling should provide for trace-back.

See Section 4.2. of the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

11. Design and management of inspection programmes

In meeting animal and public health objectives prescribed in national legislation or required by *importing countries*, *Competent Authorities* contribute through the direct performance of some tasks or through the auditing of animal and public health activities conducted by other agencies or the private sector.

Operators in the *feed* and *feed ingredients* business and other relevant industries should implement procedures to ensure compliance with regulatory standards for harvest, handling, storage, processing, distribution and use of *feed* and *feed ingredients*. Operators have ~~the primary~~ full responsibility for implementing systems for ~~process~~ quality control. Where such systems are applied, the *Competent Authority* should verify that they meet all regulatory requirements.

12. Assurance and certification

Competent Authorities are responsible for providing assurances domestically and to trading partners that regulatory requirements have been met.

13. Hazards associated with aquatic animal feed

a) Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, fungi and parasites. The scope of these recommendations covers OIE-listed diseases and other agents that cause an adverse effect on animal and/or public health.

b) Chemical hazards

Chemical hazards that may occur in *feed* and *feed ingredients* include naturally occurring chemicals (such as mycotoxins, gossypol and free radicals), industrial and environmental contaminants (such as heavy metals, dioxins and PCBs), residues of veterinary drugs and pesticides and radionuclides.

c) Physical hazards

Physical hazards that may occur in *feed* and *feed ingredients* include foreign objects (such as pieces of glass, metal, plastic or wood).

14. C~~ross-c~~ontamination

~~It is important to avoid cross-contamination during the manufacture, storage, distribution (including transport) and the use of *feed* and *feed ingredients*. Appropriate provisions should be included in the regulatory framework. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of *risks*, should be drawn upon in developing this framework.~~

~~It is necessary that the prevention of~~ Procedures to minimise the risk of contamination of feed or feed ingredients during their ~~the manufacture, storage, distribution (including transport) and the use of feed and feed ingredients and relevant provisions should~~ should be included in current regulations and standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of risks, should be drawn upon in developing this framework.

Procedures, such as flushing, sequencing and physical clean-out, should be used to reduce the likelihood of contamination between batches of feed or feed ingredients.

~~Procedures such as flushing, sequencing and physical clean-out should be used to avoid cross-contamination between batches of *feed* or *feed ingredients*. National regulations should be followed in order to avoid the use of unauthorised *feed ingredients* with a *risk* of cross-contamination.~~

15. Antimicrobial resistance

Concerning the use of antimicrobials in animal *feed* refer to Section X.X.X. of the *Aquatic Code* (under study).

16. Management of information

The *Competent Authority* should establish requirements for the provision of information by the private sector in accordance with the regulatory framework.

Annex XIII (contd)

The private sector should maintain records, in a readily accessible form, on the production, distribution, importation and use of *feed* and *feed ingredients*. These records are required to facilitate the prompt trace-back of *feed* and *feed ingredients* to the immediate previous source, and trace-forward to the next/subsequent recipients, to address *aquatic animal* health and/or public health concerns. The private sector should provide information to the *Competent Authority* in accordance with the regulatory framework.

Animal identification (in the case of *aquatic animals* this will normally be on a group basis) and traceability are tools for addressing animal health and food safety *risks* arising from animal *feed* (see ~~Section 3.5.~~ Chapters 4.1. and 4.2. of the OIE *Terrestrial Animal Health Code*; Section 4.3 of CAC/RCP 54-2004).

~~Article 4.5.5.~~

~~Pathogens in feed~~

~~1. Pathogens can be introduced into *feed* in the following ways:~~

~~a) via the harvest of infected *aquatic animals*;~~

~~b) during storage, processing and transport, due to poor hygienic practices, the presence of pests, or residues of previous batches of *feed* remaining in processing lines, *containers* or transport *vehicles*.~~

~~2. *Aquatic animals* can be exposed to pathogens in *feed* in the following ways:~~

~~a) Direct exposure~~

~~The use of unprocessed *feed* derived from *aquatic animals* to feed *aquatic animals* presents a direct route of exposure, particularly when feeding whole *aquatic animals* and unprocessed products of *aquatic animals* to animals of the same species. For example feeding salmonid offal to salmonids or feeding rotifers or Artemia species to crustaceans presents a heightened *risk* of *disease* transmission.~~

~~b) Indirect exposure~~

~~Pathogens in *feed* may be transmitted to *aquatic animals* in *aquaculture* and wild *aquatic animals* via contamination of the environment or *infection* of non-target species.~~

~~Article 4.5.6.~~

~~Chemical agents in feed~~

~~[under study]~~

~~Article 4.5.7.~~

~~Physical agents in feed~~

~~[under study]~~

Article 4.5.8.

Recommended approaches to aquatic animal health risk mitigation

1. Commodities

a) Safe commodities

Some ~~The following~~ *commodities* undergo extensive processing such as heat treatment, acidification, extrusion and extraction. There ~~is~~ may be a negligible *risk* that pathogens will survive in such products if they have been produced in accordance with Good Manufacturing Practice. ~~normal commercial practice~~: Such *aquatic animal products* are listed in disease specific chapters in the *Aquatic Code* in Article X.X.3.

~~i) fish oil;~~

~~ii) crustacean oil;~~

~~iii) fish solubles (a by-product of the fish oil production system, comprising the product remaining when water is drawn off [evaporated] from the residual aqueous phase);~~

~~iv) fish *meal*;~~

~~v) crustacean *meal*;~~

~~vi) squid *meal* and squid liver *meal*;~~

~~vii) bivalve *meal*;~~

~~viii) finished *feed* (e.g. flake, pelleted and extruded *feed*).~~

~~For these *commodities*, *Competent Authorities* should not require conditions in relation to *aquatic animal diseases*, regardless of the *aquatic animal* health status of the *exporting country*, *zone* or *compartment*.~~

b) Other commodities

Competent Authorities should consider the following *risk* mitigation measures:

i) sourcing *feed* and *feed ingredients* from a *disease free country*, *free zone* or *free compartment*; or

ii) confirmation (e.g. by testing) that pathogens are not present in the *commodity*; or

iiii) treatment (e.g. by heat or acidification) of the *commodity* using a method approved by the *Competent Authority* to inactivate pathogens; or

iv) use of *feed* only in populations that are not susceptible to the pathogen(s) in question and where *aquatic animals* that are susceptible to the pathogen(s) in question will not come into contact with the *feed* or its waste products.

In addition, *risks* associated with the disposal of effluents and waste material from *feed* processing plants and *aquaculture establishments* should be considered.

c) Whole fish (fresh or frozen)

The practice of trading fresh or frozen whole marine fish for use as *aquatic animal feed* presents a *risk* of introducing *diseases* into populations. *Risk* mitigation measures include sourcing fish only from stocks where there is no evidence of *infection* with any of the *OIE-listed diseases* or treatments that inactivate *aquatic animal* pathogens.

2. Feed production

To prevent contamination by pathogens during production, storage and transport of *feed* and *feed ingredients*:

a) flushing, sequencing or physical clean-out of manufacturing lines and storage facilities should be performed between batches as appropriate;

b) buildings and equipment for processing and transporting *feed* and *feed ingredients* should be constructed in a manner that facilitates hygienic operation, maintenance and cleaning and prevents contamination;

c) in particular, *feed* manufacturing plants should be designed and operated to avoid cross-contamination between batches;

d) processed *feed* and *feed ingredients* should be stored separately from unprocessed *feed ingredients*, under appropriate storage conditions;

e) *feed* and *feed ingredients*, manufacturing equipment, storage facilities and their immediate surroundings should be kept clean and pest control programmes should be implemented;

f) measures to inactivate pathogens, such as heat treatment or the addition of authorised chemicals, should be used where appropriate. Where such measures are used, the efficacy of treatments should be monitored at appropriate stages in the manufacturing process;

g) labelling should provide for the identification of *feed* and *feed ingredients* as to the batch/lot and place and date of production. To assist in tracing *feed* and *feed ingredients* as may be required to deal with animal disease incidents, labelling should provide for identification by batch/lot and place and date of production.

3. Importing countries

Competent Authorities should consider the following measures:

a) imported *feed* and *feed ingredients* should be delivered to *feed* manufacturing plants or *aquaculture* facilities for processing and use under conditions approved by the *Competent Authority*;

b) effluent and waste material from *feed* manufacturing plants and *aquaculture* facilities should be managed under conditions approved by the *Competent Authority*, including, where appropriate, treatment before discharge into the aquatic environment;

c) *feed* that is known to contain pathogens should only be used in a *zone* or *compartment* that does not contain species susceptible to the *disease* in question;

d) the importation of raw unprocessed *feed* derived from *aquatic animals* to feed *aquatic animal* species should be avoided where possible.

Article 4.5.9.

Certification procedures for feeds and feed ingredients of aquatic animal origin

When importing *feed* and *feed ingredients* of *aquatic animal* origin other than those mentioned in point 1a of Article 4.5.8., 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 should certify:

1. that *feed* and *feed ingredients* of *aquatic animal* origin were obtained from a country, *zone* or *compartment* that is free from relevant *aquatic animal diseases*; or

2. that *feed* and *feed ingredients* of *aquatic animal* origin were tested for relevant *aquatic animal diseases* and shown to be free of these *diseases*; or

3. that *feed* and *feed ingredients* of *aquatic animal* origin have been processed to ensure that they are free of relevant *aquatic animal diseases*.

Specific provisions for OIE-listed diseases may be found in relevant *disease* chapters of the *Aquatic Code*.

The certificate should be in accordance with the Model Certificate in Chapter 5.10.

Article 4.5.10.

Risk pathways for ~~chart of~~ pathogen transmission and contamination through harvest, manufacture and use of aquatic animal feed

1. Pathogens can be introduced into *feed* in the following ways:

   a) via the harvest of infected *aquatic animals*;

   b) during storage, processing and transport, due to poor hygienic practices, the presence of pests, or residues of previous batches of *feed* remaining in processing lines, *containers* or transport *vehicles*.

2. *Aquatic animals* can be exposed to pathogens in *feed* in the following ways:

   a) Direct exposure

      The use of unprocessed *feed* derived from *aquatic animals* to feed *aquatic animals* presents a potential direct route of exposure. For example feeding salmonid offal to salmonids presents a heightened *risk* of *disease* transmission because tissue from a *susceptible species* is being fed to a *susceptible species*.

b) Indirect exposure

Pathogens in *feed* may be transmitted to *aquatic animals* in *aquaculture* and wild *aquatic animals* via contamination of the environment or *infection* of non-target species.

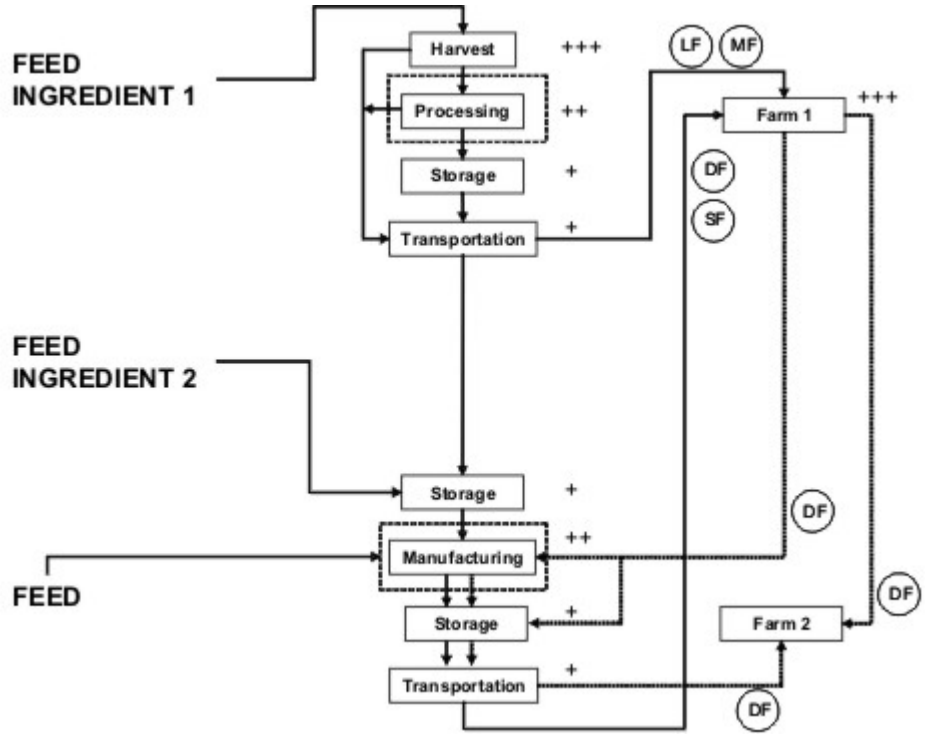
Figure 1 illustrates the possible pathways for transmission of pathogens within the *feed* production and utilisation process.

Feed ingredients of aquatic origin used in *aquaculture* can be a source of pathogens (viruses, bacteria and parasites) to cultured *aquatic animal* species. In *aquaculture establishments* pathogens in *feed* can infect the animals directly (via consumption of *feed*) or indirectly via environmental sources. *Live feed* and moist *feed* are more likely to contain pathogens because their ingredients are either in a raw state or subject to minimal treatment.

Feed and *feed ingredients* harvested from infected countries, *zones* or *compartments* may have a high pathogen load. *Feed* and *feed ingredients* from these sources should be processed (e.g. using heat or chemical treatments) to reduce, or eliminate, the pathogen load. After processing care should be taken to avoid post processing contamination during storage and transportation of these *commodities*. For example, when two or more batches of *ingredients* of different sanitary status are handled, stored and/or transported together without appropriate biosecurity measures, there is a *risk* of cross-contamination of the *feed*.

An *aquaculture* facility can also be a source of pathogens in *aquatic animal feed*. For example, *feed* can be contaminated with pathogens through poor hygiene practices at an infected *aquaculture establishment*. If the *feed* is redistributed from the *aquaculture* facility to the manufacturing facility for recycling, or distributed to another farm, pathogens can be transferred to other *aquaculture establishments*.

Figure 1: ***Risk chart of pathogen transmission and contamination through harvest, manufacture and use of aquatic animal feed***



LF	Live feed	——> Possibility for risk reduction
MF	Moist feed	
SF	Semi-moist feed	
DF	Dry feed	
+++	High risk of pathogen presence	..... Redistribution or recycling of finished feed
++	Moderate risk of pathogen presence	
+	Low risk of pathogen presence	

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Annex XIV

CHAPTER 5.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

EU positions

The EU supports the adoption of the revised chapter.

Article 5.1.1.

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 *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 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.

These requirements should be included in the certificates drawn up in accordance with the model *international aquatic animal health certificates* provided for in Chapter 5.10. of the *Aquatic Code*.

Certification should be exact and concise, and should clearly address the requirements of the *importing country*. For this purpose, prior consultation between *Competent Authorities* of *importing* and *exporting countries* may be necessary. This consultation helps to determine the exact requirements of the certification.

Certificates should be issued and signed by a single competent official authorized by the *Veterinary Authority* or other *Competent Authority* to perform inspections, and endorsed through signature and/or official stamp of the *Veterinary Authority* or other *Competent Authority*. The certification requirements should not include conditions for *diseases* that are not transmitted by the *commodity* concerned. ~~There should only be one signing certifying official for one certificate.~~ The certificate should be signed in accordance with the provisions of Chapter 5.2.

When officials 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. This visit should be mutually agreed upon between *Competent Authorities*.

Article 5.1.2.

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. *Importing countries* should restrict their requirements to those necessary to achieve the national appropriate level of protection. If these are stricter than the OIE standards, 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 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 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*.

3. The *international aquatic animal health certificate* should not include measures against *disease agents* or *diseases* that are not OIE listed, unless the *importing country* has demonstrated through an import *risk analysis*, carried out in accordance with Section 2., that the *disease agent* or *disease* poses a significant *risk* to the *importing country*.

4. The transmission of *import country* requirements or certificates from ~~by~~ the *Competent Authority* of the *importing country* ~~certificates~~ and ~~or~~ the communication of import requirements to persons other than the *Competent Authority* of another country necessitates that copies of these documents be also sent to the *Competent Authority* of the *exporting country*. This important procedure avoids delays and difficulties that may arise between traders and *Competent Authorities* when the authenticity of the certificates or permits is not established.

   The transmission of this information is the responsibility of *Competent Authorities* of the *exporting country*. However, it can be 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 *Competent Authorities*.

5. Situations may arise that result in changes to the consignee, identification of the means of transportation, or *frontier post* after a certificate is issued. If it is determined that 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 5.1.3.

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* free from OIE-listed diseases, and on the pathway followed to achieve disease freedom ~~i.~~e.g. historical freedom, absence of susceptible species or targeted surveillance, including the regulations and procedures in force to maintain the free status;

   b) regular and prompt information on the occurrence of *OIE-listed diseases*;

   c) details of the country's ability to apply measures to control and prevent *OIE-listed diseases*;

   d) information on the structure of the *Competent Authority* and the authority that they exercise;

   e) technical information, particularly on biological tests and vaccines applied in all or part of the country.

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 of oversight and accountability, ~~covering~~ including possible suspension and termination of the ~~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 *Competent Authority* of the *exporting country* is ultimately accountable for certification used in *international trade*.

Article 5.1.4.

Responsibilities in case of an incident 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 *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. 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*, a *disease* condition appears, within a reasonable period after importation, in *aquatic animals* in the *importing country*, 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. *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.

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Annex XV

CHAPTER 5.2.

CERTIFICATION PROCEDURES

EU positions

The EU supports the adoption of the revised Chapter.

Article 5.2.1.

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~~ should be respected and safeguarded.

It is essential ~~not~~ to include in ~~the~~ the certificate ~~any requirements additional specific matters that cannot~~ only those specific statements that can 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, or the occurrence of which the signing *certifying official* is not necessarily informed about. ~~Equally,~~ It is unacceptable 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*.

Article 5.2.2.

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 ~~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 have verified or 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 5.2.3.

Preparation of international aquatic animal health certificates

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 bear the signature of the *certifying official* and the official identifier (stamp) 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.

Annex XV (contd)

2. Certificates ~~They~~ should be written ~~in~~ using terms that are ~~as~~ simple, unambiguous and as easy to understand as possible, without losing their legal meaning.

3. If so required, certificates ~~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. Certificates ~~They~~ should require appropriate identification of *aquatic animals* and *aquatic animal products* except where this is impractical (e.g. eyed eggs).

5. Certificates ~~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, when presented to the *certifying official* ~~*veterinarian*~~, certificates ~~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. The~~ir~~ text of a certificate should not be amended except by deletions that ~~must~~ should be signed and stamped by the *certifying official*.

8. The signature and stamp ~~must~~ should be in a colour different to that of the printing of the certificate. The stamp may be embossed instead of being a different colour.

9. Only original certificates should be accepted by the *importing country*.

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 replacements should be provided by the issuing authority and 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 5.2.4.

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~~ should 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~~ should have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.

4. The *certifying official* ~~must~~ should be officially responsible for the secure use of his/her electronic signature.

- - - - - - - - - - - - - - -

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Annex XVI

CHAPTER 5.10.

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

EU positions

The EU supports the adoption of the revised Chapter.

Article 5.10.1.

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.

Annex XVI (contd)

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~~ 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~~ 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.

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.	Details of the means of transport. 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.
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.	Total quantity or weight of the commodity. For live aquatic animals ~~and gametes~~ and gametes give the total count or weight. For aquatic animals products give the gross weight and the net weight in kg of the whole consignment.
Box I.18.	Temperature of products for transport and storage.
Box I.19.	For live aquatic animals ~~or gametes~~ and 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.	Intended use of the imported live aquatic animals or aquatic animal products. Breeding: applies to gametes and broodstock. Grow out: applies to live aquatic animals~~, aquatic eggs and aquatic larvae~~ aquatic eggs and aquatic larvae requiring time in culture. Slaughter: applies to live aquatic animals for slaughter. Restocking: applies to live aquatic animals for the purpose of rebuilding stocks. Ornamental: applies to live aquatic animals kept for companionship or enjoyment. Competition/Display: applies to live aquatic animals used for display or competition purposes. Human consumption: applies to live aquatic animals (without further aquaculture involved) or aquatic animals products intended for human consumption.

Annex XVI (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~~ 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); Approval number of establishment(s) (e.g. processing plant; cold store); Lot identification/date code; Number of packages.

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 *Aquatic Code*.
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 XVI (contd)

Article 5.10.2.

Model Health Certificate for International Trade in Live Aquatic Animals ~~and Gametes~~ 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: Aeroplane □ Ship □ Railway Road vehicle □ Other □ wagon □ Identification:	I.13. Expected border post: I.14. CITES permit No(s).**:
	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. Type of packaging:
	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) Age * Identification system* Batch number* Sex *	

* Optional and ** If referenced in Part II.

Annex XVI (contd)

COUNTRY :

Part II. Zoosanitary information		II.a. Certificate reference number:

II. The undersigned Certifying Official certifies that the aquatic animal(s) and gametes described above satisfy(ies) the following requirements:

Certifying Official:

Name and address (in capital letters):

Official position:

Date:

Signature:

Stamp:

Article 5.10.3.

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

COUNTRY :

<table>
<tr><td rowspan="11">Part I: Details of dispatched consignment</td><td colspan="2">I.1. Consignor:
Name:</td><td>I.2. Certificate reference number:</td></tr>
<tr><td colspan="2">Address:</td><td>I.3. Competent Authority:</td></tr>
<tr><td colspan="3">I.4. Consignee:
Name:

Address:</td></tr>
<tr><td colspan="2">I.5. Country of origin: ISO code*</td><td>I.6. Zone or compartment of origin**:</td></tr>
<tr><td colspan="2">I.7. Country of destination: ISO code*</td><td>I.8. Zone or compartment of destination**:</td></tr>
<tr><td colspan="3">I.9. Place of origin:
Name:

Address:</td></tr>
<tr><td colspan="2">I.10. Place of shipment:</td><td>I.11. Date of departure:</td></tr>
<tr><td colspan="2" rowspan="2">I.12. Means of transport:

Aeroplane □ Ship □ Railway wagon □
Road vehicle □ Other □

Identification:</td><td>I.13. Expected border post:</td></tr>
<tr><td>I.14. CITES permit No(s).**:</td></tr>
<tr><td colspan="2">I.15. Description of commodity:</td><td>I.16. Commodity code (ISO code):</td></tr>
<tr><td colspan="2"></td><td>I.17. Total quantity/weight:</td></tr>
<tr><td colspan="2">I.18. Temperature of product:
Ambient □ Chilled □ Frozen □</td><td>I.19. Total number of packages:</td></tr>
<tr><td colspan="2">I.20. Identification of container/seal number:</td><td>I.21. Type of packaging:</td></tr>
<tr><td colspan="3">I.22. Commodities intended for use as:
Human consumption □ Aquatic animal feed □
Further processing □ Other technical use □
Other □ Technical use in live aquatic animals □
If other, specify…… If Technical use, specify……</td></tr>
<tr><td colspan="3">I.23.</td></tr>
<tr><td colspan="3">I.24. Identification of commodities:

Amphibian□ Crustacean □ Fish □ Mollusc □
Wild stock □ Cultured stock □

Species (Scientific name) Approval number of establishments Lot ID/date code</td></tr>
</table>

* Optional and ** If referenced in Part II.

Annex XVI (contd)

COUNTRY :

Part II. Zoosanitary information

II.a. Certificate reference number

II. The undersigned Certifying Official certifies that the product(s) of aquatic animal origin described above satisfy(ies) the following requirements:

Certifying Official:

Name and address (in capital letters):

Official position:

Date:

Signature:

Stamp:

Annex XVII

CHAPTER 7.2.

~~TRANSPORT WELFARE~~ WELFARE OF FARMED FISH DURING TRANSPORT ~~DURING TRANSPORT~~

EU position

The EU can support the adoption of the revised Chapter on Welfare of Farmed Fish during Transport.

Specific EU comments are provided within the text for further development of the Chapter.

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 by air, by sea or on land within a country and between countries, and only considers the issues related to their welfare. Recommendations for measures to control the *aquatic animal* health *risks* related to the transport of fish are included in Chapter 5.4. ~~on~~ Recommendations for safe transport of *aquatic animals* and *aquatic animal products*.

Article 7.2.1.

Responsibilities

All personnel handling fish throughout the transportation process are responsible for ensuring that consideration is given to the potential impact on the welfare of the fish.

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 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 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~~ trained personnel supervise operations at their facilities for fish to be loaded and unloaded in a manner that causes minimum stress and injury;

EU comment

In point (2)b of Article 7.2.1, the word "*competent*" should be kept in addition to "*trained*", and the point should be read: "*ensuring trained and competent personnel supervise operations (…)*"

Justification

Personnel should be both trained and competent, in consistency with the Chapters on animal welfare during transport in the Terrestrial Code.

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;

EU comment

The EU encourages the OIE to provide guidance on the development of contingency plans

d) ensuring ~~the~~ fish have a suitable environment to enter at their destination that ensures their welfare is maintained.

3. Transport companies, in cooperation with the 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 a well maintained *vehicle* that is appropriate to the species to be transported;

Annex XVII (contd)

b) ensuring ~~that competent~~ trained staff are available for loading and unloading; and to ensure swift, humane killing of the fish, if required;

EU comment

In point (3)b of Article 7.2.1, the word "*competent*" should be kept in addition to "*trained*", and the point should be read: "*ensuring trained and competent staff are available (…)*"

Justification
Staff should be both trained and competent, in consistency with the Chapters on animal welfare during transport in the Terrestrial Code.

c) having *contingency plans* to address emergencies and minimise stress during transport;

d) selecting 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 recommendations for welfare of fish during transport.

Article 7.2.2.

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 7.2.1.

2. *Competent Authority*, farm owners/managers, and transport companies have a responsibility in providing training to their respective 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. on the Humane killing of fish for disease control purposes (in preparation);

g) logbooks and record keeping.

Article 7.2.3.

Planning the transport

1. 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. 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 5.4.).

2. Vehicle design and maintenance

a) *Vehicles* and *containers* used for transport of fish should be appropriate to the species, size, weight and number of 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.

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.

3. Water

a) Water quality (e.g. oxygen, CO_2 and NH_3 level, pH, temperature, salinity) should be appropriate for the species being transported and method of transportation.

b) Equipment to monitor and maintain water quality may be required depending on the length of the transport.

4. 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. Generally, only fish that are fit for transport should be loaded. ~~[Except for~~ Transport for disease control purposes~~.~~ should be in accordance with Chapter X.X. on the humane killing of fish for disease control purposes (in preparation). ~~(under study)]~~ ~~Only fish that are fit for transport should be loaded~~.

Annex XVII (contd)

c) 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).

EU comment

In point (4)c of Article 7.2.3, the following point should be added as a point iv):

iv) *"insufficient or excessive length of fasting"*.

Justification

Fasting could impact on the welfare of the fish at the moment of transport. It should be managed in relation to the water temperature and the fish weight.

5. 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 7.2.4.

Documentation

1. Fish should not be loaded until the required documentation is complete.

2. The documentation accompanying the consignment (the transport log) should include:

a) description of the consignment (e.g. date, time, and place of loading, species, biomass load);

b) description of the transport plan (e.g. including route, water exchanges, expected time, date and place of arrival and unloading and receiver contact information).

3. 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 7.2.5.

Loading the fish

1. The issues which should be addressed to avoid unnecessary stress and injury to the fish include:

   a) crowding procedure in farm pond, tank, net or cage prior to loading;

   b) 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.

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 7.2.6.

Transporting the fish

1. General considerations

a) Periodic inspections should take place during the transport to verify that acceptable welfare is being maintained.

b) Ensure that water quality is monitored and the necessary adjustments made to avoid extreme conditions.

c) Travel in a manner that minimises uncontrolled movements of the fish that may lead to stress and injury.

2. 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 6 of Article 7.2.3.).

b) If the killing of fish is necessary during the transport, ~~the person in charge should ensure that the killing~~ it should be ~~is~~ carried out humanely in accordance with Chapter X.X. on the Humane killing of fish for disease control purposes (in preparation), and in compliance with relevant legislation.

Article 7.2.7.

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. on the Humane killing of fish for disease control purposes (in preparation).

Annex XVII (contd)

Article 7.2.8.

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 Chapter 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.

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Annex XVIII

REVISED ARTICLE X.X.8.

AN EXAMPLE (DISEASE X) TO BE APPLIED ACROSS ALL DISEASE CHAPTERS (SECTIONS 8, 9, 10 AND 11)

EU position

The EU supports the adoption of the revised Article.

However, the EU requests the AAC to provide an explanation for why the EU suggestions presented to the AAC before its Februay meeting for point 4 of Article X.X.8 were not taken on board.

[…]

Article X.X.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from 'Disease X'

[…]

2. If the intention of the introduction is the establishment of a new stock, relevant aspects of 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 considered ~~followed~~.

3. For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: http://www.ices.dk/~~index fla.asp~~ pubs/Miscellaneous/ICESCodeofPractice.pdf 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 'Disease X' ~~abalone herpes-like virus~~, 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 'Disease X' ~~abalone herpes-like virus~~ and perform general examinations for pests and general health/disease status;

   g) if 'Disease X' 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 'Disease X' or specific pathogen free (SPF) for 'Disease X';

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

4. With respect to point 3e), quarantine conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If quarantine conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low infection level.

Annex XVIII (contd)

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

[…]

— text deleted

Annex XIX

CHAPTER 11.X.

INFECTION WITH ABALONE HERPES-LIKE VIRUS

EU position
The EU supports the adoption of the Chapter

Article 11.X.1.

For the purposes of the *Aquatic Code*, infection with abalone herpes-like virus means ~~herpes-like virus associated manifestation in abalone.~~ ~~any form of~~ ~~the abalone viral mortality complex (AVM) caused by abalone~~ infection with the herpes-like virus known to cause *disease* in abalone.

~~Methods for conducting *surveillance*, diagnosis and confirmatory identification of infection with abalone herpes-like virus~~ Information on methods for *diagnosis* are provided in the *Aquatic Manual* (under development).

Article 11.X.2.

Scope

The recommendations in this Chapter apply to: *Haliotis diversicolor* (subspecies *aquatilis* 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 11.X.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from abalone herpes-like virus

1. *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* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 11.2.2. intended for any purpose and complying with Article 5.3.1.

   [ ] (under study).

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.~~+~~.2.2., other than those referred to in point 1 of Article 11.2.3., *Competent Authorities* should require the conditions prescribed in Articles 11.2.7. to 11.2.11. relevant to the abalone herpes-like virus status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of infection with abalone herpes-like virus from a species not covered in Article 11.2.2. but which could reasonably be expected to pose a risk of transmission for abalone herpes-like virus, *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 XIX (contd)

~~**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 11.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 112.2.X.2. which have been prepared and packaged for direct retail trade:~~

~~i) off the shell (chilled or frozen).~~

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

~~2. When authorising the importation or transit of *commodities* of a species referred to in Article 112.2.X.2., other than *commodities* referred to in point 1 of Article 11.X.3., the *Competent Authorities* should require the conditions prescribed in Articles 11.X.7. to 11.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 11.X.2. or in point 1b) of Article 11.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 11.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 11.X.5.).

1. A country where none of the *susceptible species* referred to in Article 11.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 11.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 the corresponding c~~C~~hapter ~~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 the corresponding c~~C~~hapter ~~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 Chapter~~s~~ 1.4. 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*~~ *protection 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 Chapter~~s~~ 1.4.~~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 11.X.5.

Article 11.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.

Annex XIX (contd)

If a *zone* or *compartment* extends over more than one country, it can only be declared an 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 11.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 11.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 the corresponding c~~C~~hapter ~~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.

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 the corresponding c~~C~~hapter ~~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*, as described in Chapter~~s~~ 1.4.~~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 again be declared free from ~~*M. mackini*~~ 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*~~ *protection 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 1.4.~~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 11.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 11.X.4. or 11.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 11.X.4. or 11.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.~~ in the corresponding chapter 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 11.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 11.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~~ should certify, on the basis of the procedures described in Articles 11.X.4. or 11.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 Chapter 5.10.~~Appendix 4.1.2.~~

This Article does not apply to *commodities* referred to in point 1 of Article 11.X.3.

Article 11.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 11.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.

Annex XIX (contd)

2. If the intention of the introduction is the establishment of a new stock, relevant aspects of 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 considered ~~followed~~.

3. For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: http://www.ices.dk/~~indexfla.asp~~ pubs/Miscellaneous/ICESCodeofPractice.pdf) 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;

   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 abalone herpes-like virus ~~*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*.

4. With respect to point 3e), quarantine conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If quarantine conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low infection level.

This Article does not apply to ~~*commodities*~~ *aquatic animals* referred to in point 1 of Article 11.X.3.

Article 11.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* and *aquatic animal products* of the species referred to in Article 11~~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 is ~~be~~ delivered directly to and held in *quarantine* or containment facilities until processing ~~and/or consumption;~~ into one of the products referred to in point 1 of Article 11.X.3., or products described in point 1 of Article 11.X.11., or other products authorised by the *Competent Authority*; and

2. all effluent and waste material from the processing ~~be~~ are treated in a manner that ensures inactivation of abalone herpes-like virus or is 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 11~~2.2.X.3.

For these *commodities* 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.

Article 11~~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 11~~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~~ should certify, on the basis of the procedures described in Articles 11~~2.2~~.X.4. or 11~~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 Chapter 5.10. ~~Appendix X.X.X. (under study)~~.

This Article does not apply to *commodities* referred to in point 1 of Article 11~~2.2~~.X.3.

Article 11~~2.2~~.X.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from abalone herpes-like virus

1. *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* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   [ ] (under study)

   For these *commodities* 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.

2. When importing *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 11.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.

Annex XIX (contd)

~~**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 112.2.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 112.2.X.3.~~

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Annex XX

CHAPTER 9.X.

NECROTISING HEPATOPANCREATITIS

EU positions

The EU supports the adoption of the new Chapter.

Article 9.X.1.

For the purposes of the *Aquatic Code*, necrotising hepatopancreatitis (NHP) means *infection* with necrotising hepatopancreatitis bacteria (NHP-B). This obligate intracellular bacterium is a member of the order α-Proteobacteria.

Information on methods for *diagnosis* are provided in the *Aquatic Manual* (under development).

Article 9.X.2.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp (*Penaeus vannamei*), blue shrimp (*P. stylirostris*), northern white shrimp (*P. setiferus*) and northern brown shrimp (*P. aztecus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 9.X.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from necrotising hepatopancreatitis

1. *Competent Authorities* should not require any NHP related conditions, regardless of the NHP status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 9.X.2. intended for any purpose and complying with Article 5.3.1.:

   [ ] (under study)

2. When authorising the importation or transit of the *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.X.2., other than those listed in point 1 of Article 9.X.3., *Competent Authorities* should require the conditions prescribed in Articles 9.X.7. to 9.X.11. relevant to the NHP status of the *exporting country*, *zone* or *compartment*.

Annex XX (contd)

3. When considering the importation or transit of a *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of NHP from a species not covered in Article 9.X.2. but which could reasonably be expected to pose a risk of transmission for NHP-B, *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 9.X.4.

Necrotising hepatopancreatitis free country

A country may make a *self-declaration of freedom* from NHP 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 NHP if all the areas covered by the shared water are declared NHP free countries or *zones* (see Article 9.X.5.).

1. A country where none of the *susceptible species* referred to in Article 9.X.2. is present may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 9.X.2. are present but there has been no observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in the corresponding chapter of the *Aquatic Manual)*, may make a *self-declaration of freedom* from NHP when:

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

    b) *targeted surveillance*, as described in Chapters 1.4. of the *Aquatic Code*, has been in place for at least the last 2 years without detection of NHP-B.

OR

4. A country that has previously made a *self-declaration of freedom* from NHP but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from NHP again when the following conditions have been met:

    a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection 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 Chapter 1.4. of the *Aquatic Code*, has been in place for at least the past 2 years without detection of NHP-B 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 9.X.5.

Article 9.X.5.

Necrotising hepatopancreatitis free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from NHP 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 NHP free *zone* or *compartment* if all the relevant *Competent Authorit(ies)* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 9.X.2. is present may be declared free from NHP when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 9.X.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may be declared free from NHP when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression, as described in the corresponding chapter of the *Aquatic Manual)*, may be declared free from NHP when:

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

   b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of NHP-B.

OR

4. A *zone* previously declared free from NHP but in which the *disease* is detected may be again declared free from NHP when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection 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 Chapter 1.4. of the *Aquatic Code*, has been in place for at least the past 2 years without detection of NHP-B 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 9.X.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from NHP following the provisions of points 1 or 2 of Articles 9.X.4. or 9.X.5. (as relevant) may maintain its status as NHP free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from NHP following the provisions of point 3 of Articles 9.X.4. or 9.X.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as NHP free provided that conditions that are conducive to clinical expression of NHP, as described in the corresponding chapter 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 NHP, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 9.X.7.

Importation of live aquatic animals from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing live *aquatic animals* of the species referred to in Article 9.X.2. from a country, *zone* or *compartment* declared free from NHP, 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 9.X.4. or 9.X.5. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from NHP.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.10.

This Article does not apply to *commodities* listed in point 1 of Article 9.X.3.

Article 9.X.8.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 9.X.2. from a country, *zone* or *compartment* not declared free from NHP, 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 NHP-B.

2. If the intention of the introduction is the establishment of a new stock, relevant aspects of 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 considered.

3. For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: http://www.ices.dk/pubs/Miscellaneous/ICESCodeofPractice.pdf may be summarised to the following 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 NHP-B, 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 NHP-B and perform general examinations for pests and general health/*disease* status;

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

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

4. With respect to point 3e), quarantine conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If quarantine conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low infection level.

This Article does not apply to *aquatic animals* listed in point 1 of Article 9.X.3.

Article 9.X.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from necrotising hepatopancreatitis

When importing, for processing for human consumption, *aquatic animals* and *aquatic animal products* of the species referred to in Article 9.X.2. from a country, *zone* or *compartment* not declared free from NHP, 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* or containment facilities until processing into one of the products referred to in point 1 of Article 9.X.3., or products described in point 1 of Article 9.X.11., or other products authorised by the *Competent Authority*; and

Annex XX (contd)

2. all effluent and waste materials from the processing are treated in a manner that ensures inactivation of NHP-B or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

Article 9.X.10.

Importation of aquatic animal products from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing *aquatic animal products* of the species referred to in Article 9.X.2. from a country, *zone* or *compartment* declared free from NHP, 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 9.X.4. or 9.X.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from NHP.

The *certificate* should be in accordance with the Model Certificate in Chapter 5.10.

This Article does not apply to *commodities* listed in point 1 of Article 9.X.3.

Article 9.X.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from necrotising hepatopancreatitis

1. *Competent Authorities* should not require any NHP related conditions, regardless of the NHP status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   [ ] (under study)

   For these *commodities* 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.

2. When importing *aquatic animals or aquatic animal products,* other than those referred to in point 1 above, of the species referred to in Article 9.X.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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Annex XXI

DISINFECTED EGGS - NEW ARTICLES

EU positions

The EU can only support the adoption of the Articles, if point 2 a) is amended to read as follows: the *eggs* should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* (under study) ~~or those~~ specified by the *Competent Authority* of the *importing* country; and

Rationale:
As previously highlighted by the *ad hoc* Group on Safety of Products derived from Aquatic Animals, a prerequisite for trade in disinfected eggs from an infected country, zone or compartment is that the disinfection protocol is effective in reducing the risk of egg surface associated transmission of disease. It is the opinion of the EU that Chapter 1.1.3 of the Aquatic Manual needs further elaboration before it can be regarded as an effective disinfection protocol. As no revised version of that Chapter is presented for adoption this year, the EU proposes that the part of the Article referring to Chapter 1.1.3 of the Aquatic Manual is put under study. As long as that reference is under study, the importing country should lay down the applicable disinfection protocol.

In addition the EU would request the AAC to consider adding a new point 4 at the end of each of the Articles:

The OIE Members may wish to consider internal measures, such as renewed disinfection of the eggs upon arrival in the importing country.

Furthermore, the EU would support that Articles on egg disinfection for all listed diseases which do not exhibit true vertical transmission are developed. In the further development of this article the EU would encourage the AAC to explore whether the risk assessment referred to in point 1 of the Articles could be replaced by a description of disease specific additional risk mitigation measures to be taken by the exporting country to ensure the safe trade in disinfected eggs.

Article 10.4.X.

Importation of disinfected eggs for *aquaculture* from a country, *zone* or *compartment* not declared free from infectious haematopoietic necrosis

1. When importing disinfected *eggs* of the species referred to in Article 10.4.2 for *aquaculture*, from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the ~~conduct a *risk assessment* based on information provided by the *Competent Authority* of the *exporting country*, including~~ associated with at least:

   a) the IHN virus status of the water to be used during the *disinfection* of the *eggs*;

b) the level of *infection* with IHN virus in broodstock (ovarian fluid and milt); and

c) the temperature and pH of the water to be used for *disinfection*.

2. If the *Competent Authority* of the *importing country* concludes that the *importation* is acceptable, it should apply the following *risk* mitigation measures including:

a) the *eggs* should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* ~~or those specified by the *Competent Authority* of the *importing* country~~; and

b) between *disinfection* and the import, *eggs* ~~must~~ should not come into contact with anything which may affect their health status ~~be kept in specific pathogen free water~~.

3. When importing disinfected *eggs* of the species referred to in Article 10.4.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certified official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.4.X. have been fulfilled.

Article 10.5.X.

Importation of disinfected eggs for *aquaculture* from a country, *zone* or *compartment* not declared free from infectious salmon anaemia

1. When importing disinfected *eggs* of the species referred to in Article 10.5.2 for *aquaculture*, from a *country*, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

a) the ISA virus status of the water used during the *disinfection* of the *eggs*;

b) the level of *infection* with ISA virus in broodstock (ovarian fluid and milt); and

c) the temperature and pH of the water used for *disinfection*.

2. If the *Competent Authority* of the *importing country* concludes that the *importation* is acceptable, it should apply the following *risk* mitigation measures including:

   a) the *eggs* should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* ~~or those specified by the *Competent Authority* of the *importing country*~~; and

   b) between *disinfection* and the import, *eggs* ~~must~~ should not come into contact with anything which may affect their health status ~~be kept in specific pathogen free water~~.

3. When importing disinfected *eggs* of the species referred to in Article 10.5.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certified official* approved by the *importing country* attesting that the procedures described Article 10.5.X. point 2 have been fulfilled.

Article 10.9.X.

Importation of disinfected eggs for *aquaculture* from a country, *zone* or *compartment* not declared free from viral haemorrhagic septicaemia

1. When importing disinfected *eggs* of the species referred to in Article 10.9.2 for *aquaculture*, from a *country*, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

   a) the VHS virus status of the water used during the disinfection of the *eggs*;

   b) the level of *infection* with VHS virus in broodstock (ovarian fluid and milt); and

   c) the temperature and pH of the water used for *disinfection*.

2. If the *Competent Authority* of the *importing country* concludes that the *importation* is acceptable, it should apply the following *risk* mitigation measures including:

   a) the *eggs* should be disinfected prior to importing, according to the methods described in Chapter .1.3. of the *Aquatic Manual* ~~or those specified by the *Competent Authority* of the *importing country*~~; and

   b) between *disinfection* and the import, *eggs* ~~must~~ should not come into contact with anything which may affect their health status ~~be kept in specific pathogen free water~~.

3. When importing disinfected *eggs* of the species referred to in Article 10.9.2 for *aquaculture*, from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certified official* approved by the *importing country* attesting that the procedures described Article 10.9.X. point 2 have been fulfilled.

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Annex XXII

CHAPTER 7.3.

WELFARE ASPECTS OF STUNNING AND KILLING ~~SLAUGHTER~~ OF FARMED FISH FOR HUMAN CONSUMPTION

EU position

The EU welcomes the work carried out on the Draft Chapter on the Welfare Aspects of Stunning and Killing of Farmed Fish for Human Consumption and can support the adoption of the Chapter. The EU thanks the OIE for having taken into account a number of comments previously submitted.

Moreover, the EU wishes to encourage OIE to develop as soon as possible also the Draft Chapter on Humane Killing of Fish for Disease Control Purposes, as indicated on the Aquatic Animals Commission work plan and in consistency with the Terrestrial Code.

In finalising this draft chapter, the EU encourages OIE to take into consideration the recently adopted Council Regulation (EC) No 1099/2009 on the protection of animals at the time of killing and in particular Article 3 which is relevant to the killing of fish as well as the recently adopted EFSA opinions on the species-specific welfare aspects on the stunning and killing of fish.

Specific EU comments are provided within the text for further development of the Chapter.

Article 7.3.1.

Scope

These recommendations apply to the ~~slaughter~~ stunning and killing of farmed fish species for human consumption.

These recommendations address the need to ensure the welfare of farmed fish, intended for human consumption, during stunning and killing including transport and holding immediately prior to stunning ~~pre-slaughter and slaughter processes, until they are dead~~.

This chapter describes general principles that should be applied to ensure the welfare of fish for ~~slaughter~~ stunning and killing and also applies to fish killed for disease control purposes and intended for human consumption. Specific measures applicable to emergency killing for disease control purposes not intended for human consumption are addressed in Chapter 7.4. Humane Killing for disease control purposes (under development).

As a general principle, fish should be stunned before killing, and the stunning method should ensure immediate and irreversible loss of consciousness. If the stunning is not irreversible, fish should be killed before consciousness is recovered.

Article 7.3.2.

Personnel

Persons engaged in the handling, stunning and ~~slaughter~~ killing of fish play an important role in their welfare. Personnel handling fish for ~~slaughter~~ killing should be experienced and competent in the handling of fish, and understand their behaviour patterns as well as the underlying principles necessary to carry out their tasks. Some stunning and killing methods may pose a risk to the personnel, therefore training should cover occupational health and safety implications of any methods used.

The EU reiterates its previous position:

In the second sentence of the above paragraph of Art 7.3.2, the words "*stunning and killing*" should be added after "*the handling*".

Justification
It is important to ensure that these specific points are part of the training of the personnel.

Article 7.3.3.

Transport ~~of fish~~ ~~for slaughter~~

If fish are to be transported ~~for slaughter~~ prior to stunning and killing, this should be done in accordance with the OIE recommendations on the welfare of farmed fish during transport (see Chapter 7.2.).

Article 7.3.4.

Design of holding facilities ~~for holding fish prior to slaughter~~

1. The holding facilities should be designed and specifically constructed to hold a certain fish species or group of fish species.

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2. The holding facilities should be of a size that allows holding a certain number of fish for processing in a given timeframe without compromising the welfare of the fish.

3. Operations should be conducted with minimal injury and stress to the fish.

4. The following recommendations may help to achieve this:

   a) Nets and tanks should be ~~suitably~~ designed to minimise physical injuries;

   b) Water quality should be suitable for the fish species and stocking density;

   c) Equipment for transferring fish, including pumps and pipes, should be ~~appropriate~~ designed to minimise injury.

EU comment

In point 4. c) of Art 7.3.4 the words "*and maintained*" should be added after "*designed*".

Justification
The maintainence of the equipment is important to the fish welfare.

Article 7.3.5.

Unloading, transferring and loading ~~fish prior to slaughter~~

1. Fish should be unloaded, transferred and loaded ~~for slaughter~~ under conditions that minimise injury and stress to the fish.

2. The following points should be considered:

   a) Water quality should be assessed on arrival of fish prior to their unloading ~~for slaughter~~, and corrective action taken ~~as appropriate~~ if required.

The EU reiterates its previous comment:

Point 2. a) of Art 7.3.5 should be replaced by "*temperature and water quality (including oxygen, CO_2 level, pH and salinity) in the holding facilities should be assessed taking into account the density of fish prior to their unloading in the holding facilities*".

Furthermore, in the same sentence it is unclear if the water being reffered to is that which the fish have been transported in, or that which fish are transported into.

Justification

Water quality can only be assessed taking into account temperature and density of the fish. Moreover oxygen, CO2 level, pH and salinity are important elements of water quality.

b) Where possible any injured or moribund fish should be separated and killed humanely.

c) The crowding periods of fish ~~prior to slaughter~~ should be as short and infrequent as possible.

d) The handling of fish during transfers should be minimised and preferably fish should not be handled out of water. If fish need to be removed from water, this period should be kept as short as possible.

e) Where feasible, and when applicable, fish should be allowed to swim directly into a stunning device without handling to avoid handling stress.

f) Equipment used to handle fish, for example nets and dip nets, pumping devices and brailing devices, should be designed, constructed and operated to minimise physical injuries.

g) There should be a contingency plan to address emergencies and minimise stress during unloading, transferring and loading fish ~~prior to slaughter~~.

Article 7.3.6.

Stunning and killing methods

1. General considerations

a) The *Competent Authority* should approve the stunning and killing methods ~~for the slaughter~~ ~~of~~ for fish. The choice of ~~slaughter~~ method should take account of species-specific information where available.

b) All handling, stunning and killing ~~E~~equipment should be maintained and operated appropriately; it should be tested on a regular basis to ensure that performance is adequate.

c) Effective stunning should be verified by the absence of consciousness.

d) A backup stunning system is necessary. If mis-stunned, the fish should be re-stunned as soon as possible.

e) Stunning should not take place if killing is likely to be delayed such that the fish will recover or partially recover consciousness.

f) While absence of ~~un~~consciousness may be difficult to recognise, signs of correct stunning include i) loss of body and respiratory movement (loss in opercular activity); ii) loss of visual evoked response (VER); iii) loss of vestibulo-ocular reflex (VOR, eye rolling).

2. Mechanical stunning and killing methods

a) Percussive stunning is achieved by a blow of sufficient strength to the head applied above or immediately adjacent to the brain in order to damage the brain. Mechanical stunning may be achieved either manually or using specially developed equipment.

b) Spiking or coring are irreversible stunning and killing methods of fish based on physical damage to the brain by inserting a spike or core into the brain.

c) Shooting using a free bullet may be used for killing large fish (such as tuna). The fish may either be crowded in a net and shot in the head from the surface, or individual fish may be killed by shooting in the head from under the water (commonly called lupara).

d) Mechanical stunning is generally irreversible if correctly applied.

3. Electrical stunning and killing methods

a) Electrical stunning involves the application of an electrical current of sufficient strength, frequency and duration to cause immediate ~~unconsciousness~~ loss of consciousness and insensibility of the fish. ~~In fresh water,~~ ~~t~~The conductivity of fresh and brackish water varies, so it is essential to establish the parameters of the electrical current to ensure proper stunning ~~water conductivity is essential to establish parameters of the electrical current suitable to ensure appropriate stunning~~.

b) The electrical stunning device should be constructed and used for the specific fish species and their environment.

c) Electrical stunning may be reversible. In such ~~a~~ cases fish should be killed before consciousness is recovered.

d) Fish should be confined beneath the surface of the water, and there should be a uniform distribution of electrical current in the stunning tank or chamber.

f) In semi-dry electrical stunning systems, fish should enter the device head first to ensure rapid~~,~~ ~~painless~~ and efficient stunning.

Annex XXII (contd)

4. Other ~~stunning and~~ killing methods

The following ~~other~~ methods are known to be used for killing fish: chilling with ice in holding water, carbon dioxide (CO_2) in holding water; chilling with ice and CO_2 in holding water; salt or ammonia baths; asphyxiation by removal from water; exsanguination without stunning. However, they have been shown to result in poor fish welfare. Therefore, ~~I~~it is preferable to use the methods described in points 2.~~,~~ and3. ~~and 4~~. of this Article, as appropriate to the fish species.

The EU reiterates its previous comment:

Point 4 of Art 7.3.6 should be either deleted or it should be more clearly indicated that the stunning and killing methods listed here should not be recommended from an animal welfare point of view.

Justification

The stunning and killing methods listed in point 4 have been shown to result in poor fish welfare and therefore should not be used.

Article 7.3.7.

~~Application~~ Examples of ~~some~~ stunning/killing methods for fish groups

The following ~~stunning~~ methods enable humane killing for the following fish groups:

a) Percussive stunning: carp, catfish, salmonids, halibut;

The EU reiterates its previous comment:
The EU would wish OIE to provide the scientific basis for percussive stunning for catfish and halibut.

b) Spiking or coring: salmonids, tuna;

c) Free bullet: tuna;

d) Electrical stunning: carp, catfish, eel, salmonids, tilapia.

The EU reiterates its previous position:
The EU would wish OIE to provide the scientific basis for electrical stunning for catfish, eel and tilapia.

Article 7.3.8.

Summary table of some stunning/killing methods for fish and their respective welfare issues

The EU reiterates its previous comment:

In the table of Art 7.3.8:

It should be defined what is meant by "*small*", "*medium*" and "*large*" fish sizes. Furthermore, the following text should be included at the end of the paragraph on the disadvatages of percussive stunning method:

"and it is not suitable for mixed sizes of fsh"

Justification

Clarity

A combination of methods described in the table below may be used.

Stunning/killing method	Specific method	Key fish welfare concerns/requirements	Advantages	Disadvantages
Mechanical	Percussive stunning	The blow should be of sufficient force and delivered above or adjacent to the brain in order to render immediate unconsciousness. Fish should be quickly removed from the water, restrained and given a quick blow to the head, delivered either manually by a club or by automated percussive stunning. The effectiveness of stunning should be checked, and fish be re-stunned if necessary. It can be a stun / killing ~~method~~.	Immediate loss of consciousness. ~~Well adapted to~~ Suitable for medium to large sized fish.	Hand operated equipment may be hampered by uncontrolled movement of the fish. Mis-stunning may result from a too weak blow. Injuries may occur. Manual percussive stunning is only practicable for the killing of a limited number of fish.
	Spiking or coring	The spike should be aimed on the skull in a position to penetrate the brain of the fish and the impact of the spike should produce immediate unconsciousness. Fish should be quickly removed from the water, restrained and the spike immediately inserted into the brain. It is a stun / killing ~~method~~.	Immediate loss of consciousness. ~~Well adapted to~~ Suitable for medium to large sized fish. For small tuna, spiking under the water avoids exposure of fish to air. The pineal window of tuna facilitates spiking for this species.	Inaccurate application may cause injuries. Difficult to apply if fish agitated. It is only practicable for the killing of a limited number of fish.
	Free bullet	The shot should be carefully aimed at the brain. The fish should be positioned correctly and the shooting range should be as short as practicable. It is a stun / killing ~~method~~.	Immediate loss of consciousness. ~~Well adapted to~~ Suitable for large sized fish (e.g. large tuna).	Shooting distance; calibre need to be adapted. Excessive crowding and noise of guns may cause stress reaction. Contamination of the working area due to release of body fluids may present a biosecurity risk. May be hazardous to operators.

Annex XXII (contd)

Stunning/killing method	Specific method	Key fish welfare concerns/requirements	Advantages	Disadvantages
Electrical	Electrical stunning	Involves the application of an electrical current of sufficient strength, frequency and duration to cause immediately unconsciousness. It can be a stun / kill~~ing~~ method. Equipment should be designed and maintained correctly.	Immediate loss of consciousness. ~~Well adapted to~~ Suitable for small to medium sized fish. Suitable for large numbers of fish, and the fish do not have to be removed from the water.	Difficult to standardise for all species. Optimal control parameters are unknown for some species. May be hazardous to operators.
	Semi-dry electrical stunning	The head of the fish should enter the system first so electricity is applied to the brain first. Involves the application of an electrical current of sufficient strength, frequency and duration to cause immediately unconsciousness. Equipment should be designed and maintained correctly.	Good visual control of stunning and the ability for re-stunning of individual fish.	Misplacement of the fish may result in improper stunning. Optimal control parameters are unknown for some species. Not suitable for mixed sizes of fish.

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Annex XXIII

CHAPTER 6.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

EU position

The EU agrees with the proposed text.

The EU strongly encourages the OIE to continue its collaboration with the Codex Alimentarius Commission in the field of antimicrobal resistance. It reiterates its former comment regarding the last sentence of the third paragraph that should read: "Arising from its mandate for the protection of animal health and food safety, and in synergy with activities of the Codex Alimentarius Commission, the OIE developed these chapters to provide guidance to Members in regard to risks in the animal sector."

Article 6.1.

Objective

The purpose of this section ~~chapters (6.2., 6.3., 6.4., 6.5. under study)~~ is to provide guidance ~~methodologies~~ for ~~OIE~~ Members to appropriately address the selection and dissemination ~~emergence or spread~~ of resistant micro-organisms and antimicrobial resistance determinants ~~bacteria~~ from the use of antimicrobial agents in *aquatic animals* ~~and to contain antimicrobial resistance through controlling the use of antimicrobial agents~~.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating, controlling and preventing infectious *diseases* in *aquatic animals*. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is ~~a priority~~ important.

The OIE recognises that antimicrobial resistance is a global public and ~~*aquatic*~~ animal health concern that is influenced by the usage of antimicrobial agents in humans, ~~*aquatic*~~ *animals* and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to address the risk factors ~~prevent or minimise pressures~~ for the selection and dissemination of antimicrobial resistance ~~factors in humans and *aquatic animals*~~. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Members in regard to risks in the animal sector.

The application of *risk assessment* and *risk management* measures should be based on relevant international standards on ~~microbiological~~ *risk analysis* and supported by sound data and information when available. The ~~methodologies~~ guidance provided in these chapters should be consulted as part of the standard approach to ~~prevent and~~ reduce the risk associated with the selection and dissemination of antimicrobial resistant~~ce~~ micro-organisms and antimicrobial resistance determinants.

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Annex XXIV

CHAPTER 5.4.

~~RECOMMENDATIONS FOR SAFE TRANSPORT~~ CONTROL OF AQUATIC ANIMAL~~S~~ HEALTH RISKS ASSOCIATED WITH TRANSPORT OF ~~AND~~ AQUATIC ANIMALS ~~PRODUCTS~~

[…]

Annex XXV

CHAPTER X.X.

HANDLING, DISPOSAL AND TREATMENT OF AQUATIC ANIMAL WASTE

EU position

The EU support the adoption of this new Chapter.

Article X.1.

Introduction

The objective of this chapter is to provide guidance on storage, transport, disposal and treatment of *aquatic animal* wastes so as to manage risks to *aquatic animal* health. The recommendations in this Chapter are general in nature. The choice of one or more of the recommended methods should comply with relevant local and national legislation.

Disposal methods should take into consideration a range of factors, including the cause of mortality. It may be appropriate to carry out a *risk assessment* on the disposal options.

In the case of killing of animals for disease control purposes or unusually large mortalities, this may require approval from, or supervision by, the *Competent Authority*.

In the event of *aquatic animal* mortalities of a significant nature in aquaculture or in the wild, the Competent Authority should be notified so that necessary steps can be taken to dispose of the dead *aquatic animal*s, in order to minimise the risk for possible spread of *aquatic animal* disease.

Article X.2.

Scope

The scope of this Chapter covers *aquatic animal* waste derived from: i) routine aquaculture operations; ii) on shore processing, irrespective of origin; iii) mass killing for disease control purposes and iv) mass mortality (including in the wild).

Article X.3.

Definitions

Aquatic animal waste means the entire body or parts of *aquatic animals* that have died or been killed for disease control purposes as well as slaughtered *aquatic animals*, and their parts, that are not intended for human consumption.

High risk waste means *aquatic animal* waste that constitutes, or is suspected of constituting, a serious health risk to *aquatic animals* or humans.

Low risk waste means *aquatic animal* waste that is not high risk waste.

Article X.4.

Governance

The *Competent Authority* should oversee the efficient and effective disposal of *aquatic animal* waste. Cooperation among all relevant agencies and stakeholders involved in *aquatic animal* health is necessary to ensure safe handling and disposal. In this context the following aspects should be addressed:

1. physical, logistical and data access by relevant personnel, in cooperation with stakeholders, including access of the *Competent Authority* to the *aquatic animal* waste;

2. movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of *aquatic animal* waste to another location for disposal;

3. the determination of the method and location of disposal, and the necessary equipment and facilities, by the *Competent Authority*, in consultation with other authorities including government organisations responsible for the protection of human health and the environment.

Article X.5.

Storage, transport and labelling

Following collection, *aquatic animal* waste should be stored for the minimum time practical; however, where storage is necessary there should be sufficient capacity for the expected waste and the *Competent Authority* may require additional measures.

The storage area should be separated from *aquaculture* sites and bodies of water to minimise the risk of spread of *disease agents*. The *containers* of stored *aquatic animal* waste should be leak proof and secured to prevent contact with *aquatic animals*, other animals or birds and unauthorised personnel.

Aquatic animal waste infected by an agent causing a *disease* referred to in the *Aquatic Code* or suspected of being so, may not be transported without permission from the *Competent Authority*. The *Competent Authority* may assess the requirement for this condition based on the disease situation in the Member country (e.g. where a *disease* referred to in the *Aquatic Code* is enzootic in the Member country).

If low risk waste becomes contaminated with high risk waste, such waste should then be considered high risk waste.

Containers used for transport of *aquatic animal* waste should be leak-proof and labelled regarding content. Transport should be accompanied by appropriate documentation detailing origin, content and destination to allow tracing if required.

Equipment used for transportation should be cleaned and disinfected before being returned, as described in Chapter 4.2. on General recommendations on disinfection.

Article X.6.

Approval and operational requirements of disposal plants

1. Requirement for approval

   All disposal plants dealing with *aquatic animal* waste should be approved by the *Competent Authority*. However, disposal plants using only low risk waste for production of products not intended to be used in animals may be exempted from approval but should be registered by the *Competent Authority*.

2. Conditions for approval

   For a disposal plant to be approved to deal with *aquatic animal* waste, it should:

   a) be adequately separated from thoroughfares through which contamination may be spread, other premises (such aquaculture facilities, slaughterhouses, processing plants) and bodies of water, so as to minimise the risk of spread of *disease agents;*

b) be designed and equipped to the satisfaction of the *Competent Authority*;

c) have access to approved or accredited laboratories;

d) fulfill requirements for handling the *aquatic animal* waste and products specified by the *Competent Authority*;

Any substantial proposed changes to the disposal plant should be approved by the *Competent Authority*.

Approval should be withdrawn or suspended, as appropriate, if a disposal plant no longer fulfils the criteria given by the *Competent Authority*.

3. Operating requirements

The disposal plant should operate using procedures that minimise the risk of spread of *disease agents*, including:

a) separation of clean and unclean areas, including consideration of workflow, and good hygienic procedures for personnel;

d) equipment and surfaces should be easy to clean and disinfect;

e) handling and treatment of *aquatic animal* waste should take place as soon as possible after being received;

f) effluent waste water should be collected and disinfected before leaving the premises;

g) incorporating measures to prevent access of birds, insects, rodents or other animals to the disposal plant;

h) a system for registration and labelling of material for tracing purposes.

A system for internal control, identifying critical points and means of control for such points, should be in place at the disposal plants. A general documentation system for internal control including sampling for control of critical points should be established.

Spot checks of batches should be carried out to check the microbiological standards following processing. Products from incineration plants may be exempted from such checks. The *Competent Authority* may grant exemptions on specified conditions.

If testing of the product from processed high risk waste shows that the product is not satisfactorily produced and thus poses a risk for the spread of *disease agents*, disposal plants should report immediately to the *Competent Authority* who may then require additional measures. These products should not be transported from disposal plants without permission from the *Competent Authority*.

Results from the different samples and checks should be kept for a given period decided upon by the *Competent Authority*. Analyses and sampling should be carried out in accordance with international standards.

Disposal plants applying treatments based on time and pressure should be able to measure and record these parameters.

Annex XXV (contd)

Disposal plants should maintain records related to quantity and type of raw material received, supplier, quantity and type of finished product, receivers, critical check points, and deviations from provisions stipulated in relevant regulations. These should be made available to the *Competent Authority* on request.

Article X.7.

Methods for disposal of high risk waste

Recommended methods for disposal of high risk waste from *aquatic animal*s as follows:

1. Rendering

   Rendering will inactivate all of the known *aquatic animal* disease agents.

   Rendering is generally carried out in a closed system using a combination of mechanical treatments and time/temperature combinations leading to stable, sterilised products, such as fish meal and fish oil.

   The process typically involves pre-heating to 50-60°C, followed by cooking of the raw waste at 95-100°C for 15 to 20 minutes. The oil and proteins are separated by pressing and centrifuging involving temperatures of 90°C. The production of meal involves further high temperature treatments.

2. Incineration

   Incineration is a controlled burning process carried out in fixed incinerators or mobile air curtain incinerators. Mobile air curtain incinerators enable the process to be carried out on site thus removing the need to transport the *aquatic animal* waste.

   Incinerators may only be capable of handling limited volumes of *aquatic animal* waste.

3. Sterilisation

   The minimum requirement for sterilisation is a core temperature of at least 90□C for at least 60 minutes, but other time/temperature combinations are also available and effective.

4. Composting

   Composting does not inactivate all *disease agents*; therefore, high risk waste should be heated (85°C for 25 minutes or an equivalent temperature/time combination) prior to the composting process.

   Effective composting depends upon a combination of pH, temperature, moisture and time factors. Depending on the type of composting (e.g. windrows, closed vessel) and the raw material used, as well as the climatic conditions, the temperature parameters of the process and the heat distribution in the material may be different.

   When held in windrows, the entire material needs an exposure time of at least two weeks at 55°C, while in closed vessels exposure to 65°C for one week is required.

5. Biogas production

   Biogas production does not inactivate all *disease agents*; therefore, high risk waste should be treated to ensure inactivation of *disease agents* prior to the biogas production process. The method chosen should be shown to inactivate the *disease agents* of concern.

Biogas production is a process whereby organic matter in biological waste products is fermented under anaerobic conditions.

The two main types of biogas production are mesophilic anaerobe digestion and thermophilic anaerobe digestion .

Both processes are normally continuous, and a portion of the end material is removed every 2-12 hours. There is a risk that new material which has been in the reactor for only 2-12 hours may be removed with the finished products.

6. Ensiling

Ensiling does not inactivate all *disease agents*; therefore, high risk waste should be heated (85°C for 25 minutes or an equivalent temperature/time combination) prior to the ensiling process.

Ensiling of *aquatic animal* waste in an organic acid such as formic acid is an effective method of inactivating most disease agents within 48 hours. The pH in the ensiling process should be maintained at, or below, 4.0 throughout the process.

7. Burial

Burial may take place either in a landfill site or other locations approved by the *Competent Authority* based on *risk assessments* as regards *aquatic animal* health, public health and possible environmental impacts.

Whenever possible, the *aquatic animal* waste should be subjected to a treatment that ensures inactivation of the *disease agents* prior to burial.

In selecting an acceptable burial site, consideration should be given to the following:

Location – for example, distance from *aquaculture establishments*, bodies of water, depth of the ground water table, topography, adjacent land use; and direction of prevailing wind;

Access - easy access for equipment and delivery of *aquatic animal* waste. Fencing and restricted admittance may be necessary.

Pit construction - rocky areas should be avoided. Soils with good stability, capable of withstanding the weight of equipment used to dig and fill the pits, should be selected. If required, diversion banks can be constructed to prevent surface runoff entering the pit or to prevent any liquids escaping from the burial site. Pit dimensions depend on the volume of the *aquatic animal* waste to be buried and should be easy to fill.

Pit closure - contents should be covered with unslaked lime (CaO) at a rate of 85 kg per 1000 kg of *aquatic animal* waste to hasten decomposition and prevent scavenging.

8. Pyre-burning

Pyre burning may not be suitable for large amounts of *aquatic animal* waste.

In selecting an acceptable pyre burning site, the following considerations are important:

a) Location - the possible effects of the fire's heat, smoke and odour on nearby structures, underground and aerial utilities, roads and residential areas. The site should be surrounded by an adequate firebreak.

b) Access - for equipment to construct the pyre and maintain the fire, for the delivery of fuel and *aquatic animal* waste.

Pyre burning needs considerable amounts of fuel and all required fuel should be on site before the burning is started. If the pyre-burning is carried out correctly, *aquatic animal* wastes will be destroyed within 48 hours.

When leaving the pyre-burning site, vehicles and containers should be disinfected.

Alternatively, high risk waste may be disposed off by any methods, approved by the *Competent Authority*, which ensure an equivalent reduction of risk.

Article X.8.

Methods of disposal for low risk waste

Low risk waste can be disposed of using all methods described in Article X.7. In the case of composting or biogas production it is not necessary to heat treat the low risk waste prior to disposal.

Alternatively, the following methods may be used:

1. Ensiling

Ensiling of *aquatic animal* waste in an organic acid such as formic acid is an effective method of inactivating most disease agents within 48 hours. The pH in the ensiling process should be maintained at, or below, 4.0 throughout the process.

The *Competent Authority* may require ensiling as a treatment prior to one of the disposal methods described in Article X.7.

2. Pasteurisation

Pasteurisation does not inactivate all disease agents. Heat treatment at temperatures below 100°C can be considered as pasteurisation. Pasteurisation may use a range of time/temperature combinations.

In addition, the *Competent Authority* may permit low risk waste to be disposed of by other means, or used for any other purposes. following an assessment of the risk from such methods or uses.

Article X.9.

Mass mortality events

Mass mortality of *aquatic animals* can arise from natural events or killing for disease control purposes (refer to Chapter X.X. on the humane killing of fish for disease control purposes; in preparation). This may lead to the need for disposal of large numbers of dead *aquatic animal*s and is often subject to intense public and media scrutiny. The *Competent Authority* should conduct disposal operations within acceptable scientific principles that will address the risks of spread of the disease agent, and public and environmental concerns.

1. Preparedness

Successful disposal with minimum delay is achieved by advance planning and preparation:

a) Preparedness planning should engage other relevant government agencies and stakeholders such as industry organisations, animal welfare organisations, emergency response organisations, and media.

b) Standard operating procedures should be developed (including documented decision-making processes, training of staff).

c) Pre-arranged mechanisms to access emergency funding for the disposal operation.

d) Information sharing with officials involved in the disposal operation, stakeholders, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

e) Resource readiness planning should address such items as personnel, transport, storage facilities, equipment, fuel, protective clothing and logistical support. Special equipment, such as well boats, may be required.

2. Critical elements

Critical elements which need to be considered in planning and implementation include:

a) rapid disposal of the dead *aquatic animals*;

b) methods of treatment and disposal should address capacity issues and the risks of spread of disease agents;

c) adequate funding and staff resources;

d) addressing the risk of spread of disease agents by vectors and fomites;

e) stakeholder cooperation;

f) safety of personnel;

g) environmental concerns;

h) societal acceptance.

3. Choice of disposal methods

The *Competent Authority* may determine the dead *aquatic animals* to be either *high risk waste* or low risk waste and select an appropriate disposal method according to the risk (refer to Articles X.7. and X.8.).

Should the chosen disposal option be applied near the border of a neighbouring country, the *Competent Authority* of that country should be informed.

Annex XXVI

References to non-susceptible species in Chapter 2.4.3. in the *Manual of Diagnostic Tests for Aquatic Animals*

CHAPTER 2.4.3.

INFECTION WITH *BONAMIA OSTREAE*

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EU position

The EU agrees with the proposed text.

However, the EU would like to emphasise the importance of having a clear description of the species that for the purpose of the OIE Aquatic Code are to be regarded as susceptible to the listed diseases. The below text could benefit from further clarification in this respect. Please also see the comments made under point 2.1 of the Report to the AAC.

2.2.1. Susceptible host species

Natural host: European flat oysters, *Ostrea edulis*.

Oyster species infected when moved into endemic zones: *Ostrea puelchana, O. angasi, O. chilensis* (= *Tiostrea chilensis, T. lutaria*) (7).

It has been speculated that *Ostrea conchaphila* (= *O. lurida*), *Crassostrea angulata* and *C. ariakensis* (= *C. rivularis*) have been infected with *B. ostreae* (7), but confirmatory diagnosis has not been achieved.

Experimental works suggested that the following species are not susceptible to *B. ostreae*: *Crassostrea gigas*, *Ruditapes decussatus*, *R. philippinarum*, *Mytilus edulis*, *M. galloprovincialis* (Culotty *et al.*, 1999; Renault *et al.*, 1995).

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Annex XXVII

CHAPTER 2.4.1.

INFECTION WITH ABALONE HERPES-LIKE VIRU

EU position

The EU would agree with the proposed text.

However, the EU would like to emphasise the importance of having a clear description of the species that for the purpose of the OIE Aquatic Code are to be regarded as susceptible to the listed diseases. Point 2.2.1 of this Chapter could benefit from further clarification in this respect. Please also see the comments made under point 2.1 of the Report to the AAC.

1. Scope

For the purpose of this chapter, abalone viral ganglioneuritis is considered to be infection with abalone herpes-like virus (AbHV).

2. Disease information

2.1. Agent factors

Abalone herpes-like virus (AbHV) is the aetiological agent for abalone viral ganglioneuritis (AVG) a contagious viral disease of abalone in Australia (4, 5) and possibly abalone species in other countries (1, 8). However, whilst the relationship between the Australian viral isolate(s) and other herpes-like viral isolates has not, as yet, been elucidated, it is suggested that this virus is the second member of the Malacoherpesviridae along with Ostreid Herpesvirus-1 (3, 6).

2.1.1. Aetiological agent, agent strains

AbHV particles have been purified (7) and were observed by transmission electron microscopy to be icosahedral with electron dense cores and a diameter of 100–110 nm. The intranuclear location of the virus particles, their size and ultrastructure are characteristic of members of the Herpesviridae. Isopycnic gradient centrifugation (in potassium tartrate and caesium chloride gradients) indicated a buoyant density of 1.17–1.18 g/ml for the virus particles (7).

2.1.2. Survival outside the host

Not known – under investigation.

2.1.3. Stability of the agent (effective inactivation methods)

Under investigation.

2.1.4. Life cycle

Not applicable.

2.2. Host factors

2.2.1. Susceptible host species

Currently, species known to be susceptible to AVG in Australia are the greenlip abalone (*Haliotis laevigata*), blacklip abalone (*H. rubra*) and hybrids of these two species. Clinical signs consistent with AVG have not been reported in other molluscan species in areas where AVG is suspected to be enzootic. In Chinese Taipei, ganglioneuritis associated with a herpes-like viral infection and high mortalities in the abalone *H. diversicolor supertexta* has been reported. The disease was reported only in *H. diversicolor supertexta*, while cohabitating Japanese black abalone *H. discus* remained normal. (1). It is not known whether the Australian virus is the same as, or different to, the virus found in Chinese Taipei.

2.2.2. Susceptible stages of the host

All ages.

2.2.3. Species or subpopulation predilection (probability of detection)

No data.

2.2.4. Target organs and infected tissue

The major histopathological lesion identified in abalone affected with AVG is ganglioneuritis – inflammation confined to neural tissue. The cerebral, pleuropedal and buccal ganglia can be affected as well as the cerebral commissure and associated peripheral nerves (5).

2.2.5. Persistent infection with lifelong carriers

No data.

2.2.6. Vectors

No data.

2.2.7. Known or suspected wild aquatic animal carriers

No data

2.3. Disease pattern

Outbreaks of AVG in both farmed and wild abalone populations in Australia are associated with rapid onset of high mortality rates (up to 90%) in all age classes. Similarly, in Chinese Taipei, during the epizootic in cultured abalone (the water temperature was 16–19°C), both adult and juvenile abalone suffered from the disease, with cumulative mortalities of 70–80%. It was reported that death of all of the abalone in a pond could occur within 3 days of the onset of clinical signs. A similar disease pattern occurred with experimental infections (1, 2).

2.3.1. Transmission mechanisms

Horizontal transmission (1, 2) has been demonstrated experimentally by:

1. exposing healthy abalone to water containing diseased abalone in the same tank without direct contact between the diseased and healthy abalone;

2. placing healthy abalone in water that was previously inhabited by diseased abalone; and

3. intramuscular injection of healthy abalone with a filtered tissue homogenate from diseased abalone.

In all cases, 100% mortality was observed with a preclinical period of 1–2 days following exposure and then mortality commenced until 100% mortality occurred within 2–5 days post-infection.

2.3.2. Prevalence

In Victoria Australia, and similarly in Chinese Taipei, farms experiencing an outbreak of abalone viral ganglioneuritis can expect a rapid rise in mortality rate (up to 90% or more). Affected abalone demonstrating clinical signs (e.g. curling of the foot) are likely to die within 1 day of showing clinical signs. Ganglioneuritis is observed in sections of neural tissue by light microscopy and confirmation of the presence of abalone herpes-like virus is obtained by qPCR and/or *in-situ* hybridisation (2). Using these methods there has been very few false positives or false negatives reported. The precise prevalence of AVG in wild populations in Victorian waters is unknown.

2.3.3. Geographical distribution

Australia (Victoria and Tasmania), Chinese Taipei.

2.3.4. Mortality and morbidity

In on-farm epizootics in Victoria Australia cumulative mortality in all age classes can reach >90%. In experimental trials, 100% mortality can occur within 5 days post-exposure. The vast majority of abalone that display clinical signs are likely to die within 1–2 days.

2.3.5. Environmental factors

In Australia, the initial outbreak occurred on-farm in the summer months of 2005/2006 and subsequently appeared to spread to wild populations which experienced mortality throughout the following year i.e. during all seasons. All experimental infections to date have been carried out in artificial seawater in the temperature range 15–18°C. In Chinese Taipei, during the epizootic, the water temperature was 16–19°C, and experimental infections were carried out at 17–20°C. The precise temperature range for this virus is yet to be determined.

2.4. Control and prevention

In the absence of efficacious anti-viral agents, implementing high levels of on-farm biosecurity is recommended. Following an on-farm outbreak, destruction of infected stock, disinfection of water and equipment, and fallowing procedures appear to be effective at preventing reinfection. Prior to restocking the use of sentinel abalone can be used to test the status of the previously infected premises.

2.4.1. Vaccination

No vaccines available.

2.4.2. Chemotherapy

No data.

2.4.3. Immunostimulation

No data.

2.4.4. Resistance breeding

No data.

2.4.5. Restocking with resistant species

No data.

2.4.6. Blocking agents

No data.

2.4.7. Disinfection of eggs and larvae

No data.

2.4.8. General husbandry practices

To-date, experimental data indicates that the virus is highly virulent. Practices that could be implemented to reduce the severity of the disease have not been identified.

3. Sampling

3.1. Selection of individual specimens

At the first sign of an increase in weak or abnormally behaving abalone, or a sudden onset in mortality, live moribund individuals should be selected for sampling. If moribund or freshly dead abalone are not present, samples of healthy abalone from all parts of the farm and representing all age classes should be selected for sampling.

3.2. Preservation of samples for submission

Samples should be collected for examination by i) light microscopy (i.e. histology) and should be fixed in 10% formalin; ii) electron microscopy (fixed in 2.5% glutaraldehyde); iii) PCR (fixed in PCR preservative such as 95% ethanol). If fixatives are not available samples should be kept chilled (on ice) and forwarded to arrive at the laboratory within 24 hours. Alternatively, samples can be sent frozen (not suitable for histology or electron microscopy but can be used for PCR).

3.3. Pooling of samples

Fixed tissues can be pooled according to age class and pond/farm/geographical location.

3.4. Best organs or tissues

Neural tissue such as the cerebral, pleuropedal and buccal ganglia.

3.5. Samples/tissues that are not suitable

To date, lesions have not been detected consistently in non-neural tissues.

4. Diagnostic methods

4.1. Field diagnostic methods

4.1.1. Clinical signs

In Victoria Australia, AVG outbreaks in both farmed and wild populations were associated with high mortality rates (up to 90% on farm). Clinically, abalone may demonstrate one or more of the following signs: irregular peripheral concave elevation of the foot; swollen and protruding mouth parts; eversion of the radula; minimal movement of the pedal muscle; excessive mucus production; absence of the marked extension of the foot shown in the righting reflex when healthy abalone are turned onto their backs; reduced pedal adhesion to the substrate. In Tasmania, affected abalone observed in processing plants exhibited ‘hard foot’ or tetany; excessive mucus production; abnormal spawning; ‘bloating’ (4). Similar signs have been reported for an epizootic in Chinese Taipei (1).

4.1.2. Behavioural changes

AVG is an acute disease. Abalone are likely to die within 1–2 days of demonstrating clinical signs the disease.

4.2. Clinical methods

4.2.1. Gross pathology

Abalone that are loosely attached to the substrate due to abnormalities of the pedal muscle should be selected for sampling. If this gross pathology is due to acute AVG, it is likely that these abalone will die within 1-2 days.

4.2.2. Clinical chemistry

No data.

4.2.3. Microscopic pathology

Abalone affected with AVG demonstrate inflammation (increased infiltration by haemocytes) and necrosis confined to neural tissue (cerebral, pleuropedal and buccal ganglia, branches of the pedal nerve and peripheral nerves) as observed in histological sections of neural tissue stained with haematoxylin and eosin and examined by light microscopy (4, 5).

4.2.4. Wet mounts

Not applicable.

4.2.5. Fixed sections

In-situ hybridisation localises AbHV-infected cells within the neural tissue which, on histological examination, demonstrates ganglioneuritis typified by an inflammatory change with increased cellularity involving mainly haemocytes and glial cells, and cell necrosis in the affected nerves.

4.2.6. Electron microscopy/cytopathology

Transmission electron microscopy can be used to confirm the presence of viral particles in infected ganglia. AbHV particles are icosahedral with electron dense cores and a diameter of 100–110 nm. The intranuclear location of the particles and their ultrastructure are characteristic of members of the Herpesviridae (7).

4.3. Agent detection and identification methods

4.3.1. Direct detection methods

4.3.1.1. Microscopic methods

Neural tissue (cerebral, pleuropedal and buccal ganglia, branches of the pedal nerve and peripheral nerves) is the prime target and should be sampled and fixed (using 10% formaldehyde and processed using standard procedures, and stained with haematoxylin and eosin) for histological examination.

Tissue samples (containing pleuropedal ganglion) for examination by electron microscopy should be fixed using 2.5% (v/v) glutaraldehyde and 2–4% (v/v) paraformaldehyde in 0.1 M cacodylate buffer and post-fixed in 1% (w/v) osmium tetroxide, washed in reverse osmosis water (3 × 5 minutes), dehydrated in a graded series of 'analytical grade' ethanol (70%, overnight at 4°C; 95%, 20 minutes; 100%, 3 × 20 minutes), infiltrated in 100% Spurr's resin (overnight) and then embedded in Spurr's resin.

4.3.1.1.1. Wet mounts

Not applicable.

4.3.1.1.2. Imprints

Not applicable.

4.3.1.1.3. Fixed sections

Neural tissue (cerebral, pleuropedal and buccal ganglia, branches of the pedal nerve and peripheral nerves) is the prime target and examination of histological sections reveals ganglioneuritis – increased cellularity involving mainly haemocytes and glial cells, and cell necrosis.

4.3.1.2. Agent isolation and identification

4.3.1.2.1. Cell culture/artificial media

To date, attempts to culture the virus in both vertebrate and invertebrate cell lines have been unsuccessful.

4.3.1.2.2. Antibody-based antigen detection methods (*IFAT, ELISA, etc.*)

Not applicable

4.3.1.2.3. Molecular techniques (*PCR, ISH, sequencing, etc.*)

Neural tissue samples should be fixed in preservative (80% reagent grade ethanol; 19.75% glycerol; 0.25% β-mercaptoethanol) or, alternatively, 95% ethanol.

4.3.1.2.3.1 Nucleic acid extraction

The pleuropedal ganglion and/or pedal nerve cords are dissected from the fixed tissue and placed in 1.5 ml tubes for DNA extraction. Nucleic acid from AbHV-infected and uninfected abalone tissues (approximately 20 mg of muscle and neural tissue) are extracted using a commercial kit, e.g. QIAamp DNA mini kit (QIAGEN) or equivalent, according to the manufacturer's instructions. Nucleic acid, bound to minicolumns, is eluted and resuspended in a final volume of 100 µl of buffer (~100 ng μl^{-1}) provided in the kit.

4.3.1.2.3.2 Conventional one-step PCR

Following DNA extraction, PCR amplification is performed on DNA samples extracted from tissues derived from i) positive (known AbHV-infected) control, ii) negative (known uninfected), and iii) test (submitted) abalone samples.

The PCR mixture for a single sample consists of the following reagents: 9.5 µl water; 12.5 µl HotStar Taq Master mix; 0.5 µl forward primer (20 µM); 0.5 µl reverse primer (20 µM); 2 µl DNA. The mixture is incubated in an automatic thermal cycler programmed with the following cycling conditions: one cycle at 94°C for 15 minutes; 35 cycles at 94°C for 15 seconds, 52°C for 30 seconds and 72°C for 30 seconds; and, finally, one cycle at 72°C for 5 minutes. Amplified DNA is detected following resolution of the amplicons by agarose (2%) gel electrophoresis.

Primers used:

Forward primer (007F): 5'-GCC-TTC-GCT-GGA-AGC-ATA-C-3'

Reverse primer (007R): 5'-GTG-GTC-GCG-AGA-AGA-GAA-C-3'

Interpretation

At the completion of the PCR, specific PCR fragments of the correct size (486 bp) are resolved by agarose gel electrophoresis:

- The negative control sample must have no evidence of specific amplified products.
- A positive control sample must yield a specific AbHV fragment (486 bp in size).
- Amplified fragments of the correct size are then extracted from the gel, and the DNA sequence is determined (by using the PCR primers as sequencing primers).
- Sequence identity is determined by sequence alignment.

4.3.1.2.3.3 TaqMan PCR assay

Following DNA extraction, a real-time PCR is carried out in a 96-well plate using 25 µl reaction volume containing 12.5 µl of TaqMan® Fast Universal PCR Master Mix (2×), 2 µl (~100 ng per µl) of extracted DNA sample and the reaction mixture is made up to 25 µl using deionised water after primers and probes are added at the appropriate concentrations. The following thermal cycling conditions are used: 95°C for 59 seconds followed by 45 cycles of 95°C for 3 seconds and 62°C for 30 seconds.

The AbHV primers and probe sequences are as follows:

Forward primer (ORF49F): 5'-AAC-CCA-CAC-CCA-ATT-TTT-GA-3'

Reverse primer (ORF49R): 5'-CCC-AAG-GCA-AGT-TTG-TTG-TT-3'

6-carboxyfluorescein (FAM) and 6-carboxytetramethylrhodamine (TAMRA) labelled probe (ORF49Pr): 6FAM-CCG-CTT-TCA-ATC-TGA-TCC-GTG-G-TAMRA.

The AbHV primers and probe are used at a final concentration of 300 nM and 100 nM, respectively.

18S ribosomal RNA gene primers and probe (Applied Biosystems) are used to validate the nucleic acid extraction procedure and the absence of PCR inhibitors. The 18S RNA gene endogenous control primers and probe sequences are as follows:

Forward primer (18S Forward) 5'-CGG-CTA-CCA-CAT-CCA-AGG-AA-3'

Reverse Primer (18S Reverse) 5'-GCT-GGA-ATT-ACC-GCG-GCT-3'

Probe (18S VIC – TAMRA probe) 5'-TGC-TGG-CAC-CAG-ACT-TGC-CCT-C-3'

Both the 18S RNA gene primers and the probe are used at a final concentration of 100 nM.

All samples (including positive and negative controls) are tested in duplicate or triplicate. The results of a TaqMan assay are expressed in the form of software-generated characteristic amplification curves. Amplification curves from positive and negative (no template controls) should be compared to the test sample. A sample is considered above the test background level when the change in fluorescence (ΔR_n) of FAM or VIC, relative to that of ROX (internal reference dye), exceeds the threshold value which is arbitrarily set at the upper end of the linear range of the amplification plots. Results of a TaqMan assay can also be, and often are, expressed as cycle threshold (C_T) values. The cycle threshold (C_T) is defined as the cycle number at which a statistically significant increase in fluorescence output above background is detected.

At the completion of the TaqMan PCR assay, the presence of AbHV DNA is demonstrated by the presence of specific amplicons, identified by software-generated characteristic amplification curves and cycle threshold values (C_T). No-template controls must have no evidence of specific amplicons.

If the test is deemed valid, the results for the test sample wells may be interpreted using the following criteria:

- Positive test results are defined as the presence of specific amplicons expressed as a characteristic amplification curve similar to the positive control(s) and having a cycle threshold (C_T) value <35.0.
- Negative test results are defined as the absence of specific amplicons expressed by a characteristic amplification curve similar to the no-template control and having a cycle threshold (C_T) value equal to or greater than 36.0.

Indeterminate test results are defined as having a characteristic amplification curve similar to the positive control but a cycle threshold (C_T) value of 35.0–36.0. This necessitates repeating the assay with at least 3 test sample wells.

4.3.1.2.3.4 In-situ hybridisation

The *in-situ* hybridisation (ISH) procedure described here uses a digoxygenin (DIG)-labelled DNA probe to detect AbHV in formalin-fixed, paraffin-embedded (FFPE) tissue sections.

Reagents

20× SSC pH7 (store at room temperature)

175.32 g litre^{-1}	NaCl
88.23 g litre^{-1}	Sodium citrate

100× Denhardt's solution (store at –20°C)

2 g (100 ml)$^{-1}$	Bovine serum albumin (Fraction V)
2 g (100 ml)$^{-1}$	Ficoll 400
2 g (100 m)$^{-1}$l	Polyvinylpyrollidone

Hybridisation buffer (store at –20°C)

25 ml	Formamide
10 ml	20× SSC
2.5 ml	100× Denhardt's solution
10 ml	50% dextran sulphate in distilled water
500 µl	10 mg ml^{-1} herring sperm DNA

Make up to 50 ml with MilliQ water

10× Tris-buffered saline (TBS) (store at room temperature)

23.6 g litre^{-1}	Tris base
127 g litre^{-1}	Tris/HCl
87.66 g litre^{-1}	NaCl

Preparation of DIG-labelled probes

i) Perform PCR on purified AbHV DNA or a sample known to contain AbHV using a PCR DIG Probe Synthesis Kit (Roche Cat. No. 11 636 090 910) as per the manufacturers' instructions.

   a) Use AbHV_ORF66f1 (5'-TCC-CGG-ACA-CCA-GTA-AGA-AC-3') AbHV_ORF66r2 (5'-CCC-GGA-CAC-CAG-TAA-GAA-C-3') primer pair which amplifies an 848bp product from AbHV DNA.

   b) Use the following thermocycling profile: 95°C for 5 minutes followed by 30 cycles of 95°C for 30 seconds, 55°C for 30 seconds, 72°C for 60 seconds. Complete the PCR with a final elongation at 72°C for 10 minutes.

Preparation of sections

i) Section paraffin-embedded tissue at 3 µM thickness and place onto Superfrost plus slides (Menzel Catalogue No. SF41296SP) and allow to dry.

ii) Heat sections at 65°C for 30 minutes and deparaffinise in two stages of xylene.

iii) Rehydrate by placing slides in absolute ethanol for 2 minutes followed by 90% ethanol for 2 minutes, 70% ethanol for 2 minutes and then into distilled water.

iv) Place slides in 0.2 N HCl for 20 minutes and rinse in distilled water for 5–10 minutes.

v) Apply 50–100 µl of 100 µg ml^{-1} proteinase K in Tris-buffered saline (TBS) and incubate at 37°C for 30 minutes.

vi) Rinse with 0.2% glycine for 2 minutes.

vii) Wash in running water for 10 minutes.

viii) Dehydrate sample in 70% ethanol for 2 minutes followed by 90% ethanol for 2 minutes and 100% ethanol for 2 minutes.

x) Allow slides to air-dry.

Hybridisation procedure

i) Make 100 µl hybridisation solution per tissue section (4× SSC, 5× Denhardt's solution, 10 mg ml^{-1} herring sperm DNA, 10% dextran sulphate, 50% formamide, approximately 5 ng $µl^{-1}$ probe).

ii) Heat the hybridisation solution to 95–100°C for 5 minutes to denature the probe and place on ice until ready for use.

iii) Apply sufficient hybridisation solution to cover the section (approximately 50 µl) and cover with a cover-slip.

iv) Heat the slides to 95°C for 5 minutes to denature the nucleic acid in the specimen. To heat the slides to 95°C a PCR heating block can be used or a purpose built hybridisation block such as the Invitrogen SPoT hybridiser.

v) Place the slides into a humidified chamber that has been preheated to 37°C and incubate at 37°C overnight (12–16 hours).

Post-hybridisation procedure

i) Remove cover-slips by immersing slides in 2× SSC at room temperature.

ii) Place slides in a rack and immerse in 2× SSC at room temperature. Use a rocker or shaker at slow speed to ensure complete washing of the slides.

iii) Wash, with gentle rocking/shaking, in 0.5× SSC (pre-warmed to 37°C) at 37°C for 15 minutes.

iv) Wash slides briefly in TBS buffer (Solution I) at room temperature.

v) Incubate slides in blocking solution (0.5% skim milk powder in TBS) for 30 minutes at room temperature.

vi) Cover sections with 100–200 µl of sheep anti-DIG antibody conjugated to alkaline phosphatase (Roche Cat. No. 1093274) diluted 1 in 100 in blocking solution and incubate at room temperature for 1 hour.

vii) Wash in TBS buffer 3 × 3 minutes.

viii) Equilibrate in solution II (0.1 M Tris pH 8, 0.5 M NaCl, 0.1 M $MgCl_2$, pH 9) for 3 minutes at room temperature.

Colour development

i) Add 1 NBT/BCIP Ready-to-Use Tablet (Roche Cat. No. 11 697 471 001) to 10 ml of a 10% solution of polyvinyl alcohol (high molecular weight, 40–100 kD) in distilled water to prepare a ready-to-use staining solution.

ii) Cover the sections with the staining solution and place a cover-slip over them. Incubate in the dark for 3–4 hours in a humidified container, making sure that the slides do not dry out.

iii) Monitor the colour development by periodically checking the slides under a light microscope.

iv) If required the slides can be incubated, in the dark at room temperature, overnight.

v) Stop the reaction and remove the cover-slip by immersing the slides in distilled water.

vi) Wash the slides in running water for 5 minutes.

vii) Mount the slides with mounting medium (DAKO Cat. No. S3023) and a cover-slip.

Interpretation of results

Specific dark blue-black intra-cellular staining is indicative of the presence of viral DNA.

4.3.1.2.4. Agent purification

None.

4.3.2. Serological methods

None applicable.

5. Rating of tests against purpose of use

The methods currently available for targeted surveillance and diagnosis of AVG are listed in Table 1. The designations used in the Table indicate: a = the method is the recommended method for reasons of availability, utility, and diagnostic specificity and sensitivity; b = the method is a standard method with good diagnostic sensitivity and specificity; c = the method has application in some situations, but cost, accuracy, or other factors severely limits its application; and d = the method is presently not recommended for this purpose. These are somewhat subjective as suitability involves issues of reliability, sensitivity, specificity and utility. Although not all of the tests listed as category A or B have undergone formal standardisation and validation, their routine nature and the fact that they have been used widely without dubious results, makes them acceptable.

Annex XXVII (contd)

Table 5.1. *Methods for targeted surveillance and diagnosis*

Method	Targeted surveillance				Presumptive diagnosis	Confirmatory diagnosis
	Larvae	PLs	Juveniles	Adults		
Gross signs	d	d	c	c	c	d
Bioassay	d	d	d	d	d	c
Direct LM	d	d	d	d	d	d
Culture	d	d	d	d	d	d
Histopathology	d	d	b	b	b	d*
Transmission EM	d	d	d	d	d	c
Antibody-based assays	d	d	d	d	d	d
DNA Probes – *in situ*	d	d	c	c	d	a*
PCR	d	d	a	a	a	a
Sequence	d	d	d	d	d	a

PLs = postlarvae; EM = electron microscopy; PCR = polymerase chain reaction; RFLP = restriction fragment length polymorphism.

6. Test(s) recommended for targeted surveillance to declare freedom from infection with abalone herpes-like virus

The test recommended for targeted surveillance is qPCR on extracted nucleic acids from neural tissue of abalone

7. Corroborative diagnostic criteria

7.1. Definition of suspect case

The presence of AbHV shall be suspected if at least one of the following criteria is met:

i) Presence of high mortality rates (up to 90%) associated with clinical signs of the disease as described in this chapter.

ii) Histopathology (ganglioneuritis) observed in neural tissue sections of a single abalone sample

iii) Positive result by qPCR on at least one sample of abalone.

7.2. Definition of confirmed case

The presence of AbHV is considered to be confirmed if, in addition to the criteria in Section 7.1, one or more of the following criteria are met:

i) Positive result by qPCR on at least one repeat sample of abalone

ii) Positive result by in situ hybridisation on neural tissue section

iii) Positive result by conventional PCR and confirmation of AbHV sequence of the amplicon.

8. References

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* *

NB: There is an OIE Reference Laboratory for Infection with *Bonamia ostreae* (see Table at the end of this *Aquatic Manual* or consult the OIE Web site for the most up-to-date list: www.oie.int).

Annex XXVIII

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Annex XXIX

CHAPTER 6.2.

PRINCIPLES FOR RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article 6.2.1.

Purpose

These recommendations provide guidance for the responsible and prudent use of *antimicrobial agents* in *aquatic animals*, with the aim of protecting both animal and human health. The *Competent Authorities* responsible for the registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Article 6.2.2.

Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to reduce the risk associated with the selection and dissemination of antimicrobial resistant micro-organisms and antimicrobial resistance determinants in *aquatic animal* production to:

1. maintain the efficacy of *antimicrobial agents* and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety*;*

2. comply with the ethical obligation and economic need to keep *aquatic animals* in good health;

3. prevent or reduce the transfer of resistant micro-organisms or resistance determinants from *aquatic animals* to humans and *terrestrial animals*;

4. maintain the efficacy of *antimicrobial agents* used in human medicine and prolong the usefulness of the antimicrobials;

5. prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL);

6. protect consumer health by ensuring the safety of food of *aquatic animal* origin.

Article 6.2.3.

Definitions

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that at *in vivo* concentrations exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Article 6.2.4.

Responsibilities of the regulatory authorities

The national regulatory authorities, which are responsible for granting marketing authorization for antimicrobials, have a significant role in specifying the terms the authorization and in providing the appropriate information to the *veterinarian* or other *aquatic animal* health professional through product labelling and/or by other means, in support of prudent use of veterinary antimicrobial drugs in *aquatic animals*.

It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of veterinary antimicrobial drug applications.

National governments in cooperation with *animal* and public health professionals should adopt a proactive approach to promote prudent use of *antimicrobial agents* in *aquatic animals* as an element of a national strategy for the containment of antimicrobial resistance.

Other elements of the national strategy should include good animal husbandry practices, vaccination policies and development of animal health care at the farm level, and consultation with a *veterinarian* or other *aquatic animal* health professional, all of which should contribute to reduction of the prevalence of animal disease requiring antimicrobial treatment.

Regulatory authorities should expeditiously grant marketing authorizations when criteria of quality, efficacy, and safety are met.

The examination of dossiers/drug applications should include an assessment of the risks to both *animals* and humans resulting from the use of *antimicrobial agents* in *aquatic animals*. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs. The safety evaluation should include consideration of the potential impact of the proposed use in *aquatic animals* on human health, including the human health impact of antimicrobial resistance developing in food-borne micro-organisms found in *aquatic animals*. An assessment of the impact of the proposed use on the environment should be conducted.

The regulatory authority should ensure that advertising of antimicrobials complies with national legislation and marketing authorizations granted and discourage direct advertising to *aquatic animal* producers.

Information collected through pharmacovigilance programmes, including on lack of efficacy, should form part of the *competent authority's* comprehensive strategy to minimize antimicrobial resistance.

Regulatory authorities should disseminate, to *veterinarians* or other *aquatic animal* health professionals, information on trends in antimicrobial resistance collected during surveillance programmes and should monitor the performance of susceptibility testing laboratories.

Article 6.2.5.

Responsibilities of the veterinary pharmaceutical industry

The veterinary pharmaceutical industry has responsibilities for providing information requested by the authorities on the quality of antimicrobials. The responsibilities of the veterinary pharmaceutical industry covers pre- and post- marketing phases, manufacturing, sale, importation, labelling and advertising issues.

The veterinary pharmaceutical industry has the responsibility to provide the regulatory authorities with the information necessary to evaluate the amount of *antimicrobial agents* marketed. The veterinary pharmaceutical industry should ensure that the advertising of antimicrobials directly to the *aquatic animal* producer is discouraged.

Article 6.2.6.

Responsibilities of wholesale and retail distributors.

Distributors should ensure that their activities are in compliance with the national legislation.

Distributors should ensure that information for the appropriate use of the *antimicrobial agent* preparation should accompany all distributed products and should also be responsible for maintaining the product under the manufacturer recommendations.

Distributors should have responsibilities in collection and destruction of *antimicrobial agents* that have passed their expiry date.

Article 6.2.7.

Responsibilities of veterinarians and other aquatic animal health professionals

Responsibilities of *veterinarians* or other *aquatic animal* health professionals include identifying, preventing and treating *aquatic animal diseases* as well as the promotion of sound animal husbandry methods, hygiene procedures, vaccination and other alternative strategies to minimise the need for antimicrobial use in *aquatic animals*.

Veterinarians or other aquatic animal health professionals should only recommend antimicrobials for *aquatic animals* under their care.

The responsibilities of *veterinarians* or other *aquatic animal* health professionals are to carry out a proper clinical examination of the *aquatic animal(s)* and make a diagnosis, based on the clinical examination, the results of laboratory tests and evaluation of environmental factors at the production site (e.g. water quality).

If therapy with an *antimicrobial agent* is deemed appropriate it should be initiated as soon as possible. The selection of the agent should be based on the knowledge and experience of the *veterinarian* or other *aquatic animal* health professional.

As soon as possible, susceptibility testing of the target micro-organism should be used to confirm the choice of treatment. Results of all susceptibility tests should be communicated to the relevant national authority.

The *veterinarian* or other *aquatic animal* health professional should indicate precisely to the *aquatic animal* producer the treatment regime, including the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of *aquatic animals* to be treated.

The *veterinarian* or other *aquatic animal* health professional may recommend in appropriate circumstances the use of *antimicrobial agents* extra-/off-label, in conformity with the relevant national legislation and any requirements of importing countries.

Records on the use of *antimicrobial agents* should be kept in conformity with the national legislation.

Veterinarians or other *aquatic animal* health professionals should periodically review farm records on the use of *antimicrobial agents* to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens.

Article 6.2.8.

Responsibilities of aquatic animal producers

Aquatic animal producers should implement health programmes on their farms in order to promote *aquatic animal* health and food safety. This can be done through adequate planning of culture strategies to maintain aquatic animal health through biosecurity programmes, vaccination strategies, maintenance of good water quality, etc.

Aquatic animal producers should use *antimicrobial agents* only on the recommendation of a *veterinarian* or other *aquatic animal* health professional, and follow directions on the dosage, method of application, and withdrawal period.

Aquatic animal producers should ensure that *antimicrobial agents* are properly stored, handled, and disposed.

Aquatic animal producers should keep adequate records of *antimicrobial agents* used, bacteriological and susceptibility tests, and to make such records available to the *veterinarian* or other *aquatic animal* health professional.

Aquatic animal producers should inform the *veterinarian* or other *aquatic animal* health professional of recurrent disease problems and lack of efficacy of antimicrobial treatment regimes.

Article 6.2.9.

Training of antimicrobial users

The training of users of antimicrobials should involve all the relevant organisations, such as regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, and veterinary professional organisations and other approved users such as *aquatic animal* owners.

Article 6.2.10.

Research

To address the significant lack of information for numerous species of *aquatic animals*, relevant authorities and other stakeholders should encourage public- and industry-funded research.

Annex XXX

Original: English
February 2010

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

Paris (France), 8–10 February 2010

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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 8 to 10 February 2010.

The members of the *ad hoc* Group and other participants are listed at Annex I. The Agenda adopted is given at Annex II.

On behalf of the Director General of the OIE, Dr Gillian Mylrea, Chargée de Mission, International Trade Department, welcomed the *ad hoc* Group members and the Reference Laboratory experts, and thanked them for their work on this important new area.

Dr Barry Hill then took over as Chair of the meeting. He noted that the disease specific surveillance chapters are a new initiative for the Aquatic Animal Health Standards Commission and required the involvement of the designated experts for the three diseases under consideration as a first step.

Item 1. Develop the template for disease specific surveillance chapters for viral haemorrhagic septicaemia; infection with *Bonamia ostreae*; and white spot disease

The *ad hoc* Group together with the three disease experts from OIE Reference Laboratories for viral haemorrhagic septicaemia, infection with *Bonamia ostreae*, and white spot disease, developed the template for drafting the specific surveillance chapters for these three model disease chapters. The *ad hoc* Group and experts agreed on the nature and detail of the information that should be included under each heading/subheading of the template.

The next step will be for the experts to draft the disease specific chapters for which they are the designated expert. This will be done with the assistance of *ad hoc* Group members. These draft chapters will be collectively reviewed by the *ad hoc* Group and experts at the second meeting, in approximately six months time.

Annex XXX (contd)

Item 2. Review and simplify the OIE *Manual of Diagnostic Tests for Aquatic Animals* disease chapter template

After brief discussion of the template the *ad hoc* Group agreed that it would be preferable to wait for the outcome of the disease specific chapters before reviewing the *Manual of Diagnostic Tests for Aquatic Animals* chapter template.

.../Annexes

Annex I

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

Paris (France), 8–10 February 2010

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Annex XXX (contd)

Annex II

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

Paris (France), 8–10 February 2010

Adopted agenda

Welcome

Adoption of the agenda

1. Develop the template for disease specific surveillance chapters for viral haemorrhagic septicaemia; infection with *Bonamia ostreae* and white spot disease

2. Review and simplify the OIE *Manual of Diagnostic Tests for Aquatic Animals* chapter template

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Annex XXXI

Original: English
January 2010

OIE *AD HOC* GROUP ON
THE DISPOSAL OF AQUATIC ANIMAL WASTE
Paris, 26–28 January 2010

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The OIE *ad hoc* Group on the Disposal of Aquatic Animal Waste (the *ad hoc* Group) met at the OIE Headquarters from 26 to 28 January 2010.

The members of the *ad hoc* Group are listed at Annex I and the adopted Agenda is at Annex II.

Dr Gillian Mylrea, Chargée de Mission, OIE International Trade Department, welcomed the members on behalf of Dr Bernard Vallat, OIE Director General, who was not able to attend the meeting, and thanked them for their support for the OIE's work and their willingness to participate in this *ad hoc* Group.

Dr Mylrea explained the background to the convening of this *ad hoc* Group. In March 2006, a preliminary text on *'Handling and disposal of carcasses and wastes of aquatic animals'* was drafted by an OIE expert and submitted to the Aquatic Animal Health Standards Commission (Aquatic Animals Commission). The Aquatic Animals Commission revised the preliminary draft, taking into account OIE *Terrestrial Animal Health Code* Chapter 4.12. *'Disposal of dead animals'*, and circulated the draft chapter for Member comment as an annex to the report of their October 2007 meeting. In October 2008, the Commission reviewed Member comments and re-circulated a revised draft chapter to Members. At the March 2009 meeting of the Commission, in view of the large number of Member comments and the technical issues raised, it was decided to convene the *ad hoc* Group to consider the Member comments.

Dr Colin Johnston chaired the meeting.

Item. Review the draft chapter Handling and disposal of carcasses and wastes of aquatic animals.

The *ad hoc* Group reviewed comments from Argentina, Australia, Canada, the European Union, New Zealand, Norway, Organismo Internacional Regional de Sanidad Agropecuaria (OIRSA), Thailand and the USA.

Annex XXXI (contd)

The *ad hoc* Group appreciated the depth and quality of comments submitted by Members, several of whom recommended some reorganisation of the content of articles to avoid duplication and inconsistency.

The *ad hoc* Group reviewed the chapter, taking into account Member comments and the *Terrestrial Code* chapter 4.12. 'Disposal of Dead Animals', and amended the text as appropriate. Key amendments made to the chapter included: amendment of the title to more accurately reflect the syntax of the chapter; removal of duplication; amendment of the order of articles to provide a more logical flow; amendment of the Introduction, clarification of the Scope; deletion of definitions that were redundant; consolidation and the addition of new text on mass mortality events. Much of the new text was closely based on the *Terrestrial Code* Chapter 4.12. as relevant to the aquatic animal sector.

Although there have been considerable changes made to the overall layout of the chapter, the *ad hoc* Group emphasized that the technical content of the chapter was largely unchanged. The comments of Members were in nearly all cases addressed in full.

As there were many text amendments and a substantial restructuring of this chapter, the amended Chapter X.X. is provided as clean text in Annex III.

.../Annexes

Annex I

OIE *AD HOC* GROUP ON
THE DISPOSAL OF AQUATIC ANIMAL WASTE
Paris, 26–28 January 2010

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Annex XXXI (contd)

Annex II

OIE *AD HOC* GROUP ON
THE DISPOSAL OF AQUATIC ANIMAL WASTE
Paris, 26–28 January 2010

_____

Adopted agenda

Welcome

Adoption of the agenda

1. Review the draft chapter on: *Handling and disposal of carcasses and wastes of aquatic animals*:

   1.1. Consider Member comments and amend the chapter as appropriate

   1.2. Take into account the *Terrestrial Code* Chapter 4.12. *Disposal of dead animals* to ensure consistency between these texts in the two *Codes* as appropriate

2. Submit a report to the OIE Aquatic Animal Health Standards Commission by 8th February 2010

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Annex XXXI (contd)

Annex III

CHAPTER X.X.

HANDLING, DISPOSAL AND TREATMENT OF AQUATIC ANIMAL WASTE

Article X.1.

Introduction

The objective of this chapter is to provide guidance on storage, transport, disposal and treatment of *aquatic animal* wastes so as to manage risks to aquatic animal health. The recommendations in this chapter are general in nature. The choice of one or more of the recommended methods should comply with relevant local and national legislation.

Disposal methods should take into consideration a range of factors, including the cause of mortality. It may be appropriate to carry out a risk assessment on the disposal options.

In the case of killing of animals for disease control purposes or unusually large mortalities, this may require approval from, or supervision by, the *Competent Authority*.

In the event of *aquatic animal* mortalities of a significant nature in *aquaculture* or in the wild, the *Competent Authority* should be notified so that necessary steps can be taken to dispose of the dead *aquatic animals*, in order to minimise the risk for possible spread of *aquatic animal disease*.

Article X.2.

Scope

The scope of this chapter covers *aquatic animal* waste derived from: i) routine *aquaculture* operations; ii) on shore processing, irrespective of origin; iii) mass killing for disease control purposes and iv) mass mortality (including in the wild).

Article X.3.

Definitions

Aquatic animal waste means the entire body or parts of dead *aquatic animals* (not including the entire body or parts intended for human consumption).

High risk waste means *aquatic animal* waste that constitutes, or is suspected of constituting, a serious health risk to *aquatic animals* or humans.

Low risk waste means *aquatic animal* waste that is not high risk waste.

Article X.4.

Governance

The *Competent Authority* should oversee the efficient and effective disposal of *aquatic animal* waste. Cooperation among all relevant agencies and stakeholders involved in *aquatic animal* health is necessary to ensure safe handling and disposal. In this context the following aspects should be addressed:

Annex XXXI (contd)

Annex III (contd)

1. physical, logistical and data access by relevant personnel, in cooperation with stakeholders, including access of the *Competent Authority* to the *aquatic animal* waste;

2. movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of *aquatic animal* waste to another location for disposal;

3. the determination of the method and location of disposal, and the necessary equipment and facilities, by the *Competent Authority*, in consultation with other authorities including government organisations responsible for the protection of human health and the environment.

Article X.5.

Storage, transport and labelling

Following collection, *aquatic animal* waste should be stored for the minimum time practical; however, where storage is necessary there should be sufficient capacity for the expected waste and the *Competent Authority* may require additional measures.

The storage area should be separated from *aquaculture* sites and bodies of water to minimise the risk of spread of *disease agents*. The *containers* of stored *aquatic animal* waste must be leak proof and secured to prevent contact with *aquatic animals*, other animals or birds and unauthorised personnel.

Aquatic animal waste infected by an agent causing a *disease* referred to in the *Aquatic Code* or suspected of being so, may not be transported without permission from the *Competent Authority*. The *Competent Authority* may assess the requirement for this condition based on the disease situation in the Member country (e.g. where a *disease* referred to in the *Aquatic Code* is enzootic in the Member country).

If low risk waste becomes contaminated with high risk waste, such waste should then be considered high risk waste.

Containers used for transport of *aquatic animal* waste should be leak-proof and labelled regarding content. Transport should be accompanied by appropriate documentation detailing origin, content and destination to allow tracing if required.

Equipment used for transportation should be cleaned and disinfected before being returned, as described in Chapter 4.2. on General recommendations on disinfection.

Article X.6.

Approval and operational requirements of disposal plants

1. Requirement for approval

   All disposal plants dealing with *aquatic animal* waste should be approved by the *Competent Authority*. However, disposal plants using only low risk waste for production of products not intended to be used in animals may be exempted from approval but should be registered by the *Competent Authority*.

2. Conditions for approval

   For a disposal plant to be approved to deal with *aquatic animal* waste, it should:

   a) be adequately separated from thoroughfares through which contamination may be spread, other premises (such *aquaculture* facilities, slaughterhouses, processing plants) and bodies of water, so as to minimise the risk of spread of *disease agents*;

b) be designed and equipped to the satisfaction of the *Competent Authority*;

c) have access to approved or accredited laboratories;

d) fulfill requirements for handling the *aquatic animal* waste and products specified by the *Competent Authority*;

Any substantial proposed changes to the disposal plant should be approved by the *Competent Authority*.

Approval should be withdrawn or suspended, as appropriate, if a disposal plant no longer fulfils the criteria given by the *Competent Authority*.

3. Operating requirements

The disposal plant should operate using procedures that minimise the risk of spread of *disease agents*, including:

a) separation of clean and unclean areas, including consideration of workflow, and good hygienic procedures for personnel;

d) equipment and surfaces should be easy to clean and disinfect;

e) handling and treatment of *aquatic animal* waste should take place as soon as possible after being received;

f) effluent waste water should be collected and disinfected before leaving the premises;

g) incorporating measures to prevent access of birds, insects, rodents or other animals to the disposal plant;

h) a system for registration and labelling of material for tracing purposes.

A system for internal control, identifying critical points and means of control for such points, should be in place at the disposal plants. A general documentation system for internal control including sampling for control of critical points should be established.

Spot checks of batches should be carried out to check the microbiological standards following processing. Products from incineration plants may be exempted from such checks. The *Competent Authority* may grant exemptions on specified conditions.

If testing of the product from processed high risk waste shows that the product is not satisfactorily produced and thus poses a risk for the spread of *disease agents*, disposal plants should report immediately to the *Competent Authority* who may then require additional measures. These products should not be transported from disposal plants without permission from the *Competent Authority*.

Results from the different samples and checks should be kept for a given period decided upon by the *Competent Authority*. Analyses and sampling should be carried out in accordance with international standards.

Disposal plants applying treatments based on time and pressure should be able to measure and record these parameters.

Annex XXXI (contd)

Annex III (contd)

Disposal plants should maintain records related to quantity and type of raw material received, supplier, quantity and type of finished product, receivers, critical check points, and deviations from provisions stipulated in relevant regulations. These must be made available to the *Competent Authority* on request.

Article X.7.

Methods for disposal of high risk waste

Recommended methods for disposal of high risk waste from *aquatic animals* as follows:

1. Rendering

   Rendering will inactivate all of the known *aquatic animal disease agents*.

   Rendering is generally carried out in a closed system using a combination of mechanical treatments and time/temperature combinations leading to stable, sterilised products, such as fish meal and fish oil.

   The process typically involves pre-heating to 50–60°C, followed by cooking of the raw waste at 95–100°C for 15 to 20 minutes. The oil and proteins are separated by pressing and centrifuging involving temperatures of 90°C. The production of meal involves further high temperature treatments.

2. Incineration

   Incineration is a controlled burning process carried out in fixed incinerators or mobile air curtain incinerators. Mobile air curtain incinerators enable the process to be carried out on site thus removing the need to transport the *aquatic animal* waste.

   Incinerators may only be capable of handling limited volumes of *aquatic animal* waste.

3. Sterilisation

   The minimum requirement for sterilisation is a core temperature of at least 90°C for at least 60 minutes, but other time/temperature combinations are also available and effective.

4. Composting

   Composting does not inactivate all *disease agents*; therefore, high risk waste should be heated (85°C for 25 minutes or an equivalent temperature/time combination) prior to the composting process.

   Effective composting depends upon a combination of pH, temperature, moisture and time factors. Depending on the type of composting (e.g. windrows, closed vessel) and the raw material used, as well as the climatic conditions, the temperature parameters of the process and the heat distribution in the material may be different.

   When held in windrows, the entire material needs an exposure time of at least two weeks at 55°C, while in closed vessels exposure to 65°C for one week is required.

5. Biogas production

   Biogas production does not inactivate all *disease agents*; therefore, high risk waste should be treated to ensure inactivation of *disease agents* prior to the biogas production process. The method chosen should be shown to inactivate the *disease agents* of concern.

Biogas production is a process whereby organic matter in biological waste products is fermented under anaerobic conditions.

The two main types of biogas production are mesophilic anaerobe digestion and thermophilic anaerobe digestion.

Both processes are normally continuous, and a portion of the end material is removed every 2–12 hours. There is a risk that new material which has been in the reactor for only 2–12 hours may be removed with the finished products.

6. Ensiling

Ensiling does not inactivate all *disease agents*; therefore, high risk waste should be heated (85°C for 25 minutes or an equivalent temperature/time combination) prior to the ensiling process.

Ensiling of *aquatic animal* waste in an organic acid such as formic acid is an effective method of inactivating most *disease agents* within 48 hours. The pH in the ensiling process should be maintained at, or below, 4.0 throughout the process.

7. Burial

Burial may take place either in a landfill site or other locations approved by the *Competent Authority* based on *risk assessments* as regards *aquatic animal* health, public health and possible environmental impacts.

Whenever possible, the *aquatic animal* waste should be subjected to a treatment that ensures inactivation of the *disease agents* prior to burial.

In selecting an acceptable burial site, consideration should be given to the following:

Location – for example, distance from *aquaculture establishments*, bodies of water, depth of the ground water table, topography, adjacent land use; and direction of prevailing wind.

Access – easy access for equipment and delivery of *aquatic animal* waste. Fencing and restricted admittance may be necessary.

Pit construction – rocky areas should be avoided. Soils with good stability, capable of withstanding the weight of equipment used to dig and fill the pits, should be selected. If required, diversion banks can be constructed to prevent surface runoff entering the pit or to prevent any liquids escaping from the burial site. Pit dimensions depend on the volume of the *aquatic animal* waste to be buried and should be easy to fill.

Pit closure – contents should be covered with unslaked lime (CaO) at a rate of 85 kg per 1,000 kg of *aquatic animal* waste to hasten decomposition and prevent scavenging.

8. Pyre burning

Pyre burning may not be suitable for large amounts of *aquatic animal* waste.

In selecting an acceptable pyre burning site, the following considerations are important:

a) Location – the possible effects of the fire's heat, smoke and odour on nearby structures, underground and aerial utilities, roads and residential areas. The site should be surrounded by an adequate firebreak.

Annex XXXI (contd)

Annex III (contd)

b) Access – for equipment to construct the pyre and maintain the fire, for the delivery of fuel and *aquatic animal* waste.

Pyre burning needs considerable amounts of fuel and all required fuel should be on site before the burning is started. If the pyre-burning is carried out correctly, *aquatic animal* wastes will be destroyed within 48 hours.

When leaving the pyre burning site, *vehicles* and *containers* should be disinfected.

Alternatively, high risk waste may be disposed off by any methods, approved by the *Competent Authority*, which ensure an equivalent reduction of risk.

Article X.8.

Methods of disposal for low risk waste

Low risk waste can be disposed of using all methods described in Article X.7. In the case of composting or biogas production it is not necessary to heat treat the low risk waste prior to disposal.

Alternatively, the following methods may be used:

1. Ensiling

Ensiling of *aquatic animal* waste in an organic acid such as formic acid is an effective method of inactivating most *disease agents* within 48 hours. The pH in the ensiling process should be maintained at, or below, 4.0 throughout the process.

The *Competent Authority* may require ensiling as a treatment prior to one of the disposal methods described in Article X.7.

2. Pasteurisation

Pasteurisation does not inactivate all *disease agents*. Heat treatment at temperatures below 100°C can be considered as pasteurisation. Pasteurisation may use a range of time/temperature combinations.

In addition, the *Competent Authority* may permit low risk waste to be disposed of by other means, or used for any other purposes following an assessment of the risk from such methods or uses.

Article X.9.

Mass mortality events

Mass mortality of *aquatic animals* can arise from natural events or killing for disease control purposes (refer to Chapter X.X. on the humane killing of fish for disease control purposes; in preparation). This may lead to the need for disposal of large numbers of dead *aquatic animals* and is often subject to intense public and media scrutiny. The *Competent Authority* should conduct disposal operations within acceptable scientific principles that will address the risks of spread of the *disease agent*, and public and environmental concerns.

1. Preparedness

Successful disposal with minimum delay is achieved by advance planning and preparation:

a) Preparedness planning should engage other relevant government agencies and stakeholders such as industry organisations, *animal welfare* organisations, emergency response organisations, and media.

b) Standard operating procedures should be developed (including documented decision-making processes, training of staff).

c) Pre-arranged mechanisms to access emergency funding for the disposal operation.

d) Information sharing with officials involved in the disposal operation, stakeholders, politicians and the media is essential. A well informed spokesperson should be available at all times to answer enquiries.

e) Resource readiness planning should address such items as personnel, transport, storage facilities, equipment, fuel, protective clothing and logistical support. Special equipment, such as well boats, may be required.

2. Critical elements

Critical elements which need to be considered in planning and implementation include:

a) rapid disposal of the dead *aquatic animals*;

b) methods of treatment and disposal should address capacity issues and the risks of spread of *disease agents*;

c) adequate funding and staff resources;

d) addressing the risk of spread of *disease agents* by vectors and fomites;

e) stakeholder cooperation;

f) safety of personnel;

g) environmental concerns;

h) societal acceptance.

3. Choice of disposal methods

The *Competent Authority* may determine the dead *aquatic animals* to be either high risk waste or low risk waste and select an appropriate disposal method according to the risk (refer to Articles X.7. and X.8.).

Should the chosen disposal option be applied near the border of a neighbouring country, the *Competent Authority* of that country should be informed.

Annex XXXII

Original: English
February 2010

MEETING OF THE OIE *AD HOC* GROUP ON SAFETY OF PRODUCTS DERIVED FROM AQUATIC ANIMALS
Paris, 1–3 February 2010

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The OIE *ad hoc* Group on Safety of Products Derived from Aquatic Animals (*ad hoc* Group) met at the OIE Headquarters from 1 to 3 February 2010.

Dr Sarah Kahn, Head of the International Trade Department, on behalf of the 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. Dr Franck Berthe chaired the meeting.

Details of members and the adopted agenda are given at Annexes I and II.

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

The *ad hoc* Group was pleased to note that a number of Members submitted comments on these chapters but noted that some comments were not provided in the requested format and did not include a science based rationale. The *ad hoc* Group requested that the Aquatic Animal Health Standards Commission (Aquatic Animals Commission) remind Members to submit comments as specific proposed text changes supported by a scientific rationale.

1.1. ''Example Article'' X.X.3., X.X.9., X.X.11./12.

Comments were received from Australia, Canada, European Union and New Zealand. The *ad hoc* Group reviewed these comments and amended the text accordingly.

A number of Members commented on the use of the terms 'commodity', 'live aquatic animal' and 'aquatic animal product'. The *ad hoc* Group considered these comments and amended the text to use the terms 'live aquatic animal' and 'aquatic animal product' throughout these Articles rather than the term 'commodity', because the definition of a commodity includes biological products and pathological materials, which are no longer covered in these Articles. This also ensured consistency between the title and the content of the Articles.

The *ad hoc* Group clarified the scope of each of these articles, as follows:

Article X.X.3. addressed the importation of live aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from Disease X.

Article X.X.9. addressed the importation of live aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from Disease X.

Article X.X.12. (fish chapters) /Article X.X.11. (crustacean and mollusc chapters) addressed the importation of live aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Disease X.

The *ad hoc* Group wished Members to note that these amended Articles X.X.3., X.X.9., X.X.11./12 will be applied to all disease specific chapters in the *Aquatic Code*.

The amended text is presented in Annex III.

1.2. Amended text for epizootic haematopoietic necrosis (Articles 10.1.3., 10.1.9., 10.1.12.), Taura syndrome (Articles 9.4.3., 9.4.9., 9.4.11.) and for Infection with *Bonamia ostreae* (Articles 11.2.3., 11.2.9., 11.2.11.)

Comments were received from Australia, Canada, the European Union and New Zealand. The *ad hoc* Group reviewed these comments and amended the text accordingly.

The *ad hoc* Group amendments to these three chapters also included all changes made in Example Articles X.X.3., X.X.9., X.X.11./12 (see Item 1.1.).

A number of Members commented on the need for a specific description of the products listed under Articles X.X.3. and Article X.X.11./12. To address these comments the *ad hoc* Group modified some of the descriptions of the products listed to clarify the nature of the product.

Consequently, ‘canned products’ are now described as ‘heat sterilised hermetically sealed products (i.e. a heat treatment at 121^{o}C for at least 3.6 minutes or equivalent)’. The *ad hoc* Group also proposed to accept equivalent time/temperature combinations that are sufficient to inactivate the pathogens assessed.

Pasteurisation is a food treatment process that is well defined for milk products, but is not well defined for fish products. There are a number of time/temperature combinations that may be used depending on the product. Officially specified conditions will tend to be determined by the requirement to inactivate bacteria of concern to human health. As such both the United States of America Food and Drug Administration (2001. Fish and Fisheries Products Hazards and Controls Guidance, 3rd Edition) and Gould (1999. Sous vide foods: conclusions of an ECFF botulinum working party. Food Control 10:47-51) indicate that 90oC for 10 minutes is required to achieve a 6D reduction in Clostridium botulinum. Inacitvation standards for Listeria monocytogenes are considerably lower.

Pasteurised products are now described in terms of a specified time/temperature combination. As pasteurisation conditions vary there may also be equivalent treatments that result in the same degree of thermal inactivation of the pathogens of concern. This is reflected in the qualifier “or to any time/temperature combination that is equivalent”. Acceptability of equivalent treatments should be based on information demonstrating inactivation of the specific pathogen. For example, the description proposed in the EHNV chapter for ‘pasteurised products’ is, ‘pasteurised fish products that have been subjected to heat treatment at 90^{o}C for 10 minutes or to an equivalent treatment that has been demonstrated to inactivate EHNV.’

Cooking may involve heat, pressure, microwave and infrared treatments or a combination of these. The *ad hoc* Group only considered heat treatments at atmospheric pressure because information on the viability of the assessed pathogens or surrogate pathogens was usually only available for heat treatment. Therefore, a time/temperature combination is specified for 'cooked products', based on thermal tolerance data for the assessed pathogen. For example, the product description proposed in the chapter on Taura syndrome is 'cooked crustacean products that have been subjected to heat treatment at 70°C for at least 30 minutes or to any equivalent treatment which has been demonstrated to inactivate TSV'.

Artificially dried products are now referred to as 'mechanically dried products (i.e. a heat treatment at 100°C for at least 30 minutes or equivalent)'.

EHN articles: the *ad hoc* Group assessed 'mechanically dried eviscerated fish' in the EHN draft chapter against Criteria 5.3.1. and found it to be eligible for listing in Article X.X.3. Consequently, the *ad hoc* Group proposed moving this product from Article X.X.12. to Article X.X.3. The *ad hoc* Group also assessed heat sterilised, hermetically sealed fish products and found them to be eligible for listing in Article X.X.3. Consequently, the *ad hoc* Group proposed that this product be added to Article X.X.3.

Taura syndrome articles: the *ad hoc* Group made no additional changes to the products listed under Article X.X.3. and X.X.11. for Taura syndrome except to clarify product descriptions, as described above.

Bonamia ostreae articles: the *ad hoc* Group deleted 'canned and pasteurised products' from Article X.X.3. of the chapter on Infection with *Bonamia ostreae* as these products are not significant in international trade. The *ad hoc* Group assessed 'frozen oyster meat' and 'frozen half-shell oysters', in regard to *Bonamia ostreae* infection, against Criteria 5.3.1. and found these products to be eligible for listing in Article X.X.3. Consequently, the *ad hoc* Group proposed moving these products from Article X.X.11. to Article X.X.3. Product descriptions were also clarified as described above.

The *ad hoc* Group updated the product assessments for EHN, Taura syndrome and *Bonamia ostreae* (previously provided in Annex XXV of the September 2009 Report of the Aquatic Animals Commission) to take into account the modified product descriptions and also undertook some additional product assessments.

The updated product assessments for EHN, Taura syndrome and *Bonamia ostreae* are presented in Annex IV.

As a number of amendments were made to the products listed under X.X.3. and X.X.11/12., the amended text is presented as clean text in Annex V(A). and text with changes shown in Annex V(B).

1.3. Criteria to assess the safety of aquatic animal commodities (Ch 5.3.)

Comments were received from Australia, Canada, the European Union and the United States of America. The *ad hoc* Group reviewed these comments and amended the text accordingly.

To ensure consistency between the criteria listed in Chapter 5.3. and the disease specific articles, the terms 'live aquatic animal' and 'aquatic animal product' were used throughout these articles, rather than 'commodity', because the definition for commodity includes biological products and pathological materials, which are no longer covered in these articles.

Australia proposed amendments to the wording in Article 5.3.2. for clarification. The *ad hoc* Group considered this comment and made some amendments. However, the *ad hoc* Group did not agree with Australia's proposal to modify the criteria to include consideration of pathogen titre given the lack of key information, such as decline of pathogen titre, tissue distribution and infectious dose.

The amended text is presented in Annex VI.

1.4. Measures concerning international transport of aquatic animal disease agents and pathological material (Article 5.9.1.)

A Member suggested to include a list of accepted treatment methods for safe transport of pathogens in this chapter. The *ad hoc* Group considered this was outside the Group's terms of reference. The *ad hoc* Group made no further amendments to the proposed text.

The text is presented in Annex VII.

1.5. Disinfection of salmonid eggs – (Article 10.4.X., Article 10.5.X., Article 10.9.X.)

The *ad hoc* Group reviewed comments from the EU, Norway and the United States of America on draft new articles on trade measures for disinfected salmonid eggs (with respect to viral haemorrhagic septicaemia (VHS); infectious salmon anaemia (ISA) and infectious haematopoietic necrosis (IHN) and amended the text accordingly.

Norway questioned the need to consider additional measures, other than disinfection, for the importation of eggs from an infected country, zone or compartment. The *ad hoc* Group identified the following prerequisites for trade in disinfected eggs from an infected country, zone or compartment: (i) there is no true vertical transmission of the disease and (ii) the disinfection protocol is effective in reducing the risk of egg surface associated transmission of the disease.

The *ad hoc* Group considered that the following diseases do not exhibit true vertical transmission: IHN, VHS and ISA. The *ad hoc* Group noted that egg disinfection is a mitigation measure against egg surface associated transmission but may not always be effective, particularly where eggs have been exposed to high levels of virus or where water quality is variable. The *ad hoc* Group recommended maintaining point 1 of the draft new articles on trade measures for disinfected salmonid eggs requesting that an assessment of the risk be conducted prior to importation.

The *ad hoc* Group noted that the OIE Reference Laboratory for EHN had no further information on true vertical transmission of EHNV and therefore proposed not to include an article on trade measures for disinfected salmonid eggs in the EHN chapter of the *Aquatic Code*.

The amended text is presented in Annex VIII.

2. Assess aquatic animals and aquatic animal products in all disease specific chapters for crustacean, fish and mollusc diseases of the *Aquatic Code* using Chapter 5.3.

The *ad hoc* Group continued their work to conduct assessments for products currently listed in the disease specific chapters of the *Aquatic Code* (Articles X.X.3. 1a. and b.) for crustacean, fish and mollusc disease specific chapters using Articles 5.3.1. and 5.3.2. The *ad hoc* Group will continue to conduct these out of session and will review them at their next meeting.

The *ad hoc* Group recognised the need for assessment of live amphibian animals and amphibian products and undertook to address this work.

3. Review Ref Lab information regarding EHNV and vertical transmission

See Item 1.5.

4. Develop a supporting document for OIE website

Noting that the detailed product assessments are not appropriate for inclusion in the *Aquatic Code*, the *ad hoc* Group proposed to develop a reference document setting out the rationale of assessments and make this document available to Members on the OIE website. The *ad hoc* Group asked the Aquatic Animals Commission to consider this proposal.

5. Develop a paper for publication on the OIE commodity based approach to trade in aquatic animals and aquatic animal products

The *ad hoc* Group proposed to develop a paper on the commodity based approach by the OIE for trade in live aquatic animals and aquatic animal products for publication in the *OIE Scientific and Technical Review* pluri-thematic edition. The purpose of this paper is to explain the rationale for the development of the criteria, the new articles and the assessments in the context of OIE standards and global trade in aquatic animal products.

.../Annexes

Annex XXXII (contd)

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON SAFETY OF PRODUCTS DERIVED FROM AQUATIC ANIMALS
Paris, 1–3 February 2010

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Appendix I (contd)

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON SAFETY OF PRODUCTS DERIVED FROM AQUATIC ANIMALS
Paris, 1–3 February 2010

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Adopted agenda

Welcome

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

   1.1. Example Article X.X.3., X.X.9., X.X.12.

   1.2. Amended text for epizootic haematopoietic necrosis (Articles 10.1.3., 10.1.9., 10.1.12.), Taura syndrome (Articles 9.4.3., 9.4.9., 9.4.11.) and for infection with *Bonamia ostreae* (Articles 11.2.3., 11.2.9., 11.2.11.)

   1.3. Criteria to assess the safety of aquatic animal commodities (Ch 5.3.)

   1.4. Measures concerning international transport of aquatic animal disease agents and pathological material (Article 5.9.1.)

   1.5. Disinfection of salmonid eggs – (Article 10.4.X., Article 10.5.X., Article 10.9.X.)

2. Assess aquatic animals and aquatic animal products in all disease specific chapters for crustacean, fish and mollusc diseases of the *Aquatic Animal Health Code* using criteria in Chapter 5.3.:

   2.1. Fish disease chapters

   2.2. Mollusc diseases chapters

   2.3. Crustacean diseases chapters

3. Review Ref Lab information regarding EHNV and vertical transmission

4. Develop a supporting document for OIE website

5. Develop a paper on the commodity based approach by the OIE for trade in aquatic animals and aquatic animal products

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Appendix III

AN EXAMPLE (DISEASE X)

TO BE APPLIED ACROSS ALL DISEASE CHAPTERS (SECTIONS 8, 9, 10 AND 11)

Article X.X.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose ~~regardless of the Disease X status of the~~ from a ~~exporting~~ country, zone or compartment not declared free from Disease X

1. *Competent Authorities* should not require any Disease X related conditions, regardless of the Disease X status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article X.X.2. intended for any purpose and complying with Article 5.3.1.:

   [i) aquatic animal product(s).*] (under study)

2. When authorising the importation or transit of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article X.X.2., other than those referred to in point 1 of Article X.X.3., *Competent Authorities* should require the conditions prescribed in Articles X.X.7. to X.X.12. relevant to the Disease X status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of ~~*a commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of Disease X of ~~from~~ a species not covered in Article X.X.2. but which could reasonably be expected to pose a risk of transmission for Disease X, *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 X.X.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 Disease X

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

Annex XXXII (contd)

Appendix III (contd)

1. the consignment is delivered directly to and held in *quarantine* or containment facilities until ~~for~~ processing into one of the products referred to in point 1 of Article X.X.3., or products described in point 1 of Article X.X.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 Disease agent X or is disposed in a manner that prevents contact of waste with *susceptible species*.

For these *commodities* 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.

[…]

Article X.X.12. (fish chapters) /Article X.X.11. (mollusc and crustacean chapters)

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Disease X

1. *Competent Authorities* should not require any Disease X related conditions, regardless of the Disease X status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   [i) commodity (s)*] (under study)

   For these *commodities* 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.

2. When importing ~~*live*~~ *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article X.X.2. from a country, *zone* or *compartment* not declared free from Disease X, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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* As currently listed in the *Aquatic Code* for each disease specific chapter. This list is considered under study until specific assessments have been completed and adopted

Annex XXXII (contd)

Appendix IV

Aquatic Animal Product Assessments

A. Aquatic Animal Product Assessments for epizootic haematopoietic necrosis (EHN)

1. Assessments using criteria in Article 5.3.1.

The following aquatic animal products were assessed and did meet the criteria in Article 5.3.1.:

i) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

ii) pasteurised fish products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent which has been demonstrated to inactivate EHNV;

iii) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or equivalent);

iv) fish skin leather;

v) fish oil; and

vi) fish meal.

Product under consideration		**Heat sterilised hermetically sealed fish products**	
Criteria 5.3.1.		**Assessment**	
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.*	EHN virus is present in muscle and other edible tissues (Ariel *et al.*, 2009).	No
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.*	Water is used to process the product but the water is potable and the final product is sealed.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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).*	Commercial canning involves time temperature treatments of 121°C for 3.6 minutes, or equivalent e.g. 111°C for 36 minutes (Ababouch, 1999 and 2002). EHN virus is inactivated after 15 minutes at 60°C (Langdon, 1989).	Yes
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke.)*		
AND/OR			
2c.	*Biological (e.g. fermentation).*		
Conclusion	EHN virus will be inactivated by this process, therefore heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent are eligible for inclusion in Article 10.1.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Pasteurised fish products**	
Criteria 5.3.1.		**Assessment**	
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.*	EHN virus is present in muscle and other edible tissues (Ariel *et al.*, 2009).	No.
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.*	Water is used to process the product but the water is potable and the final product is sealed.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	Pasteurisation involves heating at 90°C for 10 minutes (or equivalent e.g. 86°C for 37 minutes) (FDA, 2001; Gould, 1999). EHN virus is inactivated after 15 minutes at 60°C (Langdon, 1989).	Yes
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke.)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	EHN virus will be inactivated by this process, therefore pasteurised fish products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent which has been demonstrated to inactivate EHNV are eligible for inclusion in Article 10.1.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Fish skin leather**	
Criteria 5.3.1.		**Assessment**	
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.*	The EHN virus can be found in skin (Redacliff and Whittington, 1996).	No
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.*	Water is used to process the leather but the final product is dry and not transported in water.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	Skin is exposed to alkaline metal sulphide, solvents, proteases, acid pH 1.5-4, chromium or other tanning solutions and dyes. The final leather product is usually pH <5. Each step takes between 15 minutes to 24 hours in a commercial setting (Pocket Book for the Leather Technologist 4th edition). pH <4 or >12 for 1 hour will inactivate EHN virus (Langdon, 1989).	Yes
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	EHN virus will be inactivated by this process, therefore fish skin leather products are eligible for inclusion in Article 10.1.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Mechanically dried eviscerated fish**	
Criteria 5.3.1.		**Assessment**	
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.*	EHN virus is present in muscle and other edible tissues (Ariel *et al.*, 2009).	No
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.*	Water is used to process the product but the end product is not shipped in water.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	Artificially drying involves heating at 100°C for 30 minutes (or equivalent). EHN virus is inactivated after 15minutes at 60°C; (Langdon, 1989).	Yes
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		N/A
AND/OR			
2c.	*Biological (e.g. fermentation)*		N/A
Conclusion	EHN virus will be inactivated by this process, therefore mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or equivalent) are eligible for inclusion in Article 10.1.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Fish oil and fish meal**	
Criteria 5.3.1.		**Assessment**	
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.*	EHN virus occurs in multiple tissues in infected fish. Fish oil is derived from whole fish or by-products of processing.	No
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.*	If the fish are infected then the water is likely to be contaminated.	No
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	During production, fish oil and fish meal undergoes multiple heat treatments and the final water content of the product is extremely low. Raw material is cooked (may be pre-heated to 50-60°C before cooking at temperatures of 95-100°C for 15-20 minutes. For energy cost reasons and nutritional content, some processors use 80-85°C for 20 minutes). Cooked material is pressed to produce press liquor and presscake that can be dried (75-80°C, ≥30 minutes) and milled to presscake meal. Press liquor is heated to 90-95°C, which produces oil and stick-water. Oil is purified with hot water (at 90°C). Stickwater is evaporated at ≥100°C (<130°C) and the resulting fish solubles are added to the presscake. Presscake + fish soluble mix dried at 75-80°C for ≥30 minutes to reduce water content to ≤12%. This is then milled to whole fishmeal. EHN virus is inactivated after 15minutes at 60°C (Langdon, 1989).	Yes
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	EHN virus will be inactivated by this process, therefore fish oil and fish meal are eligible for inclusion in Article 10.1.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

2. Assessments amended criteria in Article 5.3.2.

The following aquatic animal products were assessed and did meet the criteria in Article 5.3.2.:

i) fillets or steaks (chilled or frozen)

The following aquatic animal products were assessed and did not meet the criteria in Article 5.3.2.:

i) eviscerated fish (chilled or frozen);

ii) naturally dried eviscerated fish

Product under consideration		**Fillets or steaks (chilled or frozen)**	
Criteria 5.3.2.		**Assessment**	
1.	*The aquatic animal product is prepared and packaged for direct retail trade for human consumption.*	It is part of the commodity definition.	Yes
AND *EITHER*			
2.	*It includes only a small amount of waste tissues.*	Wastes include skin and bones.	Yes
OR			
3.	*The disease agent is not normally found in the waste tissues.*	Virus can be present in skin (Redacliff and Whittington, 1996). EHN virus can persist in frozen fish tissues for more than 2 years and EHN virus can persist in chilled fish tissues for more than 1 week (Langdon, 1989).	No
Conclusion	Fillets or ~~cutlets~~ steaks (chilled or frozen) that are prepared and packaged for retail trade for human consumption may produce small amounts of wastes. Therefore, this product is considered to be eligible for inclusion in the proposed Article 10.1.12. for EHN.		

Product under consideration		**Eviscerated fish (chilled or frozen)**	
Criteria 5.3.2.		**Assessment**	
1.	*The aquatic animal product is prepared and packaged for direct retail trade for human consumption.*	It is part of the commodity definition.	Yes
AND *EITHER*			
2.	*It includes only a small amount of waste tissues.*	Wastes include head, backbone and skin.	Yes
OR			
3.	*The disease agent is not normally found in the waste tissues.*	EHN virus can be present in gills and skin (Redacliff and Whittington, 1996) and brain (Langdon, Humphrey and Williams, 1988). EHNV can persist in frozen fish tissues for more than 2 years and EHN virus can persist in chilled fish tissues for more than 1 week (Langdon, 1989).	No
Conclusion	Eviscerated fish (chilled or frozen) that are prepared and packaged for retail trade for human consumption may produce amounts of wastes that cannot be considered small; the disease agent may be found in the waste (skin and gills). Therefore, this product is not considered eligible for inclusion in the proposed Article 10.1.12. for EHN.		

Product under consideration		**Naturally dried eviscerated fish**	
Criteria 5.3.2.		**Assessment**	
1.	*The aquatic animal product is prepared and packaged for direct retail trade for human consumption.*	It is part of the commodity definition.	Yes
AND *EITHER*			
2.	*It includes only a small amount of waste tissues.*	Waste includes head, backbone and skin.	No
OR			
3.	*The disease agent is not normally found in the waste tissues.*	Virus can be present in skin (Redacliff and Whittington, 1996) and brain (Langdon, Humphrey and Williams, 1988).	No
Conclusion	Naturally dried eviscerated fish that are prepared and packaged for retail trade for human consumption may produce amounts of wastes that cannot be considered small; the disease agent may be found in the waste tissues. Therefore, this product is not considered eligible for inclusion in the proposed Article 10.1.12. for EHN.		

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Annex XXXII (contd)

Appendix IV (contd)

B. Aquatic Animal Product Assessments for Taura syndrome (TS)

1. Assessments using criteria in Article 5.3.1.

The following aquatic animal products were assessed and did meet the criteria in Article 5.3.1.:

i) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

ii) cooked crustacean products that have been subjected to heat treatment at 70°C for at least 30 minutes or to any equivalent treatment which has been demonstrated to inactivate TSV;

iii) pasteurised crustacean products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent.

iv) crustacean oil;

v) crustacean meal; and

vi) chemically extracted chitin.

Product under consideration		**Heat sterilised hermetically sealed crustacean products**	
Criteria 5.3.1.		**Assessment**	
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.*	Meat contains TSV.	No
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.*	Water is used to process the product but the water is potable and the final product is sealed.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	Heat treatment is 121°C for 3.6 minutes or equivalent (e.g. 111°C for 36 minutes) (Ababouch, 1999, 2002). Although there is no specific information about inactivation of TSV, another picornavirus (Foot and Mouth Disease Virus) is inactivated in meat at 70°C for 30 minutes (*Terrestrial Code*, 2009).	
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	TSV is highly likely to be inactivated by this process and heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent) are therefore eligible for inclusion in Article 9.4.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Cooked crustacean products**	
Criteria 5.3.1.		**Assessment**	
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.*	Meat contains TSV	No
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.*		NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	Although there is no specific information about inactivation of TSV, another picornavirus (FMDV) is inactivated in meat at 70°C for 30 minutes (Terrestrial Code, 2009).	
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	TSV is likely to be inactivated by heat treatment at 70°C for at least 30 minutes. Cooked crustacean products that have been subjected to heat treatment at 70°C for at least 30 minutes or to any equivalent treatment which has been demonstrated to inactivate TSV, are therefore eligible for inclusion in Article 9.4.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Pasteurised crustacean products**	
Criteria 5.3.1.		**Assessment**	
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.*	Meat contains TSV.	No
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.*		NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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).*	Heat treatment of 90°C for 10 minutes or equivalent (e.g. 86°C for 37 minutes)FDA, 2001; Gould 1999).. Although there is no specific information about inactivation of TSV, another picornavirus (FMDV) is inactivated in meat at 70°C for 30 minutes (*Terrestrial Code*, 2009).	
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke).*		
AND/OR			
2c.	*Biological (e.g. fermentation).*		
Conclusion	TSV is likely to be inactivated by this process and. Therefore, pasteurised crustacean products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent are eligible for inclusion in Article 9.4.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Crustacean oil**	
Criteria 5.3.1.		**Assessment**	
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.*	Virus is present in cuticular epithelium, ectodermal and mesodermal tissues. All these tissues may be used in the commodity.	No
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.*	Water is used to process the product but the water is potable and the final product is sealed.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	Raw material is cooked (may be pre-heated to 50-60^{o}C before cooking at temperatures of 95-100^{o}C for 15-20 minutes. For energy cost reasons and nutritional content, some processors use 80-85^{o}C for 20 minutes). Cooked material is pressed to produce press liquor and press liquor heated to 90-95^{o}C, which produces oil. Oil is purified with hot water (at 90^{o}C) (FAO, 1986). Although there is no specific information about inactivation of TSV, another picornavirus (FMDV) is inactivated in meat at 70^{o}C for 30 minutes (*Terrestrial Code*, 2009).	
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	TSV is highly likely to be inactivated by this process and crustacean oil is therefore eligible for inclusion in Article 9.4.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Crustacean meal**	
Criteria 5.3.1.		**Assessment**	
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.*	Virus is present in cuticular epithelium, ectodermal and mesodermal tissues. All these tissues may be used in the commodity.	No
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.*	Water is used in the processing but the product undergoes a drying process.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	The process involves cooking, usually boiling at least 100°C for 3 minutes; a drying step of between 115-138°C (Velez, 1991). Although there is no specific information about inactivation of TSV, another picornavirus (FMDV) is inactivated in meat at 70°C for 30 minutes (*Terrestrial Code*, 2009).	
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	TSV is likely to be inactivated by this process and crustacean meal is therefore eligible for inclusion in Article 9.4.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Chemically extracted chitin**	
Criteria 5.3.1.		**Assessment**	
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.*	Virus is present in cuticular epithelium. This tissue is used in the commodity.	No
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.*	Water is used in the processing but given the chemicals used it is unlikely water would remain contaminated.	NA
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	Hydrochloric acid is used in the processing and involves heating at 60-70°C for a few hours (Gagné, 1993). Although there is no specific information about inactivation of TSV, another picornavirus (FMD Virus) is inactivated in meat at 70°C for 30 minutes (*Terrestrial Code*, 2009).	
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	TSV is likely to be inactivated by this process and chemically extracted chitin is therefore eligible for inclusion in Article 9.4.3. point 1.		

Annex XXXII (contd)

Appendix IV (contd)

2. Assessments using criteria in Article 5.3.2.

The following aquatic animal products were assessed and did meet the criteria in Article 5.3.2.:

i) frozen, peeled shrimp (shell off, head off).

The following aquatic animal products were assessed and did not meet the criteria in Article 5.3.2.:

ii) frozen, shell on, head on shrimp.

Product under consideration		**Frozen, peeled shrimp (shell off, head off)**	
Criteria 5.3.2.		**Assessment**	
1.	*The aquatic animal product is prepared and packaged for direct retail trade for human consumption.*	It is part of commodity definition.	Yes
AND *EITHER*			
2.	*It includes only a small amount of waste tissues.*	There are no waste tissues as the entire product is consumed.	Yes
OR			
3.	*The disease agent is not normally found in the waste tissues.*		
Conclusion	Frozen, peeled shrimp (shell off, head off) that are prepared and packaged for retail trade for human consumption do not produce waste; Therefore, this product is considered to be eligible for inclusion in the proposed Article 9.4.11. for Taura syndrome. As there is no waste, this product is considered to be eligible for inclusion in the proposed Article 9.X.11. for all crustacean disease chapters.		

Product under consideration		**Frozen, shell on, head on shrimp**	
Criteria 5.3.2.		**Assessment**	
1.	*The aquatic animal product is prepared and packaged for direct retail trade for human consumption.*	It is part of commodity definition.	Yes
AND *EITHER*			
2.	*It includes only a small amount of waste tissues.*	Waste includes shell, cephalothorax, legs.	No
OR			
3.	*The disease agent is not normally found in the waste tissues.*	Exoskeleton and cephalothorax contains the virus. Freezing and cold storage for normal periods will not eliminate the virus (Brock *et al.*, 1997; Lightner, 1995).	No
Conclusion	Frozen, shell on, head on shrimp that are prepared and packaged for retail trade for human consumption may produce amounts of wastes that cannot be considered small; the disease agent may be found in the waste. Therefore, this product is not considered eligible for inclusion in the proposed Article 9.4.11. for Taura syndrome.		

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Annex XXXII (contd)

Appendix IV (contd)

C. Aquatic Animal Product Assessments for Infection with *Bonamia ostreae*

1. Assessments using criteria in Article 5.3.1.

The following aquatic animal products were assessed and did meet the criteria in Article 5.3.1.:

i) frozen oyster meat

ii) frozen half-shell oysters.

The following aquatic animal products were not assessed because they are not believed to be traded internationally:

i) heat sterilised hermetically sealed oyster products

ii) pasteurised oyster products.

Product under consideration		**Frozen oyster meat**	
Criteria 5.3.1.		**Assessment**	**Yes/No**
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.*	The product includes all tissues of the oyster except the shell and a portion of the adductor muscle. *B. ostreae* is an intrahaemocytic parasite (Pichot *et al.*, 1979) and will occur in all tissues of the oyster.	No
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.*	The commodity is processed with clean seawater or potable water (WHO and FAO, 2009). *B. ostreae* does not occur in freshwater; survival is favoured by high salinities (2010 OIE *Aquatic Animal Health Code*).	No
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	*B. ostreae* will not survive the freezing process (*B. ostreae* does not form spores or cysts); in general, protozoa require a cryopreservation technique with preservative in order to survive frozen storage (Dalgleish, 1972).	Yes
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	*Bonamia ostreae* will be inactivated by this process, therefore frozen off the shell oyster meat is eligible for inclusion in Article 11.2.3, point 1.		

Annex XXXII (contd)

Appendix IV (contd)

Product under consideration		**Frozen half shell oysters**	
Criteria 5.3.1.		**Assessment**	**Yes/No**
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.*	The product includes all tissues of the oyster except the shell and a portion of the adductor muscle. *B. ostreae* is an intrahaemocytic parasite (Pichot *et al.*, 1979) and will occur in all tissues of the oyster.	No
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.*	The commodity is processed with clean seawater or potable water (WHO and FAO, 2009). *B. ostreae* does not occur in freshwater; survival is favoured by high salinities (2010 OIE *Aquatic Animal Health Code*).	No
OR			
2.	***Even if the disease agent is present in, or contaminates in 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)*	*B. ostreae* will not survive the freezing process; protozoa require a cryopreservation technique with preservative in order to survive frozen storage (Dalgleish, 1972).	Yes
AND/OR			
2b.	*Chemical (e.g. iodine, pH, salt, smoke)*		
AND/OR			
2c.	*Biological (e.g. fermentation)*		
Conclusion	*Bonamia ostreae* will be inactivated by this process, therefore frozen half shell oysters are eligible for inclusion in Article 11.2.3, point 1.		

Annex XXXII (contd)

Appendix IV (contd)

2. Assessments using criteria in Article 5.3.2.

The following aquatic animal products were assessed and did meet the criteria in Article 5.3.2.:

i) chilled oyster meat

ii) chilled half-shell oysters.

Product under consideration		**Chilled oyster meat**	
Criteria 5.3.2.		**Assessment**	
1.	*The aquatic animal product is prepared and packaged for direct retail trade for human consumption.*	It is part of the commodity definition.	Yes
AND *EITHER*			
2.	*It includes only a small amount of waste tissues.*	There are no waste tissues as the entire product is consumed.	Yes
OR			
3.	*The disease agent is not normally found in the waste tissues.*		
Conclusion	Chilled oyster meat that is prepared and packaged for retail trade for human consumption does not produce waste, therefore this product is eligible for inclusion in the proposed Article 11.2.11.		

Product under consideration		**Chilled half-shell oysters**	
Criteria 5.3.2.		**Assessment**	
1.	*The aquatic animal product is prepared and packaged for direct retail trade for human consumption.*	It is part of the commodity definition.	Yes
AND *EITHER*			
2.	*It includes only a small amount of waste tissues.*	Wastes generated include half of the shell with piece of adductor muscle attached.	Yes
OR			
3.	*The disease agent is not normally found in the waste tissues.*	*B. ostreae* does not occur in the shell.	
Conclusion	Chilled half shell oysters that are prepared and packaged for retail trade for human consumption produces small amounts of waste tissue (shell is not a tissue), therefore this product is eligible for inclusion in the proposed Article 11.2.11.		

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Annex XXXII (contd)

Appendix V(A)

CHAPTER 10.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

[…]

Article 10.1.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a exporting country, zone or compartment not declared free from EHN

1. *Competent Authorities* should not require any EHN related conditions, regardless of the EHN status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.1.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

   ii) pasteurised fish products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent which has been demonstrated to inactivate EHNV;

   iii) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or equivalent);

   iv) fish skin leather;

   v) fish oil; and

   vi) fish meal.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.1.2., other than those referred to in point 1 of Article 10.1.3., *Competent Authorities* should require the conditions prescribed in Articles 10.1.7. to 10.1.12. relevant to the EHN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of EHN from a species not covered in Article 10.1.2. but which could reasonably be expected to pose a risk of transmission for EHN, *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 10.1.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

When importing, for processing for human consumption, *aquatic animals* and *aquatic animal products* of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Annex XXXII (contd)

Appendix V(A) (contd)

1. the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.1.3., or products described in point 1 of Article 10.1.12., 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 EHNV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

[…]

Article 10.1.12.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

1. *Competent Authorities* should not require any EHV related conditions, regardless of the EHV status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) fillets or steaks (chilled or frozen).

   For these *commodities* 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.

2. When importing *aquatic animals* and *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation *measures*.

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CHAPTER 9.4.

TAURA SYNDROME

[…]

Article 9.4.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from Taura Syndrome

1. *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products f*rom the species referred to in Article 9.2.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121oC for at least 3.6 minutes or equivalent);

   ii) cooked crustacean products that have been subjected to heat treatment at 70oC for at least 30 minutes or to any equivalent treatment which has been demonstrated to inactivate TSV;

   ii) pasteurised crustacean products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent.

   iii) crustacean oil;

   iv) crustacean meal; and

   v) chemically extracted chitin.

2. When authorising the importation or transit of the *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.4.2., other than those listed in point 1 of Article 9.4.3., *Competent Authorities* should require the conditions prescribed in Articles 9.4.7. to 9.4.11. relevant to the TS status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation or transit of a *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of TS from a species not covered in Article 9.4.2. but which could reasonably be expected to pose a risk of transmission for TSV, *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 9.4.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from Taura syndrome

When importing, for processing for human consumption, *aquatic animals* and *aquatic animal products* of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Annex XXXII (contd)

Appendix V(A) (contd)

1. the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 9.4.3., or products described in point 1 of Article 9.4.11., or other products authorised by the *Competent Authority*; and

2. all effluent and waste materials ~~be~~ from the processing are treated in a manner that ensures inactivation of TSV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

[…]

Article 9.4.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Taura syndrome

1. *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) frozen, peeled shrimp (shell off, head off).

   For these *commodities* 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.

2. When importing *aquatic animals or aquatic animal products,* other than those referred to in point 1 above, of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

CHAPTER 11.2.

INFECTION WITH *BONAMIA OSTREAE*

[…]

Article 11.2.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from *B. ostreae*

1. *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 11.2.2. intended for any purpose and complying with Article 5.3.1.~~:~~

   i) frozen oyster meat

   ii) frozen half-shell oysters

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.~~1~~.2.2., other than those referred to in point 1 of Article 11.2.3., *Competent Authorities* should require the conditions prescribed in Articles 11.2.7. to 11.2.11. relevant to the *B. ostreae* status of the *exporting country*, *zone* or *compartment*.

2. When considering the importation~~/~~ or transit of *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of infection with *B. ostreae* from a species not covered in Article 11.2.2. but which could reasonably be expected to pose a risk of transmission for *B. ostreae*, ~~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 11.2.9.

Importation of aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from *B. ostreae*

When importing, for processing for human consumption, *aquatic animals* and *aquatic animal products* of the species referred to in Article 11.2.2. from a country, *zone* or *compartment* not declared free from *B. ostreae*, 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* or containment facilities until processing into one of the products referred to in point 1 of Article 11.2.3., or products described in point 1 of Article 11.2.11., 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 *B. ostreae* or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

Annex XXXII (contd)

Appendix V(A) (contd)

[…]

Article 11.2.11.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from *B. ostreae*

1. *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) chilled oyster meat;

   ii) chilled half-shell oysters.

   For these *commodities* 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.

2. When importing *aquatic animals or aquatic animal products,* other than those referred to in point 1 above, of the species referred to in Article 11.2.2. from a country, *zone or compartment* not declared free from *B. ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk mitigation* measures.

CHAPTER 10.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

[…]

Article 10.1.3.

~~Commodities~~ Importation or transit of aquatic animals and aquatic animal products for any purpose ~~regardless of the EHN status of the~~ from a exporting country, zone or compartment not declared free from EHN

1. ~~When authorising the importation or transit of the following *commodities*, the~~ *Competent Authorities* should not require any EHN related conditions, regardless of the EHN status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.1.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

   ii) pasteurised fish products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent which has been demonstrated to inactivate EHNV;

   iii) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or equivalent);

   iv) fish skin leather;

   v) fish oil; and

   vi) fish meal.

   ~~a) From the species referred to in Article 10.1.2. intended for any purpose:~~

      ~~i) *commodities* treated in a manner that inactivates the *disease agent* e.g. fish skin leather made from fish skin,;~~

      ~~ii) pasteurised products and some ready-to-eat meals; and~~

      ~~iii) fish oil; and~~

      ~~iv) 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 10.1.2. 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), OIE 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.~~

2. When authorising the importation or transit of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.1.2., other than those referred to in point 1 of Article 10.1.3., ~~the~~ *Competent Authorities* should require the conditions prescribed in Articles 10.1.7. to 10.1.12. relevant to the EHN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation~~/~~ or transit of ~~a *commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of EHN ~~of a live *commodity*~~ from a species not covered in Article 10.1.2. but which could reasonably be expected to pose a risk of transmission ~~be a potential mechanical vector~~ for EHN, ~~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 10.1.9.

Importation of ~~live~~ aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

When importing, for processing for human consumption, ~~live~~ *aquatic animals* and *aquatic animal products* of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment ~~be~~ is delivered directly to and held in *quarantine* or containment facilities until ~~for slaughter and~~ processing into one of the products referred to in point 1 of Article 10.1.3., or products described in point 1 of Article 10.1.12., 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 EHNV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* ~~OIE~~ Members may wish to consider introducing internal measures to address the *risks* associated with the *commodity* ~~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 10.1.3.~~

[…]

Article 10.1.12.

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from epizootic haematopoietic necrosis

1. *Competent Authorities* should not require any EHV related conditions, regardless of the EHV status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

~~i)~~ ~~*eviscerated fish* (chilled or frozen);~~

~~ii)~~ fillets or steaks ~~cutlets~~ (chilled or frozen)~~; and~~

~~iii)~~ ~~artificially dried *eviscerated fish* (including air dried, flame dried and sun dried).~~

For these *commodities* 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.

3. When importing ~~live~~ *aquatic animals* and *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.1.2. from a country, *zone* or *compartment* not declared free from EHV, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

~~1. the direct delivery into and holding of the consignment in facilities for processing to one of the products referred to in point 1 of Article 10.1.3. or other products authorised by the *Competent Authority*;~~

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

~~This Article does not apply to *commodities* referred to in point 1 of Article 10.1.3.~~

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CHAPTER 9.4.

TAURA SYNDROME

[…]

Article 9.4.3.

~~Commodities~~ Importation or transit of aquatic animals and aquatic animal products for any purpose ~~regardless of the Taura Syndrome status of the~~ from a ~~exporting~~ country, zone or compartment not declared free from Taura Syndrome

1. ~~When authorising the importation or transit of the following *commodities*, the~~ *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article 9.2.2. intended for any purpose and complying with Article 5.3.1.:

   i) heat sterilised hermetically sealed crustacean products (i.e. a heat treatment at 121°C for at least 3.6 minutes or equivalent);

   ii) cooked crustacean products that have been subjected to heat treatment at 70°C for at least 30 minutes or to any equivalent treatment which has been demonstrated to inactivate TSV;

   v) pasteurised crustacean products that have been subjected to heat treatment at 90°C for 10 minutes or to any pasteurisation equivalent;

   vi) crustacean oil;

   v) crustacean meal; and

   vi) chemically extracted chitin.

   ~~a) For the species referred to in Article 9.4.2. intended for any purpose:~~

      ~~i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled cooked products~~

      ~~ii) canned products; or pasteurised products and some ready-to-eat meals; and~~

      ~~iii) crustacean oil; and~~

      ~~iv) crustacean *meal* intended for use in *feed*;~~

      ~~iiv) chemically extracted chitin.~~

~~iii) crustacean products made non-infectious through processing as dry *feed* (e.g. pelleted or extruded *feed*);~~ [1]

~~iv) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.~~

~~b) [The following products destined for human consumption from species referred to in Article 9.4.2. which have been prepared and packaged for direct retail trade:] (under study)~~

2. When authorising the importation or transit of the ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.4.2., other than those listed in point 1 of Article 9.4.3., ~~the~~ *Competent Authorities* should require the conditions prescribed in Articles 9.4.7. to 9.4.11. relevant to the TS status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation~~/~~ or transit of a ~~*commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of TS ~~of a *commodity* of~~ from a species not covered in Article 9.4.2. but which could reasonably be expected to pose a risk of transmission ~~be a potential mechanical vector~~ for TSV, ~~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 9.4.9.

Importation of ~~live~~ aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from Taura syndrome

When importing, for processing for human consumption, ~~live~~ *aquatic animals* and *aquatic animal products* of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment ~~be~~ is delivered directly to and held in *quarantine* or containment facilities ~~isolation until~~ until ~~for~~ processing ~~and/or consumption;~~ into one of the products referred to in point 1 of Article 9.4.3., or products described in point 1 of Article 9.4.11., or other products authorised by the *Competent Authority*; and

2. all effluent~~, dead *aquatic animals*~~ and waste materials from the processing ~~be~~ are treated in a manner that ensures inactivation of TSV or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* ~~OIE~~ Members may wish to consider introducing internal measures to address the *risks* associated with the ~~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 9.4.3.~~

[1] Refer to page 28 of Annex XXV for the assessment of this product undertaken by the *ad hoc* Group.

Annex XXXII (contd)

Appendix V(B) (contd)

[…]

Article 9.4.11.

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from Taura syndrome

1. *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   ~~[~~i) frozen, peeled shrimp (shell off, head off)~~] (under study)~~.

   For these *commodities* 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.

2. When importing ~~*live*~~ *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 9.4.2. from a country, *zone* or *compartment* not declared free from TS, 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 9.4.3.~~

– text deleted

CHAPTER 11.2.

INFECTION WITH *BONAMIA OSTREAE*

[…]

Article 11.2.3.

~~Commodities~~ Importation or transit of ~~live~~ aquatic animals and aquatic animal products for any purpose ~~regardless of the *B. ostreae* status of the~~ from a ~~exporting~~ country, zone or compartment not declared free from *B. ostreae*

1. ~~When authorising the importation or transit of the following *commodities*, the~~ *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following ~~*commodities*~~ *aquatic animals* and *aquatic animal products* from the species referred to in Article 11.2.2. intended for any purpose and complying with Article 5.3.1.~~:~~

   i) frozen oyster meat;

   ii) frozen half-shell oysters.

   ~~a) From the species referred to in Article 11.2.2. intended for any purpose:~~

   ~~i) *commodities* treated in a manner that inactivates the *disease agent* e.g.canned or~~

   ~~ii) pasteurised 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 11.2.2. which have been prepared and packaged for direct retail trade:~~

      ~~i) off the shell (chilled or frozen);~~

      ~~ii) half shell (chilled).~~

   ~~c) All *commodities* from *Crasso streagigas*, *C. virginica*, *Rudit apesdecussa tus*, *R. philippin arum* , *Mytilusgallo provincialis* and *M.edulis*, including the live *aquatic animal*.~~

~~For the *commodities* referred to in point 1b), OIE 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.~~

2. When authorising the importation or transit of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.~~1~~.2.2., other than those referred to in point 1 of Article 11.2.3., ~~the~~ *Competent Authorities* should require the conditions prescribed in Articles 11.2.7. to 11.2.11. relevant to the *B. ostreae* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation~~/~~ or transit of ~~a *commodity*~~ *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of infection with *B. ostreae* ~~of a *commodity*~~ from ~~bivalve~~ a species not covered in Article 11.2.2. ~~or in point 1c) of Article 11.2.3.~~ but which could reasonably be expected to pose a risk of transmission ~~be a potential mechanical vector~~ for *B. ostreae*, ~~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 XXXII (contd)

Appendix V(B) (contd)

[…]

Article 11.2.9.

Importation of ~~live~~ aquatic animals and aquatic animal products for processing for human consumption from a country, zone or compartment not declared free from *B. ostreae*

When importing, for processing for human consumption, ~~live~~ *aquatic animals* and *aquatic animal products* of the species referred to in Article 11.2.2. from a country, *zone* or *compartment* not declared free from *B. ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment ~~be~~ is delivered directly to and held in *quarantine* or containment facilities ~~until~~ ~~for~~ until processing ~~and/or consumption~~ into one of the products referred to in point 1 of Article 11.2.3., or products described in point 1 of Article 11.2.11., 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 *B. ostreae* or is disposed in a manner that prevents contact of waste with susceptible species.

For these *commodities* 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.

~~This Article does not apply to *commodities* referred to in point 1 of Article 10.1.3.~~

[…]

Article 11.2.11.

Importation of ~~live~~ aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from *B. ostreae*

1. *Competent Authorities* should not require any *B. ostreae* related conditions, regardless of the *B. ostreae* status of the *exporting country*, *zone* or *compartment* when authorising the importation or transit of the following *commodities* which have been prepared and packaged for retail trade and complying with Article 5.3.2.:

   i) ~~off the shell~~ chilled oyster meat ~~(chilled or frozen)~~;

   ii) chilled half-shell oysters ~~(chilled or frozen).~~

   For these *commodities* 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.

2. When importing ~~*live*~~ *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the *species* referred to in Article 11.2.2. from a country, *zone or compartment* not declared free from *B. ostreae*, 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 10.1.3.~~

- - - - - - - - - - - - - - -

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CHAPTER 5.3.

CRITERIA TO ASSESS THE SAFETY OF AQUATIC ANIMAL COMMODITIES

In the context of this chapter the word safety is applied only to animal health considerations for OIE listed *diseases.*

Article 5.3.1.

Criteria to assess the safety of aquatic animals and aquatic animal products for any purpose ~~commodities irrespective regardless of country~~ from a country, zone or compartment not declared free from disease X ~~status~~

In all *disease* chapters, point 1~~a)~~ of Article X.X.3. lists ~~*commodities*~~ *aquatic animals* and *aquatic animal products* that can be traded for any purpose ~~irrespective~~ ~~regardless of~~ ~~country~~ from a country, zone or compartment not declared free from disease X ~~status~~. The criteria for inclusion of ~~*commodities*~~ *aquatic animals* and *aquatic animal products* in point 1~~a)~~ of Article X.X.3. are based on the absence of the *disease agent* in the traded ~~*commodity*~~ *aquatic animals* and *aquatic animal products* or inactivation of the *disease agent* by treatment or processing.

The assessment of the safety of the ~~*commodity*~~ *aquatic animals* and *aquatic animal product* 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*~~ *aquatic animal product* do not jeopardise the safety of the traded ~~*commodity*~~ *aquatic animal product*.

For an ~~*commodity*~~ *aquatic animal or aquatic animal product* to be considered safe for *international trade* under the provisions of ~~point 1a) of~~ Article X.X.3., it should comply with the following criteria:

1. Absence of *disease agent* in the traded ~~*commodity*~~ *aquatic animal or aquatic animal product*:

   a) There is strong evidence that the *disease agent* is not present in the tissues from which the ~~*commodity*~~ *aquatic animal or aquatic animal product* is derived.

      AND

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

OR

2. Even if the *disease agent* is present in, or contaminates the tissues from which the ~~*commodity*~~ *aquatic animal or aquatic animal product* is derived, the treatment or processing to produce the ~~*commodity*~~ *aquatic animal or aquatic animal product* to be traded inactivates the *disease agent*:

a) physical (e.g. temperature, drying, smoking);

AND/OR

b) chemical (e.g. iodine, pH, salt, smoke);

AND/OR

c) biological (e.g. fermentation).

Article 5.3.2.

Criteria to assess the safety of aquatic animals or ~~of~~ aquatic animal products ~~destined~~ for retail trade for human consumption from a country, zone or compartment not declared free of a ~~irrespective of country~~ disease ~~status~~

In all *disease* chapters, point 1~~b)~~ of Article X.X.12~~3~~. (fish disease chapters) and; Article X.X.X.11. (mollusc and crustacean disease chapters) lists *aquatic animals* or *aquatic animal products* for retail trade ~~destined~~ for human consumption. The criteria for inclusion of *aquatic animals* or *aquatic animal products* in point 1~~b)~~ of Article X.X.12~~3~~. (fish disease chapters) and; Article X.X.X.11. (mollusc and crustacean disease chapters) include consideration of the form and presentation of the product, the expected volume of waste tissues generated by the consumer and the likely ~~quantity~~ presence of viable *disease agent* in the waste.

For the purpose of this criterion retail means the selling or provision of ~~live~~ *aquatic animals* or *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:

i) the ~~live~~ *aquatic animals* or *aquatic animal products* ~~is~~ are used for human consumption only;

ii) waste may not always be handled in an appropriate manner that mitigates the introduction of the *disease agent*. The level of risk is related to the waste disposal practices in each Member's country or territory;

iii) 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)~~

iv) ~~that~~ any other steps in the treatment, processing and subsequent handling of the ~~live~~ *aquatic animals* or *aquatic animal products* prior to importation do not jeopardise the safety of the traded ~~live~~ *aquatic animals* or *aquatic animal products*.

For ~~live~~ *aquatic animals* or *aquatic animal products* to be considered ~~safe~~ for *international trade* under the provisions of point 1~~b)~~ of Article X.X.12~~3~~. (fish disease chapters); Article X.X.X.11. (mollusc and crustacean disease chapters), it should comply with the following criteria:

1. the *aquatic animals* or *aquatic animal product* is prepared and packaged for retail trade for human consumption; AND

EITHER

2. it includes only a small amount of waste tissues generated by the consumer;

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 generated by the consumer~~;~~.

~~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);~~

~~OR~~

~~ii) chemical (e.g. pH, salt, smoke);~~

~~OR~~

~~iii) biological (e.g. fermentation).~~

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CHAPTER 5.9.

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

Article 5.9.1.

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 5.9.2.

[…]

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Annex XXXII (contd)

Appendix VIII

DISINFECTED EGGS - NEW ARTICLES

Article 10.4.X.

Importation of disinfected eggs for *aquaculture* from a country, *zone* or *compartment* not declared free from infectious haematopoietic necrosis

1. When importing disinfected *eggs* of the species referred to in Article 10.4.2 for *aquaculture*, from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the ~~conduct a *risk assessment* based on information provided by the *Competent Authority* of the *exporting country*, including~~ associated with at least:

   a) the IHN virus status of the water to be used during the *disinfection* of the *eggs*;

   b) the level of *infection* with IHN virus in broodstock (ovarian fluid and milt); and

   c) the temperature and pH of the water to be used for *disinfection*.

2. If the *Competent Authority* of the *importing country* concludes that the *importation* is acceptable, it should apply the following *risk* mitigation measures including:

   a) the *eggs* should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* ~~or those specified by the *Competent Authority* of the *importing country*~~; and

   b) between *disinfection* and the import, *eggs* ~~must~~ should not come into contact with anything which may affect their health status ~~be kept in specific pathogen free water~~.

3. When importing disinfected *eggs* of the species referred to in Article 10.4.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certified official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.4.X. have been fulfilled.

Article 10.5.X.

Importation of disinfected eggs for *aquaculture* from a country, *zone* or *compartment* not declared free from infectious salmon anaemia

1. When importing disinfected *eggs* of the species referred to in Article 10.5.2 for *aquaculture*, from a *country*, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

   a) the ISA virus status of the water used during the *disinfection* of the *eggs*;

   b) the level of *infection* with ISA virus in broodstock (ovarian fluid and milt); and

   c) the temperature and pH of the water used for *disinfection*.

Annex XXXII (contd)

Appendix VIII (contd)

2. If the *Competent Authority* of the *importing country* concludes that the *importation* is acceptable, it should apply the following *risk* mitigation measures including:

   a) the *eggs* should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* ~~or those specified by the *Competent Authority* of the *importing country*~~; and

   b) between *disinfection* and the import, *eggs* ~~must~~ should not come into contact with anything which may affect their health status ~~be kept in specific pathogen free water~~.

3. When importing disinfected *eggs* of the species referred to in Article 10.5.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certified official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.5.X. have been fulfilled.

Article 10.9.X.

Importation of disinfected eggs for *aquaculture* from a country, *zone* or *compartment* not declared free from viral haemorrhagic septicaemia

1. When importing disinfected *eggs* of the species referred to in Article 10.9.2 for *aquaculture*, from a *country*, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

   a) the VHS virus status of the water used during the disinfection of the *eggs*;

   b) the level of *infection* with VHS virus in broodstock (ovarian fluid and milt); and

   c) the temperature and pH of the water used for *disinfection*.

2. If the *Competent Authority* of the *importing country* concludes that the *importation* is acceptable, it should apply the following *risk* mitigation measures including:

   a) the *eggs* should be disinfected prior to importing, according to the methods described in Chapter .1.3. of the *Aquatic Manual* ~~or those specified by the *Competent Authority* of the *importing country*~~; and

   b) between *disinfection* and the import, *eggs* ~~must~~ should not come into contact with anything which may affect their health status ~~be kept in specific pathogen free water~~.

Annex XXXII (contd)

Appendix VIII (contd)

3. When importing disinfected *eggs* of the species referred to in Article 10.9.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certified official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.9.X. have been fulfilled.

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Annex XXXIII

Original: English
December 2009/February 2010

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES − CRUSTACEAN TEAM − FOR THE OIE *AQUATIC ANIMAL HEALTH CODE*

Electronic Working Group: December 2009–February 2010

The OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases - Crustacean Team for the OIE *Aquatic Animal Health Code* (the *ad hoc* Group) was convened at the recommendation of the Aquatic Animal Health Standards Commission (the Aquatic Animals Commission) and met electronically between December 2009 and February 2010.

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

Below is a summary of the *ad hoc* Group deliberations on each agenda item and their recommendations to the Aquatic Animals Commission.

Item 1. Review whether milky haemolymph disease of spiny lobsters (*Panulirus* spp.), currently OIE listed as 'understudy', should be listed as an emerging disease. Taking into consideration the original assessment by the *ad hoc* Group and a Member comment

The *ad hoc* Group reviewed various publications on milky haemolymph disease of spiny lobsters *(Panulirus spp.),* its previous assessment (refer to Annex XXVI of the September 2009 Report of the Aquatic Animals Commission), a Member comment, and the assessments of *ad hoc* Group members based on the criteria for listing as outlined in Articles 1.2.1. and 1.2.2. of the *Aquatic Code.*

Assessment

The *ad hoc* Group agreed that milky hemolymph disease of spiny lobsters (*Panulirus* spp.) met most of the criteria for listing as outlined in Articles 1.2.1. and 1.2.2. of the *Aquatic Code*. However, two of the three *ad hoc* Group members believed that the disease failed to meet the provisions of Article 1.2.1. criterion 6 (potential for international spread) and Article 1.2.2. criterion 4 (significant spread in native populations of wild or cultured aquatic animals). The *ad hoc* Group recommended not to list milky hemolymph disease of spiny lobsters (*Panulirus* spp.) as an emerging disease, based on its assessment of the disease against the criteria in Article 1.2.2. Furthermore, because the *ad hoc* Group felt that disease did not meet Article 1.2.1criteria 6, it's listing according to Article 1.2.1. was also not recommended at this time.

The assessments made by the *ad hoc* Group members are in Annex III.

Annex XXXIII (contd)

Recommendation

Milky hemolymph disease of spiny lobsters (*Panulirus* spp.) does not meet the criteria for listing as outlined in Articles 1.2.1 and 1.2.2 of the *Aquatic Code* and therefore should not be listed as an emerging or a listed disease.

.../Annexes

Annex I

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES − CRUSTACEAN TEAM − FOR THE OIE *AQUATIC ANIMAL HEALTH CODE*

Electronic Working Group: December 2009–February 2010

List of participants

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Annex XXXIII (contd)

Annex II

THE OIE *AD HOC* GROUP ON AQUATIC ANIMAL DISEASES

– CRUSTACEAN TEAM –

FOR THE OIE *AQUATIC ANIMAL HEALTH CODE*

Electronic Working Group: December 2009 – February 2010

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Adopted Agenda

1. Review whether milky haemolymph disease of spiny lobsters (*Panulirus* spp.), currently OIE listed as 'understudy', should be listed as an emerging disease. Taking into consideration the original assessment by the *ad hoc* Group and a Member comment.

2. Submit a report to the OIE Aquatic Animal Health Standards Commission by 8th February 2010.

Annex XXXIII (contd)

Annex III

Summary of assessments by *ad hoc* Group experts

1. Assessment by Dr Mohan:

I. Assessment of milky hemolymph disease of spiny lobsters (*Panulirus* spp.) using the Criteria in Article 1.2.1. in the *Aquatic Code*.

Crustacean disease considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*								Recommendation
	1	2	3	4	5	6	7	8	
MHD of spiny (*Panulirus* spp.) lobsters	Yes.	Yes	No	Yes	N/A	Yes	Yes	Yes	Recommended for listing

1. Significant production losses in Vietnam. Too premature to come to the conclusion that the production losses are coming down.
2. Lobsters are an important economic resource in many countries. The possibility of the disease spreading to natural populations can't be ruled out at this stage.
3. No public health concern.
4. Etiology of the disease has been proved.
5. N/A
6. Potential for regional and international spread exists very much through movement of lobster brood-stock and seed. The treatments demonstrated are very specific and based on experimental infections. It is too early to presume that the treatment will work in all conditions. Presence of an effective treatment based on experiments should not be used as an argument for not listing a disease. In real life scenario, effective treatment may not be applied at all sites, all times and farmers may not be able to access the treatment in time. Hence there is potential risk of spread to other countries.
7. General surveillance principles can be easily applied to declare freedom.
8. Confirmatory diagnosis available.

II. Assessment of Milky hemolymph disease of spiny lobsters (*Panulirus* spp.) using the Criteria in Article 1.2.2. in the *Aquatic Code*.

Crustacean disease considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*				
	1	2	3	4	Recommendation
MHD of spiny (*Panulirus* spp.) lobsters	Yes	N/A	N	Yes	Recommended for listing

1. Infectious etiology of the disease has been proved.
2. N/A
3. No public health concern.
4. Significant spread in cultured lobster populations in Vietnam. Now reported from two species of *Panulirus* from two provinces (Binh Thuan and Phu Yen) of Vietnam suggesting possible spread of the pathogen.

Annex XXXIII (contd)

Annex III (contd)

2. Assessment by Dr Oanh:

I. Assessment of milky hemolymph disease of spiny lobsters (*Panulirus* spp.) using the Criteria in Article 1.2.1. in the *Aquatic Code*.

Crustacean disease considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*								Recommendation
	1	2	3	4	5	6	7	8	
MHD of spiny (*Panulirus* spp.) lobsters	N	NA	N	Y	NA	N	NA	Y	Do not list

Comments on criteria:

1. Losses due to MHD were estimated about 10% of expected income, the disease has only been reported in Vietnam and it can be effectively treated by Oxytetracycline (10mg/kg) so it does not meet the criteria.
2. There has not yet been any scientific evidence that MHD negatively affects wild aquatic animal population. This would need further investigation.
3. The agent of MHD isn't of public health concern.
4. From the current knowledge, the infectious aetiology of MHD is clearly proven to be rickettsial-like bacteria.
5. Not applicable as the infectious aetiology is clearly proven.
6. As MHD has occurred only in Vietnam and it can be effectively treated/control, therefore it does not have potential for international spread via like animals or related products.
7. Not applicable as MHD has only been reported in cultured lobsters in Vietnam.
8. Diagnostic methods are available.

II. Assessment of Milky hemolymph disease of spiny lobsters (*Panulirus* spp.) using the Criteria in Article 1.2.2. in the *Aquatic Code*.

Crustacean disease considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*				
	1	2	3	4	Recommendation
MHD of spiny (*Panulirus* spp.) lobsters	Y	NA	N	N	Do not list

Comments on criteria:

1. From the current knowledge, the infectious aetiology of MHD is clearly proven to be rickettsial-like bacteria.
2. Not applicable as the infectious aetiology is clearly proven.
3. The agent of MHD isn't of public health concern.
4. Does not meet the criteria as production losses were not significant.

3. Assessment by Dr Lightner:

I. Assessment of Milky hemolymph disease of spiny lobsters (*Panulirus* spp.) using the Criteria in Article 1.2.1. in the *Aquatic Code*.

Crustacean disease considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*								Recommendation
	1	2	3	4	5	6	7	8	
MHD of spiny lobsters	Yes	N/A	No	Yes	N/A	No	Yes	Yes	Do not list

1. Significant production losses have been reported in Vietnam, but none since the cause of the disease was identified and management methods were put in place.
2. There are no reports of MHD in wild spiny lobsters.
3. Not a public health concern.
4. An infectious etiology of MHD has been proven.
5. N/A
6. Potential for regional and international spread is currently limited because wild juvenile lobsters are fished and used locally for farming, and because management methods for the disease have been used successfully since its etiology was determined.
7. To date, only Vietnam has reported MHD of spiny lobsters.
8. Several repeatable and robust diagnostic methods are available.

II. Assessment of Milky hemolymph disease of spiny lobsters (*Panulirus* spp.) using the Criteria in Article 1.2.2. in the *Aquatic Code*.

Crustacean disease considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*				
	1	2	3	4	Recommendation
MHD of spiny (*Panulirus* spp.) lobsters	Yes	N/A	N/A	No	Do not list

1. An infectious etiology of the disease has been proven.
2. N/A
3. No public health concern.
4. While MHD in spiny lobsters was a very significant disease in Vietnam 2-3 years ago, knowledge of its etiology and adoption of control measures appear to have stopped the disease from subsequently occurring in most of the farming areas of Vietnam.

Annex XXXIV

Original: English
January 2010

MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 19–21 January 2010

The OIE *ad hoc* Group on the Responsible Use of Antimicrobials in *Aquatic Animals* (the *ad hoc* Group) met at OIE headquarters on 19 – 21 January 2010.

The members of the *ad hoc* Group and other participants at the meeting are listed at Appendix I. The adopted agenda is at Appendix II.

Agenda Item 1: Welcome and introduction by Dr. Kahn

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Sarah Kahn, Head of the OIE International Trade Department, welcomed all members and thanked them for their agreement to work with the OIE on this important topic. She explained that there are currently five chapters in the *Terrestrial Animal Health Code* (the *Terrestrial Code*) dealing with the prudent use of antimicrobials and associated issues. However this subject has not yet been addressed for *aquatic animals* in the *Aquatic Animal Health Code* (the *Aquatic Code*). The objective of this meeting is for this *ad hoc* group to develop appropriate text for consideration by OIE Members with a view to adoption in the *Aquatic Code*.

Dr. Vallat joined the *ad hoc* group on the third day of the meeting and thanked the members of the *ad hoc* group for their hard work. The *ad hoc* group had a very helpful discussion with Dr. Vallat and obtained his guidance on the policy context of their work.

Agenda Item 2: Confirmation of Terms of Reference and comments from Chair of the *ad hoc* Group

The chair of the *ad hoc* Group, Professor Peter Smith, welcomed all members and opened a discussion on the draft terms of reference (Appendix III), which were adopted by the *ad hoc* Group. Professor Smith proposed to focus the work at this first meeting on developing guidance on prudent use of antimicrobials, taking as the starting point the *Terrestrial Code* Chapter 6.10. Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine. It was agreed that work on other relevant topics, i.e. the harmonization of national antimicrobial resistance surveillance and monitoring programs (*Terrestrial Code* Chapter 6.8.); risk assessment for antimicrobial resistance arising from the use of antimicrobials in animals (*Terrestrial Code* Chapter 6.11.) and monitoring of the quantities of antimicrobials used in animal husbandry (*Terrestrial Code* Chapter 6.9.) should be addressed subsequently, in that order.

The members proposed the following scope for this work:

a) aquatic species reared for food;

b) aquatic species reared for release into the wild;

c) ornamental fish (captured, cultured or held for exhibition);

d) internationally traded aquatic species.

The *ad hoc* Group reviewed the draft chapter 6.1. Introduction to the recommendations for controlling antimicrobial resistance (Annex II of Appendix III: adopted terms of reference) and then developed a draft text for the *Aquatic Code* on the responsible use of antimicrobial agents, using as a starting point *Terrestrial Code* Chapter 6.7. (http://alpaga/oieint/eng/normes/mcode/en_chapitre_1.6.10.htm).

The members of the *ad hoc* Group confirmed the urgent need for international guidelines for the prudent and responsible use of antimicrobial agents in aquatic species. Although the public health impact of the use of *antimicrobial agents* in aquatic species is less well studied and may be orders of magnitude lower than the risk associated with human and terrestrial animal use, guidelines for aquatic species are needed to limit the selection and dissemination of resistant micro-organisms and preserve the efficacy of antimicrobials for aquatic species. The *ad hoc* Group especially noted the development of antimicrobial resistance among target micro-organisms (pathogens) that are of importance to aquatic animal production and believes a major contribution of guidelines and related texts in the *Aquatic Code* would be to address the situation. As such, recommendations for further research, capacity building, and collaboration among international agencies will be highlighted by the *ad hoc* Group in the development of the draft texts.

Agenda Item 3: Discussion of working documents and other relevant documents provided by members

In addition to the documents mentioned before, the following documents were distributed to the members of the *ad hoc* Group:

1. *Terrestrial Code* Chapters 6.7 – 6.11 (http://alpaga/oieint/eng/normes/mcode/en_sommaire.htm)
2. Codex Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (www.codexalimentarius.net/download/report/730/am03_01e.pdf)
3. Responsible use of antibiotics in aquaculture (FAO)(ftp://ftp.fao.org/docrep/fao/009/a0282e/a0282e00.pdf)
4. RUMA (Responsible Use of Medicines in Agriculture Alliance) fish guideline (http://www.ruma.org.uk/guidelines/antimicrobials/long/fishantimicrobialguidlineslong.pdf).

Agenda item 4: Development of draft texts for consideration by the *Aquatic Animal* Health Standards Commission at its meeting in February 2010

The *ad hoc* Group discussed several specific issues related to the topic of antimicrobial resistance in aquatic animals. These matters should be taken into account in the process of standards development for the *Aquatic Code*:

1. Both the micro-organisms associated with aquatic animals and the relationship between the micro-organisms and the hosts are different for terrestrial and aquatic animals. Only a very few of the micro-organisms that are pathogens (target organisms) for aquatic animals have been associated with food borne diseases in humans.

   The concept of a more or less permanent relationship between commensal micro-organisms and terrestrial animals cannot be similarly applied and is not relevant to aquatic animals.

   There are other sources of antimicrobials other than the naturally produced and those used in aquaculture production. Effluents from human, industrial and livestock use of these antimicrobials are likely to be the major source of these products in the aquatic environment. There are also antimicrobial resistant bacteria in the aquatic environment that derive from antimicrobial use in these terrestrial contexts.

The development of antimicrobial resistance in micro-organisms that are of importance for humans and terrestrial animals as a consequence of the use of antimicrobial agents in aquatic animals is largely indirect and operates through horizontal transmission of antimicrobial resistance determinants.

The risk of the introduction of antimicrobial resistance in micro-organisms that are of importance in humans and terrestrial animals due to the use of antimicrobial agents in aquatic animals is difficult to evaluate. The *ad hoc* Group agreed that this risk is significantly lower than that arising from the use of antimicrobial agents in humans and terrestrial animals.

2. Most of the production of aquatic animals, both as a source of dietary protein and for the purpose of international trade, is in developing countries.

   Much aquaculture production occurs in countries where adequate systems for marketing authorization of antibacterial products do not exist. It is also the case that few antimicrobial agents are registered for use in aquatic animals, especially for shrimp. Some aquaculture producing countries have an official list of banned antimicrobial products rather than a positive list of products that are authorized for the market.

   It was agreed that the marketing authorisation system is the underpinning of governance for the use of antimicrobials and minimizing the selection and dissemination of resistant micro-organism and resistance determinants.

   There are several important considerations in framing appropriate recommendations for aquatic animals, especially in developing countries. Some *ad hoc* Group members considered that it was not feasible, in the short term, for many aquaculture producing OIE Members to implement a market authorization system for aquatic animals equivalent to that for terrestrial animals and that if the OIE made such recommendations, it could have a negative impact on trade and significantly disadvantage developing countries. Others considered that a market authorization system should be a minimum condition for participation in international trade.

3. In many countries veterinarians are not the central professional responsible for aquaculture health management and are not always involved in aquatic animal health management and in prescribing antimicrobial agents for aquaculture. Particularly in developing countries, there is a lack of qualified aquatic animal health professionals. This may be one of the most important obstacles in improving governance of the use of antimicrobial agents.

   In many countries with a significant aquatic animal production, the prescription of antimicrobials for use in aquatic animals is the responsibility of non-veterinary professionals and this situation is unlikely to change quickly.

   For the purpose of the draft text, the *ad hoc* Group proposed to use the term '*veterinarian* or other *aquatic animal* health professional' to recognise this fact.

4. There is a fundamental lack of knowledge related to the use of antimicrobials in aquatic animals and the implications for the development of antimicrobial resistance. There is an urgent need to develop standardised methods for evaluating microbial susceptibility and the interpretative criteria necessary for the identification of resistance in the relevant microbial groups. Currently, such interpretative criteria have been established only for some food borne pathogens (e.g. Salmonella spp.).

   The members developed a list of priorities for scientific research:

   a) development of standardised methods and the interpretative criteria necessary for determining antimicrobial susceptibility;

   b) knowledge of the pharmacokinetics and pharmacodynamics of antimicrobials in aquatic animals to support optimization of dose regimens, improved clinical efficacy and the setting of relevant withdrawal times;

   c) management practices for production and health, particularly for new aquatic animal species, to combat disease risks and to reduce the need to use antimicrobial agents;

d) comparative cost benefit analysis of husbandry and therapy-based approaches to disease control;

e) development of capacity for clinical field trials;

f) information to support extrapolation of appropriate dose regimens and withdrawal periods in multiple aquatic animal species;

g) development of practical models for using *risk analysis* to assess the public health risks associated with the development of antimicrobial resistance in aquaculture species.

In light of these considerations, the ad hoc Group refined the 'objectives of prudent use of antimicrobial agents' (draft chapter 6.1) and developed general principles for the prudent use of antimicrobial agents in aquatic animals, for consideration by the Aquatic Animal Health Standards Commission (Aquatic Animals Commission) at its February 2010 meeting.

In addition, the *ad hoc* Group decided to develop recommendations on prudent use in *aquatic animals*, along similar lines to the *Terrestrial Code* Chapter 6.10. This document could be published on the OIE internet site as an advisory document to assist OIE Members in developing and/or updating their governance systems for antimicrobial use in aquatic animals. This document will also be discussed by the Aquatic Animals Commission at its February 2010 meeting.

Agenda Item 4.1. Review draft text 'Introduction to recommendations for controlling antimicrobial resistance in aquatic animals'.

The *ad hoc* Group discussed the draft text and proposed some amendments as appropriate to the issues discussed above, for example, the inclusion of the concept of antimicrobial resistance determinants.

The *ad hoc Group* also felt that there was a need to define antimicrobial agent for the purposes of the *Aquatic Code.* The following definition was proposed:

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that at in vivo concentrations exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

The words 'at *in vivo* concentrations' were added for clarification. It was agreed that similar modifications of the current definition in the *Terrestrial Code* should be considered by the Terrestrial Animal Health Standards Commission.

The revised draft chapter **'**Introduction to recommendations for controlling antimicrobial resistance in aquatic animals' is at Appendix IV.

Agenda Item 4.2. Development of draft principles for responsible and prudent use of *antimicrobial agents* in veterinary medicine

The *ad hoc* Group developed a second draft text for the *Aquatic Code.*

The draft chapter 'Principles for Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine is at Appendix V.

Agenda Item 4.3. Development of an advisory document 'Responsible use of antimicrobial agents in aquatic animals'

The *ad hoc* Group reviewed *Terrestrial Code* Chapter 6.10. (Responsible use of *antimicrobial agents* in veterinary medicine) and proposed several modifications to adapt the text to *aquatic animals*. The *ad hoc* Group proposes to publish this advisory document on the OIE Internet site.

The draft advisory document is at Appendix VI.

Agenda item 5: Future activities

The *ad hoc* Group considered that additional meetings would be needed to develop further advice on antimicrobial resistance for inclusion in the *Aquatic Code*. The current *Terrestrial Code* Chapters 6.8. (Harmonization of national antimicrobial resistance surveillance and monitoring programs); 6.11. (*Risk assessment* for antimicrobial resistance arising from the use of antimicrobials in animals) and 6.9. (Monitoring of the quantities of antimicrobials used in animal husbandry) provide a good starting point but the specificities relevant to *aquatic animals* need to be carefully addressed.

The *ad hoc* Group was also of the opinion that a separate working group should be convened to address the issue of the appropriate methods to be used for the determination of *antimicrobial agent* susceptibility in bacteria associate with *aquatic animals.*

.../Annexes

Annex XXXIV (contd)

Appendix I

MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 19–21 January 2010

List of participants

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Appendix II

MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 19–21 January 2010

Adopted agenda

1. Welcome and introduction – Dr. Vallat or representative.
2. Confirmation of Terms of Reference and comments from Chair of the *ad hoc* Group
3. Discussion of working documents and any other relevant documents provided by the *ad hoc* Group Members
4. Development of a draft text for consideration by the Aquatic Animal Health Standards Commission at its meeting in February 2010.
5. Review and finalise report of meeting
6. Future activities

Annex XXXIV (contd)

Appendix III

MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 19–21 January 2010

Adopted terms of reference

Taking into account:

- the relevant recommendations of the report of the meeting of the OIE Aquatic Animal Health Standards Commission (Paris, 28 September–2 October 2009, see annex I);
- the existing *Terrestrial Animal Health Code* chapters 6.7.–6.11. (see annex II, III, IV, V, VI) on prudent use of antimicrobial products in terrestrial animals; and *Manual of Diagnostic Tests for Aquatic Animals* chapter 1.1.6. on methodologies for bacterial susceptibility testing, and
- the risks for human health and *aquatic animal* health potentially associated with the use in *aquatic animals* of antimicrobial products,

Elaborate:

- draft standards for the responsible production, distribution (including international trade) and use of antimicrobials in *aquatic animals* for eventual inclusion in the *Aquatic Animal Health Code*.

These standards should cover, *inter alia*:

- appropriate definitions
- scope
- responsibilities of relevant stakeholders
- surveillance and monitoring programs, pre and post marketing
- procedures for marketing authorization, market approval and registration
- risk assessment for antimicrobial resistance arising from the use of antimicrobials in aquatic animals
- quality control and the assessment of the therapeutic efficacy and safety of antimicrobial agents in aquatic animals
- appropriate controls on distribution of antimicrobials used in aquaculture, including in international trade
- research needs.

Annex XXXIV (contd)

Appendix III (contd)

ANNEX I of the adopted terms of reference

4.2. Resistance to antimicrobials

Dr Kahn briefed the Commission on the work underway to address the issue of antimicrobial resistance as this relates to aquatic animals, including arrangements to convene an ad hoc group to review relevant information, including the current *Terrestrial Code* chapters, with the objective of developing text for inclusion in the *Aquatic Code*. The Commission reviewed the introductory text (Chapter 6.7. of the *Terrestrial Code*) and discussed the need for the ad hoc Group to also consider the issue of antibiotic treatment of wild caught ornamental fish that are transported from developing countries (mostly) to developed countries for sale. The current *Terrestrial Code* text refers to 'animal husbandry' and would exclude consideration of this practice. Nonetheless, the Commission felt that the introductory text was generally relevant to aquatic animals.

Accordingly, the Commission made some modifications to the *Terrestrial Code* text (including removing the word 'husbandry') for consistency with other chapters in the *Aquatic Code*.

The new draft chapter giving an introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.1.) is provided in Annex XXIII (I attached this annex as well) for Member comments.

ANNEX II of the adopted terms of reference

CHAPTER 6.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

Article 6.1.

Objective

The purpose of chapters (6.2., 6.3., 6.4. under study) is to provide methodologies for OIE Members to appropriately address the emergence or spread of resistant bacteria from the use of antimicrobial agents in *aquatic animals* and to contain antimicrobial resistance through controlling the use of antimicrobial agents.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating, controlling and preventing infectious *diseases* in *aquatic animals*. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is a priority.

The OIE recognises that antimicrobial resistance is a global public and *aquatic animal* health concern that is influenced by the usage of antimicrobial agents in humans, *aquatic animals* and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to prevent or minimise pressures for the selection of antimicrobial resistance factors in humans and *aquatic animals*. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Members in regard to risks in the animal sector.

The application of *risk assessment* measures should be based on international standards on microbiological *risk analysis* and supported by sound data and information when available. The methodologies provided in these chapters should be consulted as part of the standard approach to prevent and reduce antimicrobial resistance.

Annex XXXIV (contd)

Appendix IV

CHAPTER 6.1.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

Article 6.1.

Objective

The purpose of this section ~~chapters (6.2., 6.3., 6.4., 6.5. under study)~~ is to provide guidance ~~methodologies~~ for OIE Members to appropriately address the selection and dissemination ~~emergence or spread~~ of resistant micro-organisms and antimicrobial resistance determinants ~~bacteria~~ from the use of antimicrobial agents in *aquatic animals* ~~and to contain antimicrobial resistance through controlling the use of antimicrobial agents~~.

Antimicrobial agents are essential drugs for human and animal health and welfare. The OIE recognises the need for access to antimicrobial agents in veterinary medicine: antimicrobial agents are essential for treating~~,~~ controlling and preventing infectious *diseases* in *aquatic animals*. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is a priority.

The OIE recognises that antimicrobial resistance is a global public and ~~*aquatic*~~ animal health concern that is influenced by the usage of antimicrobial agents in humans, ~~*aquatic*~~ animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to address the ~~prevent or minimise~~ risk factors ~~pressures~~ for the selection and dissemination of antimicrobial resistance ~~factors in humans and *aquatic animals*~~. Arising from its mandate for the protection of animal health and food safety, the OIE developed these chapters to provide guidance to Members in regard to risks in the *aquatic animal* sector.

The application of *risk assessment* and *risk management* measures should be based on international standards on microbiological *risk analysis* and supported by sound data and information when available. The ~~methodologies~~ guidance provided in these chapters should be consulted as part of the standard approach to ~~prevent and~~ reduce the risk associated with the selection and dissemination of antimicrobial resistant~~ce~~ micro-organisms and antimicrobial resistance determinants.

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CHAPTER X

PRINCIPLES FOR RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

Article X.1.

Purpose

These recommendations provide guidance for the responsible and prudent use of *antimicrobial agents* in *aquatic animals*, with the aim of protecting both animal and human health. The *Competent Authorities* responsible for the registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Article X.2.

Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to reduce the risk associated with the selection and dissemination of antimicrobial resistant micro-organisms and antimicrobial resistance determinants in *aquatic animal* production to:

1. maintain the efficacy of *antimicrobial agents* and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety*;*
2. comply with the ethical obligation and economic need to keep *aquatic animals* in good health;
3. prevent or reduce the transfer of resistant micro-organisms or resistance determinants from *aquatic animals* to humans and *terrestrial animals*;
4. maintain the efficacy of *antimicrobial agents* used in human medicine and prolong the usefulness of the antimicrobials;
5. prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL);
6. protect consumer health by ensuring the safety of food of *aquatic animal* origin.

Article X.3.

Responsibilities of the regulatory authorities

The national regulatory authorities, which are responsible for granting marketing authorization for antimicrobials, have a significant role in specifying the terms the authorization and in providing the appropriate information to the *veterinarian* or other *aquatic animal* health professional through product labelling and/or by other means, in support of prudent use of veterinary antimicrobial drugs in *aquatic animals*.

It is the responsibility of regulatory authorities to develop up-to-date guidelines on data requirements for evaluation of veterinary antimicrobial drug applications.

National governments in cooperation with animal and public health professionals should adopt a proactive approach to promote prudent use of *antimicrobial agents* in *aquatic animals* as an element of a national strategy for the containment of antimicrobial resistance.

Other elements of the national strategy should include good animal husbandry practices, vaccination policies and development of animal health care at the farm level, and consultation with a *veterinarian* or other *aquatic animal* health professional, all of which should contribute to reduction of the prevalence of animal *disease* requiring antimicrobial treatment.

Regulatory authorities should expeditiously grant marketing authorizations when criteria of quality, efficacy, and safety are met.

The examination of dossiers/drug applications should include an assessment of the risks to both animals and humans resulting from the use of *antimicrobial agents* in *aquatic animals*. The evaluation should focus on each individual veterinary antimicrobial drug but take into consideration the class of antimicrobials to which the particular active principle belongs. The safety evaluation should include consideration of the potential impact of the proposed use in *aquatic animals* on human health, including the human health impact of antimicrobial resistance developing in food-borne micro-organisms found in *aquatic animals*. An assessment of the impact of the proposed use on the environment should be conducted.

The regulatory authority should ensure that advertising of antimicrobials complies with national legislation and marketing authorizations granted and discourage direct advertising to *aquatic animal* producers.

Information collected through pharmacovigilance programmes, including on lack of efficacy, should form part of the *Competent Authority*'s comprehensive strategy to minimize antimicrobial resistance.

Regulatory authorities should disseminate, to *veterinarians* or other *aquatic animal* health professionals, information on trends in antimicrobial resistance collected during surveillance programmes and should monitor the performance of susceptibility testing laboratories.

Article X.4.

Responsibilities of the veterinary pharmaceutical industry

The veterinary pharmaceutical industry has responsibilities for providing information requested by the authorities on the quality of antimicrobials. The responsibilities of the veterinary pharmaceutical industry covers pre- and post- marketing phases, manufacturing, sale, importation, labelling and advertising issues.

The veterinary pharmaceutical industry has the responsibility to provide the regulatory authorities with the information necessary to evaluate the amount of *antimicrobial agents* marketed. The veterinary pharmaceutical industry should ensure that the advertising of antimicrobials directly to the *aquatic animal* producer is discouraged.

Article X.5.

Responsibilities of wholesale and retail distributors

Distributors should ensure that their activities are in compliance with the national legislation.

Distributors should ensure that information for the appropriate use of the *antimicrobial agent* preparation should accompany all distributed products and should also be responsible for maintaining the product under the manufacturer recommendations.

Distributors should have responsibilities in collection and destruction of *antimicrobial agents* that have passed their expiry date.

Article X.6.

Responsibilities of veterinarians and other aquatic animal health professionals

Responsibilities of *veterinarians* or other *aquatic animal* health professionals include identifying, preventing and treating *aquatic animal diseases* as well as the promotion of sound animal husbandry methods, hygiene procedures, vaccination and other alternative strategies to minimise the need for antimicrobial use in *aquatic animals*.

Veterinarians or other *aquatic animal* health professionals should only recommend antimicrobials for *aquatic animals* under their care.

The responsibilities of *veterinarians* or other *aquatic animal* health professionals are to carry out a proper clinical examination of the *aquatic animal(s)* and make a diagnosis, based on the clinical examination, the results of laboratory tests and evaluation of environmental factors at the production site (e.g. water quality).

If therapy with an *antimicrobial agent* is deemed appropriate it should be initiated as soon as possible. The selection of the agent should be based on the knowledge and experience of the *veterinarian* or other *aquatic animal* health professional.

As soon as possible, susceptibility testing of the target micro-organism should be used to confirm the choice of treatment. Results of all susceptibility tests should be communicated to the relevant national authority.

The *veterinarian* or other *aquatic animal* health professional should indicate precisely to the *aquatic animal* producer the treatment regime, including the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of *aquatic animals* to be treated.

The *veterinarian* or other *aquatic animal* health professional may recommend in appropriate circumstances the use of *antimicrobial agents* extra-/off-label, in conformity with the relevant national legislation and any requirements of *importing countries*.

Records on the use of *antimicrobial agents* should be kept in conformity with the national legislation.

Veterinarians or other *aquatic animal* health professionals should periodically review farm records on the use of *antimicrobial agents* to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens.

Article X.7.

Responsibilities of aquatic animal producers

Aquatic animal producers should implement health programmes on their farms in order to promote *aquatic animal* health and food safety. This can be done through adequate planning of culture strategies to

maintain *aquatic animal* health through biosecurity programmes, vaccination strategies, maintenance of good water quality, etc.

Annex XXXIV (contd)

Appendix V (contd)

Aquatic animal producers should use *antimicrobial agents* only on the recommendation of a *veterinarian* or other *aquatic animal* health professional, and follow directions on the dosage, method of application, and withdrawal period.

Aquatic animal producers should ensure that *antimicrobial agents* are properly stored, handled, and disposed.

Aquatic animal producers should keep adequate records of *antimicrobial agents* used, bacteriological and susceptibility tests, and to make such records available to the *veterinarian* or other *aquatic animal* health professional.

Aquatic animal producers should inform the *veterinarian* or other *aquatic animal* health professional of recurrent *disease* problems and lack of efficacy of antimicrobial treatment regimes.

Article X.8.

Training of antimicrobial users

The training of users of antimicrobials should involve all the relevant organisations, such as regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, and veterinary professional organisations and other approved users such as *aquatic animal* owners.

Article X.9.

Research

To address the significant lack of information for numerous species of *aquatic animals*, relevant authorities and other stakeholders should encourage public- and industry-funded research.

Annex XXXIV (contd)

Appendix VI

DRAFT ADVISORY DOCUMENT:

RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN VETERINARY MEDICINE

1. Purpose

These recommendations provide guidance for the responsible and prudent use of *antimicrobial agents* in *aquatic animals*, with the aim of protecting both *animal* and human health. The *Competent Authorities* responsible for the registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Prudent use is principally determined by the outcome of the marketing authorisation procedure and by the implementation of specifications when antimicrobials are administered to *aquatic animals*.

2. Objectives of prudent use

Prudent use includes a set of practical measures and recommendations intended to reduce the risk associated with the selection and dissemination of antimicrobial resistant micro-organisms and antimicrobial resistance determinants in *aquatic animal* production to:

1. maintain the efficacy of *antimicrobial agents* and to ensure the rational use of antimicrobials in *aquatic animals* with the purpose of optimising both their efficacy and safety;

2. comply with the ethical obligation and economic need to keep *aquatic animals* in good health;

3. prevent or reduce the transfer of resistant micro-organisms or resistance determinants from *aquatic animals* to humans and *terrestrial animals*;

4. maintain the efficacy of *antimicrobial agents* used in human medicine and prolong the usefulness of the antimicrobials;

5. prevent the contamination of animal-derived food with antimicrobial residues that exceed the established maximum residue limit (MRL);

6. protect consumer health by ensuring the safety of food of *aquatic animals*.

3. Responsibilities of the regulatory authorities

A. Marketing authorisation

1. Marketing authorisation of antimicrobial agents

The national regulatory authorities are responsible for granting marketing authorisation. This should be done in accordance with the provisions of the *Aquatic Code* (under study). They have a significant role in specifying the terms of this authorisation and in providing the appropriate information to the *veterinarian* or other *aquatic animal* health professional.

2. Submission of data for the granting of the marketing authorisation

The pharmaceutical industry has to submit the data requested for the granting of the marketing authorisation. The marketing authorisation is granted only if the criteria of safety, quality and efficacy are met. An assessment of the potential risks and benefits to both *animals* and humans resulting from the use of *antimicrobial agents* in food-producing *aquatic animals* should be carried out. The evaluation should focus on each individual antimicrobial product but take into consideration the class of antimicrobials to which the particular active principle belongs. Guidance on usage should be provided for all dose ranges or different durations or different culture conditions (e.g. temperature, salinity, etc.) of treatment that are proposed.

3. Market approval

Regulatory authorities should attempt to expedite the market approval process of a new antimicrobial in order to address a specific need for the treatment of *disease*.

4. Registration procedures

Countries lacking the necessary resources to implement an efficient registration procedure for veterinary medicinal products (VMPs), and whose supply principally depends on imports from foreign countries, should undertake the following measures:

a) check the efficacy of administrative controls on the import of these VMPs, including to ensure that the product has an accurate label;

b) check the validity of the registration procedures of the exporting and manufacturing country as appropriate;

c) develop the necessary technical co-operation with experienced authorities to check the quality of imported VMPs as well as the validity of the recommended conditions of use.

Regulatory authorities of *importing countries* should request the pharmaceutical industry to provide quality certificates prepared by the *Competent Authority* of the *exporting* and manufacturing *country* as appropriate. All countries should make every effort to actively combat the manufacture, advertisement, trade, distribution and use of unlicensed and counterfeit bulk active pharmaceutical ingredients and products.

5. Quality control of antimicrobial agents

Quality controls should be performed:

a) in compliance with the provisions of good manufacturing practices;

b) to ensure that all *antimicrobial agents* are manufactured to the appropriate quality and purity;

c) to ensure that analysis specifications of *antimicrobial agents* used as active ingredients comply with the provisions of approved monographs;

d) to ensure that the quality and concentration (stability) of *antimicrobial agents* in the marketed dosage form(s) are maintained until the expiry date, established under the recommended storage conditions;

e) to ensure the adequate stability of antimicrobials when mixed with feed or administered in water to provide appropriate bioavailability.

6. Assessment of therapeutic efficacy

a) Preclinical trials

i) Preclinical trials should:

- establish the range of activity of *antimicrobial agents* on both target and non target micro-organisms;
- assess the ability of the *antimicrobial agent* to select for resistance *in vitro* and *in vivo*, taking into consideration pre-existing resistant strains;
- establish an appropriate dosage regimen necessary to ensure the therapeutic efficacy of the *antimicrobial agent* and limit the selection of antimicrobial resistance;

ii) The activity of *antimicrobial agents* towards the targeted micro-organism can be established by pharmacodynamics. The following criteria should be taken into account:

- spectrum of activity and mode of action;
- minimum inhibitory and bactericidal concentrations;
- time- or concentration-dependent activity or co-dependency;
- activity at the site of *infection*.

iii) The dosage regimens allowing maintenance of effective antimicrobial levels can be established by pharmacokinetics. The following criteria should be taken into account:

- bio-availability according to the route of administration;
- concentration of the antimicrobial at the site of infection and its distribution in the treated animal;
- metabolism that may lead to the inactivation of antimicrobials;
- excretion routes.

b) Clinical trials

Clinical trials should be performed to confirm the validity of the claimed therapeutic indications and dosage regimens established during the preclinical phase. The following criteria should be taken into account:

i) diversity of the clinical cases encountered when performing multi-centre trials;

ii) compliance of protocols with good clinical practice, such as Veterinary International Cooperation on Harmonisation (VICH) guidelines;

iii) eligibility of studied clinical cases, based on appropriate criteria of clinical and bacteriological diagnoses;

iv) parameters for qualitatively and quantitatively assessing the efficacy of the treatment.

Annex XXXIV (contd)

Appendix VI (contd)

7. Assessment of the potential of antimicrobials to select for resistance

Other studies may be requested in support of the assessment of the potential of antimicrobials to select for resistance. The party applying for market authorisation should, where possible, supply data derived in target animal species under the intended conditions of use.

For this the following may be considered:

a) the route and level of human exposure to food-borne or other resistant organisms;

b) the degree of cross-resistance within the class of antimicrobials and between classes of antimicrobials;

c) the pre-existing level of resistance in the pathogens of human health concern (baseline determination) in both *animals* and humans.

8. Establishment of acceptable daily intake, maximum residue level and withdrawal periods for antimicrobial compounds

a) When setting the acceptable daily intake (ADI) and MRL for an antimicrobial substance, the safety evaluation should also include the potential biological effects on the intestinal flora of humans.

b) The establishment of an ADI for each antimicrobial agent, and an MRL for each animal-derived food, should be undertaken.

c) For each VMP containing antimicrobial agents, withdrawal periods should be established in order to produce food in compliance with the MRL, taking into account:

i) the MRL established for the *antimicrobial agent* under consideration;

ii) the composition of the product and the pharmaceutical form;

iii) the target *aquatic animal* species;

iv) the dosage regimen and the duration of treatment or different culture conditions (e.g. temperature, salinity, etc.);

v) the route of administration.

d) The applicant should provide methods for regulatory testing of residues in food.

9. Protection of the environment

An assessment of the impact of the proposed antimicrobial use on the environment should be conducted. Efforts should be made to ensure that the environmental impact of antimicrobial use is restricted to a minimum.

10. Establishment of a summary of product characteristics for each *antimicrobial agent*

The summary of product characteristics contains the information necessary for the appropriate use of *antimicrobial agents* (veterinary antimicrobial product) and constitutes the official reference for their labelling and package insert. This summary should contain the following items:

a) active ingredient and class;

b) pharmacological properties;

c) any potential adverse effects;

d) target animal species and age or production category;

e) therapeutic indications;

f) target micro-organisms;

g) dosage and administration route;

h) withdrawal periods;

i) incompatibilities;

j) shelf-life;

k) operator safety;

l) particular precautions before use;

m) particular precautions for the proper disposal of un-used or expired products;

n) information on conditions of use relevant to the potential for selection of resistance.

11. Post-marketing antimicrobial surveillance

The information collected through existing pharmacovigilance programmes, including lack of efficacy, should form part of the comprehensive strategy to minimise antimicrobial resistance.

This information will be important to broader surveillance programs.

Specific surveillance to assess the impact of the use of a specific antimicrobial may be implemented after the granting of the marketing authorisation. The surveillance programme should evaluate not only resistance development in target animal pathogens, but also in food-borne pathogens. Such surveillance will also contribute to general epidemiological surveillance of antimicrobial resistance.

12. Supply and administration of the antimicrobial agents used in veterinary medicine

The relevant authorities should ensure that all the *antimicrobial agents* used in *aquatic animals* are:

a) prescribed by a veterinarian or other aquatic animal health professional or other authorised person;

b) supplied only through licensed/authorised distribution systems;

c) administered to *aquatic animals* by a *veterinarian* or under the supervision of a *veterinarian or other aquatic animal health professional* or by other authorised persons.

The relevant authorities should develop effective procedures for the safe collection and destruction of unused or expired *antimicrobial agents*.

13. Control of advertising

All advertising of antimicrobials should be controlled by a code of advertising standards, and the relevant authorities must ensure that the advertising of antimicrobial products complies with national regulations and the marketing authorisation granted, in particular regarding the content of the summary of product characteristics;

The veterinary pharmaceutical industry should ensure that the advertising of antimicrobials directly to the food animal producer is discouraged.

B. Surveillance and monitoring programs

In order to maintain the efficacy and safety of *antimicrobial agents* regulatory authorities should implement monitoring programs that include levels of resistance of target animal pathogens and food born pathogens and quantities of antimicrobials used.

The surveillance of animal micro-organisms resistant to *antimicrobial agents* is essential. It is critical to develop appropriate methods and interpretive criteria for aquatic micro-organisms in order that baseline data can be established and trends identified.

Regulatory authorities should implement procedures by which the data on the patterns and trends in antimicrobial resistance in target organisms can be collected. These data may be collected in national during surveillance programmes or from the records submitted by individual *veterinarians* or other *aquatic animal* health professionals. They should develop procedures by which these data can be disseminated to *veterinarians* or other *aquatic animal* health professionals.

Regulatory authorities should ensure regular monitoring of the performance of laboratories involved in antimicrobial susceptibility testing.

C. Training of antimicrobial users

The training of users of antimicrobials should involve all the relevant organisations, such as regulatory authorities, pharmaceutical industry, veterinary schools, research institutes, veterinary professional organisations and other approved users such as food-animal owners.

This training should focus on:

a) information on aquatic *disease* prevention and management strategies to reduce the need to use antimicrobial drugs;

b) the importance of relevant information including results of antimicrobial agent susceptibility testing in enabling the veterinarian or other aquatic animal health professional to use antimicrobial agents prudently;

c) the ability of antimicrobial agents to select for resistant micro-organisms and antimicrobial resistance determinants in aquatic animals that may contribute to health problems in those aquatic animals or humans and terrestrial animals;

d) the need to observe responsible use recommendations for the use of antimicrobial agents in animal husbandry in agreement with the provisions of the marketing authorisations.

D. Research

To address the significant lack of information for the numerous species of *aquatic animals* the relevant authorities should encourage public- and industry-funded research and efforts that aim to:

a) improve knowledge to optimize management practices, particularly for new species under culture to reduce the need for the use of antimicrobial agents;

b) perform a comparative cost benefit analysis of husbandry and therapeutic based approaches to disease control;

c) develop standardised methods for culturing micro-organisms and determining microbial susceptibility, appropriate for identification of resistance in relevant micro-organisms;

d) develop breakpoints and interpretive criteria to optimize the use of antimicrobial therapy;

e) encourage research to develop sufficient capacity for clinical field trials;

f) optimize to dose regimens and their efficacy by increasing the amount and utilization of pharmacokinetic and pharmacodynamic data and information on the use of antimicrobials in aquatic animals;

g) to develop information to support extrapolation of appropriate dose regimens and withdrawal periods across multiple aquatic animal species;

h) develop practical models for applying the concept of risk analysis to assess and address the potential public health impact associated with the use of antimicrobial agents in aquaculture.

4. Responsibilities of the veterinary pharmaceutical industry

1. Marketing authorisation of antimicrobial agents

The veterinary pharmaceutical industry has responsibilities to:

a) supply all the information requested by the national regulatory authorities;

b) guarantee the quality of this information in compliance with the provisions of good manufacturing, laboratory and clinical practices;

c) implement a pharmacovigilance programme and on request, specific surveillance for bacterial susceptibility and resistance.

2. Marketing and export of antimicrobial agents

For the marketing and export of *antimicrobial agents*

a) only licensed and officially approved antimicrobial agents should be sold and supplied, and then only through licensed/authorised distribution systems;

b) the pharmaceutical industry should provide quality certificates prepared by the Competent Authority of the exporting and/or manufacturing countries to the i*mporting country*;

c) ensure that the exported antimicrobial agents contain the approved labelling;

d) the national regulatory authority should be provided with the information necessary to evaluate the amount of *antimicrobial agents* marketed.

3. Advertising

The veterinary pharmaceutical industry should:

a) disseminate information in compliance with the provisions of the granted authorisation;

b) ensure that the advertising of antimicrobials directly to the aquatic animal producer is discouraged.

4. Training

The veterinary pharmaceutical industry should participate in training programmes as defined in 3C.

5. Research

The veterinary pharmaceutical industry should contribute to research as defined in.3.D.

5. Responsibilities of wholesale and retail distributors

1. Retailers distributing *antimicrobial agents* should only do so on the prescription of a veterinarian or other aquatic animal health professional or other suitably trained person authorised in accordance with the national legislation, and all products and packaging should be appropriately labelled.

2. The recommendations on the responsible use of antimicrobials should be reinforced by retail distributors who should keep detailed records of:

a) date of supply;

b) name of prescriber;

c) name of user;

d) name of product;

e) batch number;

f) quantity supplied.

3. Distributors should be responsible for safe collection and destruction of unused or out of date antimicrobial agents.

4. Distributors should ensure that information for the appropriate use of the antimicrobial agent preparation should accompany all distributed retailed products.

5. Distributors should also be involved in training programmes on the responsible use of antimicrobials, as defined in 3.C.

6. Responsibilities of veterinarians or other aquatic animal health professionals

The *veterinarians* or other *aquatic animal* health professional's responsibilities include identifying, preventing and treating *aquatic animal diseases*. The promotion of sound animal husbandry methods, hygiene procedures, vaccination and other alternative strategies to minimise the need for antimicrobial use in aquatic *animals*.

Veterinarians or other *aquatic animal* health professionals should only recommend antimicrobials for *aquatic animals* under their care.

1. Use of antimicrobial agents

Prior to a recommendation on the use of an antimicrobial, a veterinarian or other aquatic animal health professional should make a proper clinical diagnosis that should include an assessment of the relative importance of micro-organisms in the aetiopathogenesis of the disease and evaluation of environmental factors (e.g. water quality) at the production site.

The responsibilities of *veterinarians* or other aquatic animal health professionals are to carry out a proper clinical examination of the *aquatic animal(s)*.

If therapy with *antimicrobial agent* is deemed appropriate it should be initiated as soon as possible.

Initial choice may be made on the basis of clinical findings and the selection of the agent should be based on the *veterinarian* or other *aquatic animal* health professional's knowledge and experience.

2. Choosing an antimicrobial agent

As soon as possible clinical diagnosis should be confirmed by laboratory examination and treatment choice selection should be re-evaluated on the basis of data generated in susceptibility tests.

a) The expected efficacy of the treatment is based on:

i) the clinical experience of the *veterinarian* or other *aquatic animal* health professional;

ii) the activity towards the target bacterium;

iii) the appropriate route of administration;

iv) the epidemiological history of the rearing unit, particularly in relation to the antimicrobial resistance profiles of the pathogens involved.

On certain occasions, a group of *aquatic animals* that may have been exposed to pathogens may need to be treated without recourse to an accurate diagnosis and antimicrobial susceptibility testing to prevent the development of clinical *disease* and for reasons of *animal welfare* but there should be strong grounds for believing that the *animals* are thus predisposed.

b) Use of combinations of antimicrobials should only be initiated when there are scientific data indicating synergy between them.

Annex XXXIV (contd)

Appendix VI (contd)

3. Appropriate use of the antimicrobial chosen

A prescription for *antimicrobial agents* should indicate precisely the treatment regime, the dose, the treatment intervals, the duration of the treatment, the withdrawal period and the amount of drug to be delivered, depending on the dosage and the number of *aquatic animals* to be treated.

The extra-/off- label use of a veterinary antimicrobial drug may be permitted in appropriate circumstances and should be in agreement with the national legislation in force, and that of the importing country if applicable, including the withdrawal periods to be used. It is the *veterinarian* or other *aquatic animal* health professional's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, the duration of the treatment and the appropriate withdrawal period.

4. Recording

Records on veterinary antimicrobial drugs should be kept in conformity with the national legislation. Information records should include the following:

a) quantities of medication used and mode of administration;

b) a list of all medicines supplied to each aquatic animal holding;

c) a list of medicine withdrawal period;

d) a record of antimicrobial susceptibility testing. Evidence of the emergence of resistance should be reported to the appropriate regulatory authorities;

e) comments concerning the response of the *aquatic animals* to medication;

f) the results of investigation of adverse reactions to antimicrobial treatment, including lack of response due to antimicrobial resistance. Suspected adverse reactions should be reported to the appropriate regulatory authorities.

Veterinarians or other *aquatic animal* health professionals should also periodically review farm records on the use of *antimicrobial agents* to ensure compliance with their directions and use these records to evaluate the efficacy of treatment regimens.

5. Directions for use

All medicines supplied by a *veterinarian* or other *aquatic animal* health professional should be accompanied with adequate directions for use.

6. Training

Veterinary or *aquatic animal* health professional organisations should participate in the training programmes as defined in Article X.3.C. It is recommended that veterinary or *aquatic animal* health professional organisations develop for their members more specific guidelines for responsible use of *antimicrobial agents*.

7. Responsibilities of food-animal producers

1. *Aquatic animal* producers with the assistance of a *veterinarian* or *aquatic animal* health professional are responsible for implementing health and welfare programmes on their farms (good farming practice) in order to promote animal health and food safety.

2. Aquatic animal producers should:

   a) draw up a health plan with the attending *veterinarian* or *aquatic animal* health professional or producer group that outlines preventative measures (biosecurity programs, vaccination strategy, water quality);

   b) use antimicrobial agents only on prescription, and according to the provisions of the specific recommendation of the veterinarian or other aquatic animal health professional as recognized by the national authority;

   c) use antimicrobial agents in the species, for the uses and at the dosages on the approved/registered labels and in accordance with product label instructions or the advice of a veterinarian or aquatic animal health professional familiar with the aquatic animals and the production site;

   d) comply with the storage conditions of antimicrobials in the rearing unit, according to the provisions of the leaflet and package insert;

   e) address hygienic conditions regarding contacts between people (veterinarians or aquatic animal health professionals, breeders, owners, children) and the aquatic animals treated;

   f) comply with the recommended withdrawal periods to ensure that residue levels in animal-derived food comply with relevant national and international regulations;

   g) dispose of surplus antimicrobials under safe conditions for the environment; medicines should only be used within the expiry date, for the condition for which they were prescribed and, if possible, in consultation with a veterinarian or aquatic animal health professional or producer group;

   h) laboratory records of bacteriological and susceptibility tests should be kept either by the producer or by the *veterinarian* or other *aquatic animal* health professional; these data should be made available to the *veterinarian* or aquatic *animal health* professional responsible for treating the *aquatic animals*;

   i) keep adequate records of all medicines used, including the following:

      i) name of the product/active substance and batch number;

      ii) name of prescriber and/or the supplier;

      iii) date of administration;

      iv) *identification of the animal* or group of *animals* to which the *antimicrobial agent* was administered;

v) clinical conditions treated;

vi) dosage;

vii) withdrawal periods;

viii) result of laboratory tests;

ix) effectiveness of therapy;

j) inform the responsible *veterinarian* or other *aquatic animal* health professional of recurrent aquatic *animal disease* problems.

Annex XXXV

FAO UPDATE

1. Aquatic Animal Biosecurity in Southern Africa

- Aquatic Biosecurity Framework for Southern Africa: a Scoping Meeting of Regional Fisheries and Veterinary Authorities. 13-14 October 2009, Thule Hotel, Windhoek, Namibia, hosted by the Ministry of Fisheries and Marine Resources (MFMR), Namibia with the World Organisation for Animal Health (OIE) as collaborator.

- FAO/OIE/MFMR Training/Workshop on Aquatic Biosecurity, 15-18 October 2009, Kamutjonga Inland Fisheries Institute (KIFI), Divundu, Kavango Region, Namibia.

The scoping meeting was aimed at initiating a process towards developing a harmonized aquatic biosecurity framework for Southern Africa and to evaluate the needs for implementing such a framework. Presentations delivered during the scoping meeting focused on aquatic biosecurity and the challenges faced by the southern African region. The need for a regional approach to aquatic biosecurity was widely recognized and plan for concerted action proposed. A Windhoek declaration on an aquatic biosecurity framework for southern Africa outlining the concerns and commitment to developing and implementing an aquatic biosecurity framework was discussed and agreed upon by the 32 participating delegates from 10 countries. A major outcome was the "Windhoek Declaration on an Aquatic Biosecurity Framework for Southern Africa".

Thirty seven delegates representing 9 countries (Angola, Botswana, Kenya, Mozambique, Namibia, South Africa, Uganda, Zambia, Zimbabwe) including FAO staff and consultants, participated in the training/workshop. The training/workshop provided a short targeted training on aquatic animal biosecurity, including an overview of aquaculture and aquatic animal health management, emergency response and contingency planning and aquatic epidemiology delivered by FAO staff and consultants. A major outcome was further capacity building on aquatic biosecurity in the region and further input to the document "Strategy for the development of an aquatic biosecurity framework for the southern African region: a programme of capacity building activities".

A number of immediate follow-up activities include the following:

(i) finalise the report of the scoping meeting;

(ii) finalise the documents on strategy and regional TCP; (iii) continue to raise awareness of aquatic biosecurity in-house and within the Crisis Management Center and EMPRES;

(iv) work closely with interested partners such as OIE, NEPAD, WFC, SADC, etc. in moving further efforts to build capacity on aquatic biosecurity in the region.

Windhoek Declaration on an Aquatic Biosecurity Framework for Southern Africa

On 13 14 October 2009, 32 participants from 8 countries1 of the Southern Africa Development Community (SADC) and 2 countries of the East Africa Community (EAC)2 representing fisheries, veterinary agencies, universities3, together with 11 resource persons, representatives from several regional and international organizations, and a veterinary institute4, participated in a High Level Scoping Meeting of Regional Fisheries and Veterinary Authorities towards developing an Aquatic Biosecurity Framework for Southern Africa.

The participants affirmed the importance of aquaculture and fisheries as significant opportunities for economic growth, poverty reduction and improved food security in Africa, but reiterated that better management, policies, capacity, investment and a regionally harmonized approach to biosecurity5 risk management, are needed to support responsible development. The East and Southern Africa region's considerable aquatic resources, including major river systems such as the Zambezi and Nile, present an ideal opportunity for the Africa region's aquaculture and fisheries sector to contribute to the continent's own food and nutritional security and well being, poverty reduction as well as economic development. Under appropriate management these ideals can be realized with minimum impact on the environment while maximising social benefit.

The participants expressed concern about the alarming spread of the serious fish disease, Epizootic Ulcerative Syndrome (EUS), in the Zambezi River system, since late 2006, and the significant social and economic impacts of the disease, particularly among poor and vulnerable communities that are dependant on these aquatic resources for food and income.

The outbreak of EUS in Southern Africa has highlighted a serious lapse in regional aquatic biosecurity management, which now requires urgent and concerted action for improvement. Improvements are needed in the development of appropriate, effective policy and regulatory frameworks; risk management strategies as well as their efficient implementation at community, national and regional levels. Intra regional trade and shared waters mean that a coordinated, cooperative approach to aquatic biosecurity is essential. Harmonization of national policies and regulatory frameworks on aquatic biosecurity is paramount. Impacts on livelihoods of fishers and farmers caused by EUS need to be better understood, so that practical coping strategies can be identified and supported.

The participants expressed serious concern about the risk of EUS spreading from the Zambezi River system to other major river systems in Africa, such as the Nile, and the potential threat to the livelihoods of millions of people dependent of river resources. They also expressed concern over the economic impacts, including risks to domestic food supplies and valuable export industries such as the Nile perch. Concerted preventative and awareness raising measures are required by countries of the region, with assistance and cooperation from the international community.

The participants recognized and appreciated the work of the FAO since the first appearance of EUS in the Zambezi River, contributing to national capacity building in disease diagnostics, surveillance, risk assessment and primary aquatic health management in Southern African countries. The contributions by OIE on improving veterinary capacities in the regional countries were also recognized. Such cooperation should continue to be strengthened in support of capacity building for implementation of improved aquatic biosecurity measures for the region.

The participants unanimously agreed that biosecurity is of prime importance to fisheries and aquaculture development, particularly in shared watersheds like the Zambezi River basin and others in the region. It safeguards animal health, protects biodiversity, promotes environmental sustainability and enhances food safety. The livelihoods of many people, including some of the most vulnerable in the region, depend on fisheries and aquaculture. The Windhoek meeting participants have prepared a framework for action. This framework now requires political will and resources for implementation.

The participants agreed that the primary responsibility for actions to address this emerging situation rests with the governments of the region. However, FAO, in partnership with OIE and its Regional Animal Health Centers in Africa, and other agencies such as the WorldFish Center and the National Veterinary Institute of Norway, had been requested to support a regional cooperative programme to assist in implementing the regional aquatic biosecurity programme, and take preventive measures to reduce risks to fisheries, aquaculture and livelihoods from further spread of this fish disease to other river systems in Africa.

The participants further recommended that the outcome of this meeting and the current status of the EUS pandemic in Zambezi River system be communicated to relevant Secretariats of SADC and NEPAD responsible for fisheries and/or food. The meeting requested FAO to facilitate presentation of the declaration to the upcoming Fisheries Ministerial Meeting of the Southern African Development Cooperation (SADC) to be held in November 2009 in Windhoek, Namibia. The Honorable Minister of Fisheries of Uganda would also present the outcome to the next meeting of the Council of Ministers for Lake Victoria Fisheries Organization to be held on 5th 6th November in Nairobi, Kenya to raise profile and consensus on actions to improve aquatic biosecurity in Africa.

The participants thanked the Government of Namibia for hosting the meeting and declared their commitment to continue to cooperate in development and implementation of aquatic biosecurity framework, including a regional emergency action plan for Southern Africa.

1. Angola, Botswana, Malawi, Mozambique, Namibia, South Africa, Zambia and Zimbabwe.
2. Kenya, Uganda
3. University of Nairobi (Kenya), Makerere University (Uganda) and University of Zambia
4. FAO, OIE, Norwegian Veterinary Institute, WorldFish Center
5. Biosecurity is strategic and integrated approach that encompasses policy and regulatory framework for analyzing and managing relevant risks to human, animal and plant life and health, and associated risks to the environment.

2. Global Conference on Aquaculture 2010

In 1976, FAO held the first ever global conference on aquaculture, the Kyoto Conference, which explored opportunities for aquaculture development and triggered the recognition of aquaculture as a significant food production sector. Ten years after the millennium conference, with aquaculture now providing nearly 50 percent of global food fish supplies, FAO in partnership with NACA and the Thai Department of Fisheries, are organizing the Global Conference on Aquaculture 2010, to evaluate where the sector stands today and face the challenges and opportunities. Plenary lectures together with six regional reviews and one global synthesis will set the scene for six thematic sessions and associated expert panel discussions on key aspects of aquaculture development and management in the coming decades. The conference will provide a global forum to build consensus to advance sustainable aquaculture development and contribute to the Millennium Development Goals. Have your say on the future of aquaculture development: Join us in Bangkok from 9-12 June 2010. This conference will provide a global forum for national, regional and international colleagues and government representatives to appreciate the current state of aquaculture development, to discuss how technology and resources, science, governance, networking, knowledge, manpower and institutional strengthening can contribute to finding solutions to the challenges the sector faces and will face in the future. The details available at www.aqua-conference2010.org

FAO would like to make a formal request to OIE for participation and contribution to various thematic reviews. Prof. Barry Hill is already contributing to the Thematic Review on Biosecurity.

3. FAO Technical Guidelines on Aquaculture Certification

FAO is currently developing Technical Guidelines on Aquaculture Certification.

On the recommendation of the FAO Committee on Fisheries (COFI) at its twenty-eighth session, and the COFI Sub-Committee on Aquaculture at its fourth session, the Director-General of FAO, Mr Jacques Diouf, convened the Technical Consultation on the Guidelines on Aquaculture Certification (Rome, Italy, 15-19 February 2010). The Consultation was attended by 99 participants from 47 Members of FAO and by observers, from an intergovernmental and two non-governmental organizations. The Consultation expressed appreciation for the important leading role of FAO in aquaculture certification as mandated by COFI Sub-Committee on Aquaculture and encouraged continued collaboration with its Members and relevant stakeholders. The special needs and requirements of small-scale producers in developing countries

and countries in transition in participating in aquaculture certification schemes were highlighted in terms of technical and financial assistance as well as capacity building and infrastructure development. These required greater attention in the future work of FAO in this field. The Consultation strongly noted that the draft guidelines incorporated aspects relating to special considerations for implementation which take into account the special needs of developing countries and small island developing countries in the areas of financial and technical assistance, technology transfer, capacity building and training on aquaculture certification including possible support to the costs of accreditation and certification.

The Consultation build broad consensus on the draft Technical Guidelines and requested FAO to present the Guidelines to the 5th Session of FAO Committee on Fisheries Sub-Committee on Aquaculture to be held in Bangkok, Thailand, following the Global Conference on Aquaculture 2010, for international agreement.

The important issue for OIE is that Aquatic Animal Health and Welfare is considered as one of the four Minimum Substantive Criteria for Aquaculture Certification. In this respect, the guidelines recognise OIE as the normative reference for compliance with the aquatic animal health and welfare standards and issues.

Considering the importance of these guidelines for global aquaculture and the fact that both Global Conference and the 5th Session of COFI Sub-Committee is scheduled to be held in Bangkok, back-to-back, FAO would like to make a formal request to OIE for taking part in both events, representing OIE.

Annex XXXVI

AQUATIC ANIMALS COMMISSION WORK PLAN FOR 2010/2011

Aquatic Animal Health Code
• Ongoing review of the list of diseases • Review emerging diseases
• Prepare text for disease chapters for gaining and regaining freedom for compartments
• Harmonise horizontal chapters with those in the *Terrestrial Code*
• Develop disease specific surveillance model chapters (1 fish, 1 mollusc, 1 crustacean)
• Identify commodities that can be considered safe for trade and be included in the *Aquatic Code*
• Develop chapters on antimicrobials in aquatic animals
• Prepare chapter on humane killing for disease control purposes
• Antimicrobial resistance in the field of aquatic animals – contribute to OIE work
• Develop chapter on Evaluation of Competent Authorities
Manual of Diagnostic Tests for Aquatic Animals
• Revise template for disease-specific chapters
Meetings
• Make presentations on the activities of the Aquatic Animals Commission at the conferences of the OIE Regional Commissions
• Be proactive in presenting the activities of the Aquatic Animals Commission at scientific conferences
• Contribute to the 2nd OIE Global Conference on 'Contribution of Aquatic Animal Health to Global Food Security'
• Contribute to OIE Aquatic Animal Focal Point training workshops
Other issues
• Discussion paper on zoonotic diseases of aquatic animals
• Keep the Commission's web pages up to date
• Consider new candidates for OIE Reference Laboratories for listed diseases
• Provide input into the PVS to ensure its applicability to the evaluation of aquatic animal health systems
• Contribute to FAO/OIE Regional Aquatic Biosecurity Framework Project for Africa