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EUROPEAN UNION

Bruxelles, le
SANCO D1/SC/ah/ D(2011) 33168

Subject: **EU comments to the report of the meeting of the OIE Aquatic Animal Health Code Commission – 11-15 October 2010**

Dear Director General,

Please find attached an annex indicating the European Union comments on the report of the Aquatic Animal Health Commission.

I trust you will find this useful.

Thank you for your continued cooperation.

Yours sincerely,

Dr. Endre Kardeván
Chief Veterinary Officer
Hungary

Bernard Van Goethem
Director Animal Health
DG SANCO, European Commission

Encl: 1

cc: All Directors / Chief Veterinary Officers of the EU and Croatia, Iceland, Liechtenstein, Norway, Switzerland and Turkey, Ulrich Weigl (DG TRADE), Jean Weissenberger (DG MARE)

Dr. B. Vallat
Directeur Général OIE
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ANNEX

Organisation Mondiale de la Santé Animale | World Organisation for Animal Health | Organización Mundial de Sanidad Animal

Original: English
October 2010

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

Paris, 11–15 October 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 11 to 15 October 2010.

Details of participants and the adopted agenda are given at Annexes I and II.

The Aquatic Animals Commission reviewed the documents identified in the agenda, addressing comments that Members had submitted by September 10, 2010 and amended texts in the OIE *Aquatic Animal Health Code* (the *Aquatic Code*) where appropriate. The outcome of the Commission's work is presented at Annexes III to XX in this report. Amendments made during the October 2010 meeting are shown as double underlined text, with deleted text in ~~strikeout.~~.

The table below summarises the texts presented in the Annexes. Part I: Annexes III to XV(B) are presented for Members' comment; Part II: Annexes XVI to XX are presented for Members' information.

Members should note that, unless stated otherwise, texts submitted for comment may be proposed for adoption at the 79th OIE General Session. Depending on the comments received on each text, the Code Commission will identify the texts proposed for adoption in May 2011 in the report of its February 2011 meeting.

The Aquatic Animals Commission strongly encourages Members to participate in the development of the OIE's international standards by submitting comments on this report. It would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Proposed deletions should be indicated in '~~strikeout~~' and proposed additions with 'double underline'. Members **should not use the automatic 'track-change' function** provided by word processing software as such changes are lost in the process of collating Members' submissions into the Commission's working documents.

Comments on this report must reach OIE Headquarters by **14 January 2011** to be considered at the 14–18 February 2011 meeting of the Aquatic Animals Commission. Comments should be sent to the International Trade Department at: trade.dept@oie.int.

Part I: Texts for Members' comment	**Annex number**
Principles for Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (new Chapter 6.3)	Annex III
Disinfection of salmonid eggs (Article 10.4.13., Article 10.5.13. and Article 10.9.13.)	Annex IV
Quality of Aquatic Animal Health Services (Chapter 3.1.)	Annex V
Criteria to assess safety of aquatic animal commodities (Chapter 5.3.)	Annex VI
Control of hazards in aquatic animal feeds (Chapter 6.1.)	Annex VII
Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.2.)	Annex VIII
Welfare of farmed fish during transport (Chapter 7.2.)	Annex IX
Welfare aspects of stunning and killing of farmed fish for human consumption (Chapter 7.3.)	Annex X
Taura syndrome (Chapter 9.5.)	Annex XI
Epizootic haematopoietic necrosis (Chapter 10.1.)	Annex XII
Listed aquatic commodities in Articles X.X.3. and X.X.11. (amphibians and fish) / X.X.12. (crustaceans and molluscs) (all disease chapters except epizootic haematopoietic necrosis, Taura syndrome, *B. ostreae*)	Annex XIII
Killing of farmed fish for disease control purposes (new Chapter 7.4.)	Annex XIV
Aquatic Manual - chapter on amphibian disease (new)	Annex XV(A)
Aquatic Manual - text on disinfection of eggs	Annex XV(B)
Part III: Annexes for Members' information	**Annex number**
Aquatic Animals Commission Work Plan 2010/2011	Annex XVI
Report of the *ad hoc* Group on Aquatic Animal Health Surveillance	Annex XVII
Report of the *ad hoc* Group on Safety of Products Derived from Aquatic Animals	Annex XVIII
Report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals	Annex XIX
PVS Tool. Application to Aquatic Animal Health Services	Annex XX

Meeting with Dr Vallat

Dr Vallat, Director General of the OIE joined the Commission meeting and, after thanking members for their ongoing support for the OIE, opened a discussion on several key points in the agenda, as follows.

The OIE has adopted its 5th Strategic Plan (2011-2016), which, *inter alia*, places a stronger emphasis on aquatic animal health and production as a major contribution to food security and alleviating global poverty. At the next

meeting of the OIE Council (February 2011) modifications to the agenda of the General Session 2011 will be discussed and, once agreed, conveyed to the Presidents of the four specialised commissions.

Dr Vallat was pleased to inform the Commission that the OIE has secured resources to undertake a second global round of training for OIE national Focal Points. Noting that 131 OIE Members have nominated Aquatic Animal Focal points, Dr Vallat thanked members of the Commission for their participation in these seminars and invited them to make suggestions for improvement of the seminar format. Dr Vallat considered that in the next round of seminars, the emphasis should be on exchange of ideas and brainstorming on the challenges and tools for improving Members' implementation of the OIE standards.

Dr Vallat noted that the Commission had discussed the proposed publication by the FAO Committee on Fisheries, Sub-Committee on Aquaculture (COFI/SCA) concerning the technical guidelines on aquaculture certification. Health certification of aquatic animals and their products is the subject of Chapters 5.2. and 5.10.of the *Aquatic Animal Health Code* and these OIE standards have been the subject of ongoing revision and harmonisation with the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*). Dr Vallat expressed a need for a common vision between the FAO and the OIE, given the importance of health certification for international trade. Dr Kahn expressed concern about the statement in the FAO presentation that 'either public or private agencies could provide certification', in the context that the FAO draft Guidelines cover animal health and food safety (amongst other topics). OIE policy is that certification as to animal health and food safety is the sole responsibility of government and that this certification should follow the international standards of the OIE and the Codex Alimentarius Commission (CAC), which are the reference organisations for the World Trade Organization under the WTO SPS Agreement. While private organisations may provide certification on some topics, the OIE does not see a role for private organisations in certifying the health and safety of food. Given that there is already confusion in some countries about official and private standards and certification requirements, Dr Kahn considered that the fundamental role of governments in guaranteeing health and safety should be clarified in the FAO Guidelines.

Dr Reantaso, representing FAO at the Commission meeting, took note of these concerns and undertook to provide detailed comments in response to the OIE and the Commission. The Commission considered that the OIE should provide official input to the FAO before the FAO finalises the Guidelines and that the OIE should be represented at the January 2011 meeting of COFI. The Commission also agreed that it would be important to have the OIE as an observer organisation of COFI. The Commission urged OIE Members to take steps to involve themselves in the consultative process organised by the FAO with the objective of ensuring that the FAO guidelines respect the central role of governments in certifying animal health and food safety and the need for harmonisation with international standards of the OIE and CAC.

Dr Hill informed Dr Vallat of the progress of the Commission's work in the important areas of safe commodities, antimicrobial resistance, disease surveillance, and animal welfare. Dr Vallat was pleased to note the progress achieved to date and also reminded the Commission of the interest of OIE Members in standards for aquatic animal feed and the use of compartmentalisation as a tool to manage diseases and facilitate trade.

Dr Hill outlined the Commission's views on the OIE Global Conference 'Aquatic Animal Health Programmes – their benefits for global food security', to be held in Panama 28-30 June 2011. Dr Vallat noted that the conference would feature presentations on the contribution of aquatic animal health programmes to food security as well as scientific presentations. Dr Hill replied that, bearing in mind the importance of this forum, the Commission was developing proposals for speakers to address key topics that would be of interest to OIE Members and to international donors committed to strengthening the capacities of Aquatic Animal Health Services. Also on the topic of conferences, Dr Hill noted that the OIE would be well represented at the forthcoming conference in Chile on aquatic animal biosecurity, with presentations by Dr Hill, Dr Enriquez and a representative from the office of the OIE Regional Representative for the Americas. Dr Hill indicated that later in the week the Commission would review a new OIE Tool on the Evaluation of Aquatic Animal Health Services. This document, which was based on the OIE PVS Tool, had been revised in light of the pilot evaluation of an OIE Member. Dr Vallat asked the Commission to take all steps to encourage OIE Members to apply for evaluation using this Tool, as the OIE PVS Pathway has proven very helpful to Members wishing to strengthen Veterinary Services and is well accepted by major donors.

Dr Vallat noted that the Commission had reviewed two applications for Laboratory Twinning and had been disappointed with the quality of the applications. He encouraged the Commission to review the Manual on Twinning

Applications and provide recommendations to the OIE on any clarifications needed to give applicants better guidance on the preparation of applications.

Finally, Dr Hill informed Dr Vallat that the Commission would be reviewing a discussion paper prepared by Dr Berthe and Dr Haenen on 'Infectious agents of potential public health concern in aquaculture'. Dr Vallat commended the Commission on this initiative and urged it to consider the possible future need to provide guidance to assist OIE Members in preventing zoonotic diseases via action at the production/farm level.

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 on Aquatic Animal Health Surveillance, gave a summary of progress made at the *ad hoc* Group meeting held 27-29 July 2010 at the OIE Headquarters.

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

[Agenda Item 3.2. provides details of specific *ad hoc* Group items addressed by the Aquatic Animals Commission.]

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

Dr Berthe, as Chair of the *ad hoc* Group on Safety of Products Derived from Aquatic Animals, gave a summary of progress made at the *ad hoc* Group electronic meeting held from July to September 2010.

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

[Agenda Items 2.13., 2.14. and 3.1. provide details of specific *ad hoc* Group items addressed by the Aquatic Animals Commission.]

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

The Aquatic Animals Commission reviewed the report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals meeting held 4-6 October 2010.

The Commission agreed with the *ad hoc* Group comment that there are few approved antimicrobial agents in aquaculture, which is of great concern.

Draft Chapter 6.X. Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic Animals

The *ad hoc* Group developed a new draft Chapter 6.X. Harmonisation of National Antimicrobial Resistance Surveillance and Monitoring Programmes for Aquatic Animals that provided guiding principles specific to aquatic animals. The Commission agreed with the *ad hoc* Group recommendation that surveillance for antimicrobial resistance in pathogens of aquatic animals should be the main priority.

The Commission also agreed that the elements of a surveillance program for antimicrobial resistance in pathogens of public health significance (regardless of source) should be considered as the second priority. The Commission also agreed with the proposal of the *ad hoc* Group to consider whether the guidance provided in Chapter 6.7 of the *Terrestrial Code* would provide sufficient guidance for the purposes of the *Aquatic Code*.

The Commission recommended that the *ad hoc* Group continue to develop this draft text with a view to distributing it to Members in 2011.

Risk assessment for antimicrobial resistance arising from the use of antimicrobials in aquatic animals

The Commission also supported the *ad hoc* Group proposal to write a discussion paper that addresses risk assessment for antimicrobial resistance arising from the use of antimicrobials in aquatic animals, and requested that this paper be available for the Commission to discuss at their February 2011 meeting.

Draft Chapter 6.X. Monitoring of the Quantities of Antimicrobials Used in Aquatic Animals

The *ad hoc* Group developed a new draft Chapter 6.X. Monitoring of the Quantities of Antimicrobials Used in Aquatic Animals. In developing this text, the *ad hoc* Group took into consideration the situation where the majority of aquatic animals are reared in countries that lack infrastructure for the pre-market approval, distribution and use of antimicrobial agents. The Commission noted that another OIE *ad hoc* Group will review surveillance and monitoring programs in terrestrial species in the near future and agreed that the results of this work should be taken into account by the *ad hoc* Group under the Commission. The Commission recommended that the *ad hoc* Group continue to develop this draft text with a view to distributing it to Members in 2011.

Antimicrobial susceptibility testing

The *ad hoc* Group noted the lack, relative to terrestrial animals, of internationally recognised laboratory methods for bacterial culture, antimicrobial susceptibility testing, and interpretive criteria, such as clinical breakpoints and epidemiologic cut-off values, and proposed to develop a discussion paper on this topic. The Commission endorsed the development of a discussion paper and requested that the paper be available for the Commission to discuss at their February 2011 meeting.

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

[Agenda Item 2.2. provides details of other specific *ad hoc* Group items addressed by the Aquatic Animals Commission.]

2. OIE Aquatic Animal Health Code – Member comments

2.1. General comments

The Aquatic Animals Commission recognised the contribution of the following Members in providing comments: Australia, Chile, Chinese Taipei, European Union (EU), Switzerland and Thailand.

The Aquatic Animals Commission noted that a number of interventions had been made by Delegates at the 78th OIE General Session in May 2010 and that Delegates had been requested to provide written comments for the Commission to consider at their October meeting. However, the Commission could not consider these issues as no written comments had been submitted to date.

The Commission requested that written comments be submitted if Members wish to have their issues addressed.

2.2. Principles for Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals (Chapter 6.3.)

The Aquatic Animals Commission reviewed the recommendations of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals in response to Member comments on the draft Chapter 6.3 Responsible and prudent use of antimicrobial agents in veterinary medicine and agreed with the proposed amendments.

The Commission was surprised that no comments were received from some major aquatic animal producing countries and encouraged Members to review the revised draft chapter.

The draft Chapter 6.3. Principles for Responsible and Prudent Use of Antimicrobial Agents in Aquatic Animals will be proposed for adoption at the 79th General Session in May 2011 and is presented at Annex III for Member comment.

2.3. Disinfection of salmonid eggs – (Article 10.4.13., Article 10.5.13. and Article 10.9.13.)

A Member proposed that Articles be developed on egg disinfection for all listed diseases which do not exhibit true vertical transmission. The Aquatic Animals Commission agreed with the suggestion and reiterated the request that Members provide details of effective methods for disinfection of non-salmonid eggs to prevent egg surface transmission of disease agents. Such protocols are needed in the Aquatic Manual prior to the development of Articles on egg disinfection for relevant non-salmonid diseases in Aquatic Code chapters.

A Member questioned whether 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. The Commission considered that this point would be addressed by changes proposed to the Aquatic Manual chapter on disinfection (see Agenda Item 10.3.)

The Commission agreed with a Member's proposal to add a new point in 2 at the end of each of Articles 10.4.13., Article 10.5.13. and Article 10.9.13.

The revised chapter is provided at Annex IV for Member comments.

2.4. Listed Diseases (Chapter 1.3.)

A Member proposed that the necrotising hepatopancreatitis (NHP) be renamed as Texas necrotising hepatopancreatitis. In view of the fact that the bacterial agent of NHP is likely to be formally named in the near future, the Aquatic Animals Commission proposed the name of the disease be changed to 'Infection with [pathogen name once accepted]' after this has been finalised. The Commission considered that changing the disease name to Texas necrotising hepatopancreatitis would cause unnecessary confusion.

A Member provided extensive scientific information in support of a request that pancreas disease (PD) be listed as an OIE listed disease. The Commission reviewed the supporting documents and recommended that the ad hoc Group on the OIE List of Aquatic Animal Diseases (Finfish Team) be convened to undertake, via electronic meetings, a review of the Member's assessment of pancreas disease against the criteria for listing aquatic animal diseases (Chapter 1.2.) and to provide a report for the Commission to consider when they meet in February 2011.

EU Comments

The EU would be pleased to contribute to the work of the ad hoc Group on the OIE List of Aquatic Animal Diseases with European expertise on pancreas disease.

2.5. Quality of Aquatic Animal Health Services (Chapter 3.1.)

The Aquatic Animals Commission considered proposed amendments to the corresponding chapter in the *Terrestrial Code* and amended the text as appropriate for Chapter 3.1. Quality of Aquatic Animal Health Services as part of the on-going harmonisation of the two *Code*s.

The revised chapter is provided at Annex V for Member comments.

2.6. Chapter 4.2. Application of compartmentalisation (Chapter 4.2.)

The Aquatic Animals Commission did not accept a Member's proposal to move the reference to Hazard Analysis and Critical Control Point to the beginning of Article 4.2.3. as they considered the text was clear as currently written. The Aquatic Animals Commission noted that this chapter was only adopted in 2010 and decided that any proposed amendments be considered when a review of the chapter is undertaken.

2.7. Handling, disposal and treatment of aquatic animal waste (Chapter 4.6.)

A Member proposed that this chapter be split into two chapters to take account of different aquaculture management systems. The Aquatic Animals Commission noted that this chapter was only adopted in 2010 and suggested that any amendments be considered when a review of the chapter is undertaken. The Commission requested the Member to provide specific text showing how the proposed split of the chapter might be accomplished.

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

The Commission supported the proposal of a Member to amend Article 5.3.2. point 4.b) and amended the text accordingly.

The revised chapter is provided at Annex VI for Member comments.

2.9. Control of hazards in aquatic animal feeds (Chapter 6.1.)

The Aquatic Animals Commission also considered proposed amendments to the corresponding chapter in the *Terrestrial Code* and amended the text as appropriate for Chapter 6.1. Control of hazards in aquatic animal feeds, as part of the on-going harmonisation of the two *Code*s.

The revised chapter is provided at Annex VII for Member comments.

2.10. Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.2.)

A Member proposed the addition of text referring to OIE collaboration with Codex Alimentarius Commission. The Aquatic Animals Commission noted that all the OIE work on animal production food safety is conducted in active collaboration with the Codex Alimentarius Commission and therefore considered there was no need to make a specific statement to this effect in individual articles in the *Aquatic Code*.

In order to ensure harmonization with the *Terrestrial Code*, the Commission amended text in Article 6.2.1. to align with changes made by the Terrestrial Code Commission in the corresponding chapter in the *Terrestrial Code*.

The revised chapter is provided at Annex VIII for Member comments.

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

The Aquatic Animals Commission considered Member comments on Chapter 7.2. Welfare of farmed fish during transport, and amended the text accordingly.

The revised chapter is provided at Annex IX for Member comments.

2.12. Welfare aspects of stunning and killing of farmed fish for human consumption (Chapter 7.3.)

The Aquatic Animals Commission considered Members comments on Chapter 7.3. Welfare aspects of stunning and killing of farmed fish for human consumption, and amended the text accordingly.

The 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 have to be used because there are no alternative methods available for a particular fish species and location.

In response to a Member comment and the lack of currently available scientific evidence for their inclusion, the Commission deleted catfish, tilapia, halibut in Article 7.3.7. as examples for stunning/ killing methods considered to be humane. However, eel was retained as as an example species for electrical stunning since scientific evidence exists (The EFSA Journal, 2009, 1014, 1-42).

In response to a Member comment regarding the terms 'small, medium and large' fish in in Article 7.3.8., the Commission added text clarifying that the terms should be interpreted relatively to the species in question. The Commission recommended that Article 7.3.7. be moved to come after Article 7.3.8. as this was a more logical place.

The revised chapter is provided at Annex X for Member comments.

2.13. Taura syndrome (Chapter 9.5.)

A Member proposed the deletion of the time/ temperature parameters described in Article 9.5.3. point 1. The Aquatic Animals Commission stressed that this article is commodity driven and wished Members to note that the time/ temperatures parameters provided in this Article are the standard processes used by industry to process these products. The Commission reiterated the importance of including these parameters in the Articles to be sure the products described are processed so as to inactivate the pathogen of concern. The Commission noted that the full assessments developed for evaluation of the products listed in the 2010 *Aquatic Code* chapter for Taura syndrome (Chapter 9.5.) were provided in Annex XXV of the September 2009 Aquatic Animals Commission Report.

The Commission considered the review by the *ad hoc* Group on Safety of Products Derived from Aquatic Animals of the terminology for equivalence used in the newly adopted Articles 9.4.3. and 10.1.3. for Taura syndrome and Epizootic haematopoietic necrosis, respectively. The *ad hoc* Group proposed minor amendments to these Articles to ensure consistency of terminology.The Commission agreed with the *ad hoc* Group's recommendation to amend the terminology for equivalence used in Article 9.5.3. Taura syndrome, to ensure consistency of terminology.

The revised Article 9.5.3. is provided at Annex XI for Member comments.

2.14. Epizootic haematopoietic necrosis (Chapter 10.1.)

A Member proposed the deletion of the time/ temperature parameters described in Article 10.1.3. point 1. The Aquatic Animals Commission stressed that this article is commodity driven and wished Members to note that the time/ temperatures parameters provided in this Article are the standard processes used by industry to process these products. The Commission reiterated the importance of including these parameters to be sure the products described are processed so as to inactivate the pathogen of concern. The Commission noted that the full assessments developed for evaluation of the products listed in the 2010 *Aquatic Code* chapter for epizootic haematopoietic necrosis (Chapter 10.1.) were provided in Annex XXV of the September 2009 Aquatic Animals Commission Report.

A Member proposed that 'whole eviscerated fish (chilled or frozen)' and 'dried eviscerated fish (including air dried, flame dried and sun dried)' be added to products listed in Article 10.1.12. point 1. The Commission wished to remind Members that the product list is based on assessments made against the criteria in Chapter 5.3. of the *Aquatic Code*. The Commission requested that should Members propose the addition or deletion of aquatic products listed in Article 10.1.12. point 1, they need to refer to product assessments undertaken by the Commission and provide scientific comments supported by scientific references on the assessment as to where it is proposed to be amended.

The Commission agreed with the recommendation of the *ad hoc* Group on Safety of Products Derived from Aquatic Animals to amend the terminology for equivalence used in Article 10.1.3. epizootic haematopoietic necrosis to ensure consistency of terminology.

The revised Article 10.1.3. is provided at Annex XII for Member comments.

2.15. Article X.X.9.

The Aquatic Animals Commission did not accept a Member's proposal to amend text in the last sentence of Article X.X.9. in all disease chapters as they considered the text was clear as currently written.

2.16. Susceptible species list

A Member commented that the susceptible species listed in Article X.X.2 of each disease chapter of the *Aquatic Code*, should be aligned with the species listed in the *Aquatic Manual* because different lists in the *Aquatic Code* and the *Aquatic Manual* gives rise to uncertainties as to which species are susceptible. The Aquatic Animals Commission noted that the list of susceptible species in the *Aquatic Manual* are to be reviewed (see Item 10.4.) and proposed that once this work has been completed, the Commission will review the susceptible species listed in the *Aquatic Code* chapters.

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

3.1. Listed aquatic commodities in Articles X.X.3. and X.X.11. (amphibians and fish) / X.X.12. (crustaceans and molluscs) (all disease Chapters except epizootic haematopoietic necrosis, Taura syndrome and Infection with *Bonamia ostreae*)

The Aquatic Animals Commission reviewed and endorsed the aquatic products assessments and proposed product listings provided by the *ad hoc* Group on Safety of Products Derived from Aquatic Animals for amendments of Articles X.X.3. and X.X.11. (amphibians and fish) / X.X.12. (crustaceans and molluscs) for all disease chapters except epizootic haematopoietic necrosis, Taura syndrome and Infection with *B.ostreae* (as revised product listings for these 3 chapters had been proposed and adopted at the 78th General Session in May 2010).

The Commission wished to remind members that the revised product listings are based on product assessments conducted by the *ad hoc* Group using the criteria listed in Articles 5.3.1. and 5.3.2. These assessments are provided in Annex XVIII, (in Annex IV of the *ad hoc* Group report). OIE Headquarters wished Members to note that due to the large size of the product assessment document, translation onto French and Spanish will take some time to complete. However, translated versions will be made available on the OIE website once they have been completed.

The Aquatic Animals Commission welcomes Member comments on the product assessments.

The revised Articles X.X.3. and X.X.11. (amphibians and fish) / X.X.12. (crustaceans and molluscs) for all disease chapters (except epizootic haematopoietic necrosis, Taura syndrome and Infection with *B.ostreae*) are provided at Annex XIII for Member comments.

3.2. Model disease specific surveillance chapters

Dr Hill reported that the *ad hoc* Group on Aquatic Animal Health Surveillance together with the three experts from OIE Reference Laboratories for the diseases in question had made good progress with developing text on surveillance for (i) viral haemorrhagic septicaemia (ii) infection with *Bonamia ostreae,* and (iii) white spot disease, to provide model disease-specific chapters for the *Aquatic Code*. However, it had become clear that with the approach being taken for the task was very ambitious and it would require significantly more time to compile the detailed scientific information required for completing the chapters.

The Commission reviewed the latest versions of the three draft chapters provided with the report of the *ad hoc* Group (see Annex XVII) and recognised the large effort that had been put into preparing the documents but concluded that unfortunately they were now too detailed for the *Aquatic Code* and too lengthy for the *Aquatic Manual*. It was also noted that they included a lot of disease specific information already provided in the *Aquatic Manual* and detailed explanation of the scientific basis for surveillance already provided in the *Guide for Aquatic Animal Health Surveillance*. Furthermore, the Commission felt that they did not yet provide sufficient practical guidance on how to conduct sampling in surveillance for the specific disease in question.

The Commission concluded that given the significant time it would require to complete the draft chapters in their current format, the *ad hoc* Group should now focus on developing the sections on sampling considerations for surveillance for the three diseases so that these could be proposed as model chapters for inclusion in the

2012 edition of the *Aquatic Manual*. The Commission recommended that the *ad hoc* Group continue this task electronically.

The Commission wished to thank the *ad hoc* Group members for their comprehensive work and recommended that members consider continuing the work to complete the current draft comprehensive documents for placing on the OIE website and/or for publication in the *OIE Scientific and Technical Review* series.

3.3. Killing of farmed fish for disease control purposes (new Chapter 7.4.)

The Aquatic Animals Commission developed a new draft chapter on killing of farmed fish for disease control purposes. These recommendations are based on the premise that a decision to kill the farmed fish has been made, and address the need to ensure the welfare of the farmed fish until they are dead.

The new draft chapter is provided in Annex XIV for Member comments.

4. Other relevant activities

4.1. *Aquatic Code* harmonisation

The Aquatic Animals Commission was joined by Dr Alejandro Thiermann, President of the OIE Terrestrial Animal Health Standards Commission for a brief meeting. The Commission and Dr Thiermann agreed to continue to work together to ensure ongoing harmonisation of the two *Codes*.

The Commission supported the recommendation of OIE Headquarters to align Articles in Chapter 1.1. with equivalent Articles in the *Terrestrial Code* and recommended these amendments be made as silent changes in the 2011 edition of the *Aquatic Code* as the essential content will not change.

4.2. PVS Tool – *modification* for use in the evaluation of aquatic animal health services

Dr Kahn informed the Commission on the production of an OIE Tool for the evaluation of performance of aquatic animal health services. This document, which was based on the OIE PVS Tool, had been revised by Dr Bar-Yaacov, Delegate of Norway, working with Dr Schneider, Chair of the OIE *ad hoc* Group on the Evaluation of Veterinary Services, in light of a pilot evaluation of an OIE Member. While most of the competencies of Veterinary Services had been included in the new document, some competencies that specifically relate to the training and governance of veterinarians (e.g. the role of the Veterinary Statutory Body) had been removed or revised to take account of the practical situation with aquatic animal health professionals. In conducting evaluations, the indicators of performance are for the most part the same as those for veterinary services.

Dr Kahn clarified that where aquatic animals are under the regulatory responsibility (full or partial) of veterinary services, the OIE PVS Tool would continue to be used. Where aquatic animals are not covered by veterinary services, the Tool for the Evaluation of Aquatic Animal Health Services would be used. This latter Tool would be made available to evaluators when planning missions to OIE Members requesting assessments. The Commission discussed means of encouraging OIE Members to apply for evaluation using this Tool and agreed that members of the Commission would take every opportunity to remind Members of this possibility, as the OIE PVS Pathway has proven very helpful to Members wishing to strengthen Veterinary Services and is well accepted by major donors. The Commission agreed that the topic ‘competence of aquatic animal health services’ should be included on the agenda of regular OIE meetings, including of Regional Commissions and Aquatic Focal Point seminars, and other conferences as appropriate.

The Aquatic Animals Commission noted and endorsed the OIE Tool for the evaluation of performance of aquatic animal health services.

The OIE PVS Tool: Application to Aquatic Animal Health Services is provided for information at Annex XX.

4.3. Communication

The Aquatic Animals Commission noted the report of *ad hoc* Group on Communication and the Terrestrial Animal Health Standards Commission proposal to include new text on communication in the *Terrestrial Code*.

The Commission supported this area of work and proposed to wait until the *Terrestrial Code* text is finalised before developing corresponding text in the *Aquatic Code*.

4.4. Veterinary education

Dr Kahn informed the Commission on the work of the OIE *ad hoc* Group on Veterinary Education. Following the successful First OIE Global Conference on Veterinary Education (Paris, December 2009), the OIE convened an *ad hoc* Group comprising veterinary deans from the five OIE regions, the President of the World Veterinary Association, and representatives of major donors (the EC and the World Bank). The Group held its first meeting in June 2010 and produced a report, which was endorsed by the Terrestrial Code Commission at its meeting in September 2010.

The *ad hoc* Group made recommendations on the key competencies of a 'day 1 veterinary graduate' with regard to the OIE recommendations for performance of veterinary services. The Aquatic Commission briefly reviewed the recommendations of the *ad hoc* Group and endorsed the overall approach. The Commission discussed the issue of variable coverage of aquatic animal health and welfare in the veterinary curriculum and noted that many veterinary education establishments do not cover this topic in any detail. As with veterinary teaching relating to species other than the common terrestrial species (i.e. livestock and companion animals), the coverage of aquatic animals varies according to the importance of the aquatic sector in countries and regions. In many parts of the world, aquatic animal health and medicine is regarded as a post graduate specialisation. Members of the Commission agreed that the OIE should consider the need to make recommendations on basic coverage of aquatic animals in the undergraduate veterinary curriculum.

The *ad hoc* Group report can be seen at Annex XXXVI of the Terrestrial Code Commission September 2010 Report, which is available on-line at http://www.oie.int/downld/SC/2010/A_TAHSC_Part%20B_Sep%202010.pdf.

5. Cooperation with FAO

Dr Reantaso thanked OIE for the invitation to attend the Commission's meeting. She presented an overview of FAO's cooperative activities with OIE and provided some updates on the global work of FAO involving aquatic animal health, such as the aquaculture certification guidelines and aquatic biosecurity. She expressed gratitude to OIE for having supported the following activities: (i) FAO/WFC Training Workshop on Risk Assessment Methodologies and Tools for Aquaculture in Sub-Saharan Africa (28th June - 2nd July, 2010, Siavonga, Zambia); (ii) FAO Expert Workshop on Prudent and Responsible Use of Veterinary Medicines in Aquaculture (15-18 December 2009, Bangkok, Thailand) and (iii) the FAO/OIE/Namibia Ministry of Marine Resources High Level Scoping Meeting of Regional Fisheries and Veterinary Authorities towards Developing an Aquatic Biosecurity Framework for Southern Africa (13-14 October 2009, Windhoek, Namibia).

The Commission was informed that the development of the aquaculture certification guidelines started in 2006 and involved two sessions of the FAO Committee on Fisheries (COFI28, 2008; and COFI29, 2011), three sessions of COFI Sub-Committee on Aquaculture (SCA III – India, 2006; SCA IV, Chile, 2008; and SCA V, Thailand, 2010), one Technical Consultation (Italy, 2010) and 6 stakeholder consultations between 2007 and 2008 (Thailand, Brasil, India, United Kingdom, China and the United States of America). The guidelines, which were endorsed during SCA V, will be submitted to COFI 29 for approval. The guidelines consider a range of issues which should be considered relevant for the certification in aquaculture, including: a) animal health and welfare, b) food safety, c) environmental integrity and d) socio-economic aspects associated with aquaculture. The scope of the guidelines is to provide guidance for the development, organization and implementation of credible aquaculture certification schemes. Developing and implementing a certification scheme may be undertaken by any entity qualified to do so in accordance with the requirements of these guidelines.

The Commission was informed that the fifth Session of the SCA (SCA V) included an agenda item on aquatic biosecurity as a key sustainability issue for aquaculture; the presentation was well-received and many countries recognized the importance of the subject. Other ongoing activities were also presented including the following: aquatic biosecurity capacity and performance survey done in southern Africa, the Gulf region and the Western Balkan region; capacity building on risk analysis in southern Africa and the Pacific Island region; national activities on aquatic animal health in Bangladesh, Bosnia and Herzegovina, and China. At FAO corporate level, the meeting was informed of efforts to integrate aquatic biosecurity in contributing to One Health goals under the FAO One Health Programme - A Comprehensive Approach to Health, Animals and the Environment.

Potential areas for further collaboration with OIE include activities related to the following projects which are under various stages of development: 1) Western Balkan regional proposal 'Assistance for improving compliance with international standards on aquatic animal health'; 2) WTO Standards and Trade Facility proposal for assisting African countries to implement SPS Agreement; 3) Risk analysis training courses requested by FAO members; and 4) promoting activities that will strengthen cooperation and functional linkages between fisheries/aquaculture and veterinary authorities. FAO considered the OIE PVS tool as a useful tool and will be promoted by FAO to countries requesting assistance on capacity building from FAO.

6. OIE Conferences and relevant 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:

- Second Global Conference of OIE Reference Laboratories and Collaborating Centres (21–-23 June 2010, Paris, France);

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

7. Upcoming OIE Conferences and relevant 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:

- 20th Conference of the OIE Regional Commission for the Americas (Uruguay, 16-19 November 2010);
- 9th Annual General Meeting of NACA Regional Advisory Group on Aquatic Animal Health (Bangkok, 8-10 November 2010).

8. OIE Regional aquatic animal focal points training workshops

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

Middle East – Dubai, UAE: 27-29 Sept 2010

Africa – Namibia: 16-18 June 2010

Europe – Dubrovnik, Croatia: 16-18 November 2010

Americas – Roatan, Honduras: 23-25 November 2010

Far East, Asia Pacific: 2011.

9. OIE Global Conference on Aquatic Animal Health: 'Aquatic Animal Health Programmes: their benefit to global food security' 28-30 June 2011 Panama.

The Aquatic Animals Commission reviewed the draft conference programme and endorsed the proposed topics and speakers. The Commission encouraged Members to participate in this important event and to refer to the OIE website for the latest information about the conference (http://www.oie.int).

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. Comments from one OIE Member on the sixth edition of the Aquatic Manual

Two comments had been received from an OIE Member on the sixth edition of the *Aquatic Manual*. It was decided to consult the OIE Reference Laboratory experts for technical advice on the first comment. The Aquatic Animals Commission agreed with the second comment that in the section of the *Aquatic Manual* chapters on geographical distribution of a disease only confirmed reports of disease should be cited and not unconfirmed or unpublished report. The web version of the chapter on Infectious myonecrosis would be amended accordingly.

10.2. Review of new *Aquatic Manual* chapters on amphibian diseases

The Aquatic Animals Commission reviewed and accepted the draft chapter on Infection with ranavirus.

The draft chapter is presented at Annex XV(A) for Member comment.

Any amendments that are made based on the comments received shall be circulated again to Members with the report of the February meeting, and that version shall be the version that will be proposed for adoption in May

2011 by the World Assembly of Delegates of the OIE; if adopted, the chapter shall be added to the web version of the *Aquatic Manual*.

10.3. Review text on disinfection of eggs

The *Aquatic Code* chapter on disinfection of eggs had been adopted by the Assembly in May 2010 on condition that the section of chapter 1.1.3. of the *Aquatic Manual* that deals with disinfection of eggs be reviewed. The Aquatic Animals Commission updated the *Aquatic Manual* chapter taking into account comments received earlier from the *ad hoc* Group on Safe Commodities.

The updated *Manual* chapter can be found at Annex XV(B) for Member comment.

10.4. Feedback on guidance document on considering species as susceptible to infection with a specific pathogen

EU Comments

The EU would thank the Commission for its work in this area. However, the EU would appreciate if the new revision of the guidance document would be made available to Members for comments, as the establishment of the list of susceptible species is an essential basic element of the OIE disease standards. The EU would also like to reiterate the importance of having a clear and unambigous description of the species that shall be subject to the provisions of the OIE Code.

The Aquatic Animals Commission considered the responses it had received from the OIE Reference Laboratory experts on the guidance it had drafted on considering species as susceptible to infection with a specific pathogen, and amended the text accordingly. A table containing examples of the evidence required to support criteria for considering species as susceptible had been added to the guide. As the table did not yet include guidance on all the OIE listed diseases of aquatic animals, the Commission recommended that an electronic *ad hoc* Group be convened to undertake this work. Once completed (by mid-November, 2010), the guidance document would be re-sent to the OIE Reference Laboratory experts for comment before being provided to the authors of the *Aquatic Manual* disease chapter for consideration when updating their chapters in 2011.

10.5. Template for disease-specific chapters

The Aquatic Animals Commission concluded that the *ad hoc* Group on Aquatic Animal Health Surveillance would not have enough time to amend the disease-specific chapter template before it is sent to authors in January 2011. The Commission agreed to use the current template for the seventh edition of the *Aquatic Manual*. Should it be deemed necessary, the template could be revised and amended for the eighth edition (2015).

10.6. Development process for revised/new *Aquatic Manual* chapters

During the General Session in May 2010, one Delegate had commented to the Biological Standards Commission that the time given to send comments on draft *Terrestrial Manual* chapters had been very short and that the Assembly had not being given an opportunity to see the chapters amended in accordance with the comments received. To address this issue and to improve production standards, the Biological Standards Commission reviewed and approved a revised production schedule. This new time table provided for sending the amended chapters for comment a second time prior to the General Session such that the Delegates receive the texts that will be proposed for adoption and eventual publication. This implied that the production cycle for a new or revised chapter would be extended to 18–24 months, which was similar to the *Terrestrial Code*. The Aquatic Animals Commission agreed to follow the same process for the *Aquatic Manual*.

11. OIE Reference Laboratories and Collaborating Centres

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

The Second Global Conference for OIE Reference Laboratories and Collaborating Centres, which had been held earlier in the year, was deemed to be a success. The Aquatic Animals Commission was strongly in favour of a third Global Conference and suggested that more time be allocated in the programme for break-out groups to discuss aquatic animal specific issues. One of the limitations of the Second Global Conference was that not enough time had been giving to this important networking and information-gathering process.

11.2. New applications for Reference Laboratory status

Three applications had been received for OIE Reference Laboratories, one for white spot disease and infectious hypodermal and hematopoietic necrosis from People's Republic of China, one for abalone herpes-like virus from Australia, and one for and spring viraemia of carp from China. In each case, the Aquatic Animals Commission had full confidence in the technical ability and excellence of the laboratories concerned. However, before reaching a final decision, the Commission would seek assurance that the laboratories have the capacity for speedy receipt and shipment of samples and reference reagents and materials. Such capacity is crucial to the proper functioning of an OIE Reference Laboratory.

All three applications would be reconsidered at the February 2011 meeting of the Commission.

11.3. Necrotising hepatopancreatitis

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

11.4. Review nominations for replacement experts

The OIE had been notified of the following change of experts at an OIE Reference Laboratory:

The Aquatic Animals Commission recommended that for koi herpesvirus disease, Dr Kei Yuasa should replace Dr Motohiko Sano at the National Research Institute of Aquaculture, Fisheries Research Agency, Minami-ise, Mie, Japan.

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. As this disease is no longer an OIE listed disease, the Delegate would be asked if he supports continuation of this laboratory's designation.

11.5. Review of the Report of the Meeting of the OIE *ad hoc* Group on the Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres

The Aquatic Animals Commission reviewed the changes proposed by the OIE *ad hoc* Group on the Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres to the Mandate, Internal Rules, and Guidelines for applicants for designation as OIE Reference Laboratory.

The Commission noted that no mention is made of the candidate laboratory's capacity for timely import and export of reference materials. It would like to include confirmation and details of this capacity in the guidelines for applicants. The Commission proposed some other amendments to the Mandate, which would be forwarded to the Biological Standards Commission and the ad hoc Group.

The Commission also noted that the Council had requested the Biological Standards Commission to implement the 4-year re-designation scheme of Reference Laboratories and Collaborating Centres, in an effective,

practicable and sustainable manner, and had stated that objective criteria are needed and should be documented. The Aquatic Animals Commission believed that one criterion that could be used in the review process was whether or not the disease in currently listed or if its listing is under study. The 4-year review could be a timely moment to consider the continuation of OIE Reference Laboratories for delisted diseases.

12. Laboratory Twinning Projects

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

The Aquatic Animals Commission encouraged Members to consider opportunities for future laboratory twinning projects. All applicants are encouraged to read the Laboratory Twinning Manual (http://www.oie.int/downld/LABREF/A_Guide.pdf) that is updated regularly.

13. Any other business

13.1. Infectious agents of potential public health concern in aquaculture

Dr Haenen presented a summary of a discussion paper on Infectious Agents of Potential Public Health Concern in Aquaculture with particular emphasis on topically acquired infections.

Dr Hill thanked the two members of the Commission for preparing this paper and considered this a timely topic. The Commission concluded that potentially topically acquired bacterial zoonotic agents at the production phase are an important public health issue. The Commission recommended that a paper be prepared for publication in the OIE Bulletin to highlight the importance of this subject.

13.2. Strain differentiation

EU Comments

The EU would be pleased to contribute to the work of the ad hoc Group on strain differentiation with European expertise on the matter.

In response to a Member comment on the need for addressing the issue of pathogen strain differentiation including notification, the Aquatic Animals Commission noted that this issue is on their work programme. The Commission recommended that an *ad hoc* Group be convened to consider the scientific arguments for and against strain differentiation and propose a way forward with the view to report to the Commission February 2011 meeting.

14. Review of the Aquatic Animals Commission's work plan for 2010/11

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

15. Date of the next meeting

14-18 February 2011

…/Annexes

Annex I

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 11-15 October 2010

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Annex II

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 11–15 October 2010

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 Safety of Products Derived from Aquatic Animals

1.3. 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. Principles for Responsible and Prudent Use of Antimicrobial Agents in Veterinary Medicine (new Chapter 6.3)

2.3. Disinfection of salmonid eggs – (Article 10.4.13., Article 10.5.13. and Article 10.9.13.)

2.4. Listed Diseases (Chapter 1.3.)

2.5. Quality of Aquatic Animal Health Services (Chapter 3.1.)

2.6. Application of compartmentalisation (Chapter 4.2.)

2.7. Handling, disposal and treatment of aquatic animal waste (Chapter 4.6.)

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

2.9. Control of hazards in aquatic animal feeds (Chapter 6.1.)

2.10. Introduction to the recommendations for controlling antimicrobial resistance (Chapter 6.2.)

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

2.12. Welfare aspects of stunning and killing of farmed fish for human consumption (Chapter 7.3.)

2.13. Taura syndrome (Chapter 9.5.)

Annex II (contd)

2.14. Epizootic haematopoietic necrosis (Chapter 10.1.)

2.15. Article X.X.9.

2.16. Susceptible species list

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

3.1. Listed aquatic commodities in Articles X.X.3. and X.X.11. (amphibians and fish) / X.X.12. (crustaceans and molluscs) (all disease chapters except epizootic haematopoietic necrosis, Taura syndrome and Infection with *B. ostreae*)

3.2. Model disease specific surveillance chapters

3.3. Killing of farmed fish for disease control purposes (new Chapter 7.4.)

4. Other relevant activities

4.1. *Code* harmonisation

4.2. PVS Tool – modification for use in the evaluation of Aquatic Animal Health Services

4.3. Communication

4.4. Veterinary Education

5. Cooperation with FAO

6. OIE Conferences and relevant meetings

7. Upcoming OIE Conferences and relevant meetings

8. OIE Regional aquatic animal focal points training workshops

9. OIE Global Conference on Aquatic Animal Health: 'Aquatic Animal Health Programmes: their benefit to global food security' 28-30 June 2011, Panama

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

10.1. Comments from Thailand on the sixth edition of the *Aquatic Manual*

10.2. Review of new *Aquatic Manual* chapters on amphibian diseases

10.3. Review text on disinfection of eggs

10.4. Feedback on guidance document on considering species as susceptible to infection with a specific pathogen

10.5. Template for disease-specific chapters

10.6. Development process for revised/new *Aquatic Manual* chapters

Annex II (contd)

11. OIE Reference Laboratories and Collaborating Centres

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

11.2. New applications for Reference Laboratory status

11.3. Necrotising hepatopancreatitis

11.4. Review nominations for replacement experts

11.5. Review of the Report of the Meeting of the OIE *ad hoc* Group on the Scientific Partnerships among OIE Reference Laboratories and Collaborating Centres

12. Laboratory Twinning Projects

13. Any other business

13.1. Infectious agents of potential public health concern in aquaculture

13.2. Strain differentiation

14. Review of the Aquatic Animals Commission's work plan for 2010/11

15. Date of the next meeting

Annex III

CHAPTER 6.3.

PRINCIPLES FOR RESPONSIBLE AND PRUDENT USE OF ANTIMICROBIAL AGENTS IN ~~VETERINARY MEDICINE~~ AQUATIC ANIMALS

EU comment
The EU thanks and supports the OIE for this very important work, that have lead to the proposed new version of the chapter and thanks the OIE for having taken into account most of the EU comments previosly submitted.
However, the EU would like to see that the below comments are taken into account before supporting the inclusion of the chapter in the OIE Code.

Article 6.3.1.

Purpose

These principles ~~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 marketing authorization, registration and control of all groups involved in the production, distribution and use of veterinary antimicrobials have specific obligations.

Article 6.3.2.

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* both for veterinary and human medicine 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 both resistant micro-organisms and ~~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) occurring in the food;

6. ~~protect consumer health by ensuring the safety of food of *aquatic animal* origin.~~

Article 6.3.3.

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.

EU Comments

The above definition is identical with the definition of the Terrestrial Code. The EU notes that the Terrestrial Animal Health Code Commission proposes in their report of September 2010 an amendment in that definition. It should be ensured the above definition is aligned with any amendment made in the Terrestrial Code.

Annex III (contd)

Article 6.3.4.

Responsibilities of the *Competent authorities*

EU Comments

The term "Regulatory Authorities" in the title and in paragraphs 1, 2 and 5 should be replaced with "Competent Authorities" for reasons of consistency of terminology.

The EU would reiterate its comment that the term "drug" should be avoided. The EU would suggest that in paragraphs 1 and 2 "veterinary antimicrobial drugs" is simply replaced by "veterinary antimicrobials". For the sake of simplification, the same term could be used in paragraph 6 replacing the term "antimicrobial veterinary medicinal product".

The word "national" should be deleted in paragraphs 3 and 4, as such a strategy may also be established at other levels. For the same reason, in paragraph 7, the word "national" should be replaced with the word "the relevant".

In Paragraph 6, the EU would propose to replace the word "principle" in the second sentence with "substance" to harmonise the wording with the definition of antimicrobial agent. The EU would furthermore propose to delete the word "food-borne" in the third sentence, since antimicrobial resistance can develop in other microorganisms than foodborne ones. This would be in line with the objectives of the chapter, see point 3 of Article 6.3.2. which refers to resistance determinants.

In the last paragraph, the word "develop" should be replaced by "provide for", as it would not necessarily be the Competent Authority that would develop the strategy. but they should ensure that such procedures are developed.

The ~~national~~ Regulatory Authorities, which are responsible for granting marketing authorization for antimicrobials, have a significant role in specifying the terms of the authorization and in providing the appropriate information to the *veterinarian* or other *aquatic animal* health professional through product labeling 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~~ *Competent Authorities* 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~~ marketing authorization applications should include an assessment of the risks to ~~both~~ animals, ~~and~~ humans and the environment resulting from the use of antimicrobial agents in *aquatic animals*. The evaluation should focus on each individual ~~veterinary~~ antimicrobial ~~drug~~ veterinary medicinal product ~~but~~ and 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~~ *Competent Authorities* should aim to 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~~ *Competent 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.

The *Competent Authorities* should develop effective procedures for the safe collection and destruction of unused or out-of-date antimicrobials.

Article 6.3.5.

Responsibilities of the veterinary pharmaceutical industry

EU Comments

The term "Regulatory Authorities" in paragraph 1 should be replaced with "Competent Authorities" for reasons of consistency.

The EU is of the opinion that the pharmaceutical industry play an crutial role in increasing the focus on prudent use of antimicrobials and would suggest that the following is added in the end of paragraph 1 of Article 6.3.5: "and pharmacovigilance".

The veterinary pharmaceutical industry has responsibilities for providing information requested by the Regulatory Authorities on the quality of antimicrobials. The responsibilities of the veterinary pharmaceutical industry covers pre- and post- marketing phases, manufacturing, sale, importation, labeling and advertising issues.

The veterinary pharmaceutical industry has the responsibility to provide the regulatory *Competent 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 6.3.6.

Responsibilities of wholesale and retail distributors.

EU Comments

In the interest of simplification and coherence with the other articles of this chapter, in paragraph 1, the words "national or regional" legislation should be deleted, alternatively replaced by the word "relevant".

Distributors should ensure that their activities are in compliance with the legislation.

Distributors should ensure that information for the appropriate use and disposal of the antimicrobial agent preparation should accompany all distributed products and should also be responsible for maintaining and disposing off the product under according to the manufacturer recommendations.

Distributors should have responsibilities in collection and destruction of *antimicrobial agents* that have passed their expiry date.

Article 6.3.7.

Responsibilities of veterinarians and other aquatic animal health professionals

EU Comments

The EU would reiterate its comment regarding the importance of antimicrobial veterinary medicinal products being prescribed by authorised personell. The EU would therefore propose to delete the words "or recommend" in paragraphs 2 and 7.

The EU acknowledges that in the veterinary field, not only veterinarians, but also other aquatic animal health professionals are carrying out important duties and agree that this should be recognised in this Article. However, the right to prescribe veterinary medicine, needs a specific authorisation. The EU would therefore propose that the words "authorised to prescribe veterinary medicines" are added after the words "aquatic animal health professionals" in paragraphs 2, 3, 4, 6 and 7.

In paragraph 3, EU would propose that the term "clinical examination" is replaced by "clinical assessment". The proposed wording better reflect the kind of investigation undertaken. In many cases it will not be feasible to conduct a proper "clinical examination" of the individual aquatic animal.

In paragraph 6 the word "drug" should be replaced by "antimicrobials".

As regards Paragraph 7 The EU would like to reiterate its view that extra-/off-label antimicrobial agents should only be prescribed in exceptional circumstances. Furthermore, the EU continues to question the relevance of referring to requirements of importing countries in this paragraph on the use of off-label use of antimicrobial agents. The equivalent paragraph of the OIE Terrestrial code does not contain such a reference. Paragraph 7 should in the opinion of the EU read:

The *veterinarian* or other *aquatic animal* health professional may prescribe ~~or recommend~~ in exceptional ~~appropriate~~ circumstances the use of antimicrobial agents extra-/off-label, in conformity with the relevant ~~national~~ legislation ~~and any requirements of importing countries~~.

The word "national" should be deleted in paragraph 8, see the EU comments on Article 6.3.4 and 6.3.6.

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 prescribe or recommend ~~antimicrobia~~l a specific course of antimicrobial treatment 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~~ necessary 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~~ retained and should be available to the relevant ~~national~~ Competent Authority~~.~~

Annex III (contd)

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 prescribe or 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 *aquatic animal* health professionals should also periodically review farm records on the use of the antimicrobial agents to ensure compliance with their directions and use these records to evaluate the effectiveness of treatment regimens. Suspected adverse reactions, as well as a lack of effectiveness, should be reported to the *Competent Authorities*. The associated susceptibility data should accompany the report of lack of effectiveness.

~~*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 6.3.8.

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 prescription or recommendation of a *veterinarian* or other *aquatic animal* health professional, and follow directions on the dosage, method of application, and withdrawal period.

EU Comments

The EU would reiterate its comment regarding the importance of antimicrobials prescribed by authorised personell, see EU comment on Article 6.3.7. The EU would therefore propose that paragraph 2 of Article 6.3.8 reads as follows:

Aquatic animal producers should use antimicrobial agents only on the prescription ~~or recommendation~~ of a *veterinarian* or other *aquatic animal* health professional authorised to prescribe veterinary medicines, and follow directions on the dosage, method of application, and withdrawal period.

The EU would furthermore propose that in paragraph 5 the words "authorised to prescribe veterinary medicines" are added after the words "aquatic animal health professionals".

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 6.3.9.

Training of antimicrobial users

The training of users of antimicrobials should involve all the relevant organisations, such as *Competent* ~~*regulatory*~~ *Authorities*, pharmaceutical industry, veterinary schools, research institutes, and veterinary professional organisations and other approved users such as *aquatic animal* owners.

Article 6.3.10.

Research

To address the significant lack of information for numerous species of *aquatic animals*, ~~relevant~~ *Competent Authorities* and other stakeholders should encourage public- and industry-funded research.

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— text deleted

Annex IV

CHAPTER 10.4.

INFECTIOUS HAEMATOPOIETIC NECROSIS

EU comment

The EU can support the proposed changes.

[…]

Article 10.4.13.

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 *risk* 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* (under study) or those specified by the *Competent Authority* of the *importing country*; and

   b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status;

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

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 *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.4.13. have been fulfilled.

[…]

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

— text deleted

Annex IV (contd)

CHAPTER 10.5.

INFECTIOUS SALMON ANAEMIA

EU comment

The EU can support the proposed changes.

[…]

Article 10.5.13.

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 to be 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 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* (under study) or those specified by the *Competent Authority* of the *importing country*; and

   b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status;

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

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 *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.5.13. have been fulfilled.

[…]

– text deleted

Annex IV (contd)

CHAPTER 10.9.

VIRAL HAEMORRHAGIC SEPTICAEMIA

EU comment

The EU can support the proposed changes. Please note that in point 1, it is referred to ISA instead of VHS.

[…]

Article 10.9.13.

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 ISA, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

   a) the VHS virus status of the water to be 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 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* (under study) or those specified by the *Competent Authority* of the *importing country*; and

   b) between *disinfection* and the import, eggs should not come into contact with anything which may affect their health status;

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

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 *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.9.13. have been fulfilled.

[…]

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— text deleted

Annex V

CHAPTER 3.1.

QUALITY OF AQUATIC ANIMAL HEALTH SERVICES

EU comment

The EU can support the proposed changes.

Article 3.1.1.

The quality of the *Aquatic Animal Health Services* depends on a set of factors, which include ~~of OIE Members need to embody the~~ fundamental principles of an ethical, organisational, legislative, regulatory and technical nature. The *Aquatic Animal Health Services* shall 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 *Aquatic Animal Health Service* is important in the establishment and maintenance of confidence in its *aquatic animal health status* and *international aquatic animal health certificates* by the *Aquatic Animal Health Service* of other Members.

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

The ability of *Aquatic Animal Health Services* to deliver appropriate services, monitor and control *aquatic animal diseases* based on Members' *aquatic animal* health legislation and regulations, can be measured through an evaluation or audit whose general principles are described in Articles 3.1.3. and 3.1.4.

A procedure for evaluating *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

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

1. Professional judgement

   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 *Aquatic Animal Health Service* personnel are free from any commercial, financial, hierarchical, political or other pressures which may inappropriately influence their judgement or decisions.

3. Impartiality

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.

Annex V (contd)

4. Integrity

Aquatic Animal Health Services are responsible for ensuring 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

Aquatic Animal Health Services should conduct themselves, in an objective, transparent and non-discriminatory manner.

6. Aquatic animal health legislation and regulations

Aquatic animal health legislation and regulations are a fundamental element that supports good governance and provides the legal framework for all key activities of the *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, they should define and document the responsibilities and structure of the organisations in charge of traceability and control of *aquatic animal* movements, *aquatic animal disease* control and reporting systems, epidemiological *surveillance* and communication of epidemiological information.

7. General organisation

Aquatic Animal Health Services should be able to demonstrate by means of an appropriate legislation and regulations, 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.

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.

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 *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.

8. Quality policy

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.

9. Procedures and standards

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*, *Aquatic Animal Health Services* should comply with these standards when applying *aquatic animal* health measures and when issuing *international aquatic animal health certificates*.

10. Information, complaints and appeals

Aquatic Animal Health Services should undertake to reply to requests from *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 *Aquatic Animal Health Services*.

11. Documentation

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

Annex V (contd)

12. Self-evaluation

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 *Aquatic Animal Health Services* by OIE experts, on a voluntary basis, is described in Article 3.1.5.

13. Communication

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

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 *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 *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 *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 *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 *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 *Aquatic Animal Health Services* of Members. Members can make a request to the OIE for an evaluation of their *Aquatic Animal Health Services*.

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 *Aquatic Animal Health Services* of the Member using the OIE PVS Tool: Application to *Aquatic Animal Health Services* applied as appropriate to the context of the evaluation.

The expert(s) produce(s) a report in consultation with the *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.

– text deleted

Annex VI

CHAPTER 5.3.

CRITERIA TO ASSESS THE SAFETY OF AQUATIC ANIMAL COMMODITIES

EU comment

The EU can support the proposed changes.

[…]

Article 5.3.2.

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

1. In all *disease* chapters, point 1 of Article X.X.12. (amphibian and fish *disease* chapters) and Article X.X.11. (crustacean and mollusc *disease* chapters) lists *aquatic animals* or *aquatic animal products* for retail trade for human consumption. The criteria for inclusion of *aquatic animals* or *aquatic animal products* in point 1 of Article X.X.12. (amphibian and fish *disease* chapters) and Article X.X.11. (crustacean and mollusc *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 presence of viable *pathogenic agent* in the waste.

2. For the purpose of this criterion retail means the selling or provision of *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.

3. It is assumed that:

   a) the *aquatic animals* or *aquatic animal products* are used for human consumption only;

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

   c) treatment or processing prior to importation is conducted according to Good Manufacturing Practices, and

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

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

a) the *aquatic animal* or *aquatic animal product* is prepared and packaged for retail trade for human consumption; AND

EITHER

b) it includes only a small amount of raw waste tissues generated by the consumer;

OR

c) the *pathogenic agent* is not normally found in the waste tissues generated by the consumer.

– text deleted

Annex VII

CHAPTER 6.1.

CONTROL OF HAZARDS IN AQUATIC ANIMAL FEEDS

EU comment

The EU supports the amendments of the chapter. Please find below some comments for consideration:

The EU would propose that paragraph 2 of Article 6.1.1 is replaced by the following:

"The objective of this chapter is furthemore to complement the guidance provided by the Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) which deals primarily with food safety, and related other Codex texts covering animal feeding, e.g. Code of Practice for Source Directed Measures to Reduce Contamination of Food with Chemicals (CAC/RCP 49-2001) and by the Food and Agriculture Organization of the United Nations (FAO) (Technical Guidelines for Responsible Fisheries – Aquaculture Development: 1. Good aquaculture feed manufacturing practice. FAO 2001)

These recommendations should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code*."

Justification: The proposed wording would harmonise the text with the parallell text in the OIE Terrestrial Code. Furthermore, EU is of the opinion that the OIE Code should not make references to documents produced or co-produced by private organisations. The reference to the document prepared by International Feed Industry Federation (IFIF) in cooperation with FAO is therefore proposed deleted.

In the second sub paragraph of paragraph 1 and in point b) of paragraph 14 of Article 6.1.3. the word "drugs" should be replaced by "medicines".

Justification: See the EU comments to Chapter 6.3.

In paragraph 10 of Article 6.1.3. EU would propose that the words " the waybill and other sales" are replaced by "accompanying".

Justification: Clarity and simplification of wording.

In paragraph 12 of Article 6.1.3. EU would propose that the first sentence should read:

"Feed business operators are responsible for demonstrating the safety of the establishments under their control and the feed they place on the market."

Justification: The responsibility of the feed business operators as regards the safety of the feed they place on the market should be highlighted.

Article 6.1.1.

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 should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code*. 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 VII (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 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 *pathogenic agent*/host species combinations.

Article 6.1.2.

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 6.1.3.

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. 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 certain tissues and therefore tend to accumulate through the food chain.

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.

Annex VII (contd)

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).~~

Labelling should be informative, unambiguous, legible and conspicuously placed on the package if sold in package form and on the waybill and other sales documents if sold in bulk, un-packaged form, and should comply with regulatory requirements and Section 4.2. Labelling of Codex Code of Practice on Good Animal Feeding (CAC/RCP 54-2004), including listing of ingredients and instructions on the handling, storing and use. All claims made on a label should be able to be substantiated.

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 full responsibility for implementing systems for quality control. Where such systems are applied, the *Competent Authority* should verify that they meet all regulatory requirements.

12. Assurance and certification

Feed business operators are responsible for demonstrating the safety of the establishments under their control. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory requirements have been met. For *international trade* in aquatic animal product based feeds, *Competent Authorities* are required to provide *international aquatic animal health certificates.*

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.

Annex VII (contd)

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. Contamination

Procedures to minimise the *risk* of contamination during the production, processing, storage, distribution (including transport) and the use of *feed* or *feed ingredients* should be included in current regulations and standards. Scientific evidence, including the sensitivity of analytical methods and on the characterisation of *risk*, should be drawn upon in developing this framework.

Procedures such as flushing, sequencing and physical clean-out should be used to avoid cross-contamination between batches of *feed* or *feed ingredients*.

15. Antimicrobial resistance

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

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 Chapters 4.1. and 4.2. of the OIE *Terrestrial Animal Health Code*; Section 4.3 of CAC/RCP 54-2004).

Article 6.1.4.

Recommended approaches to aquatic animal health risk mitigation

Annex VII (contd)

1. Commodities

a) Safe commodities

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

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

iii) 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;

Annex VII (contd)

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 6.1.5.

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 6.1.4., 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*.

Annex VII (contd)

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 6.1.6.

Risk pathways for 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 *pathogenic agents* 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.

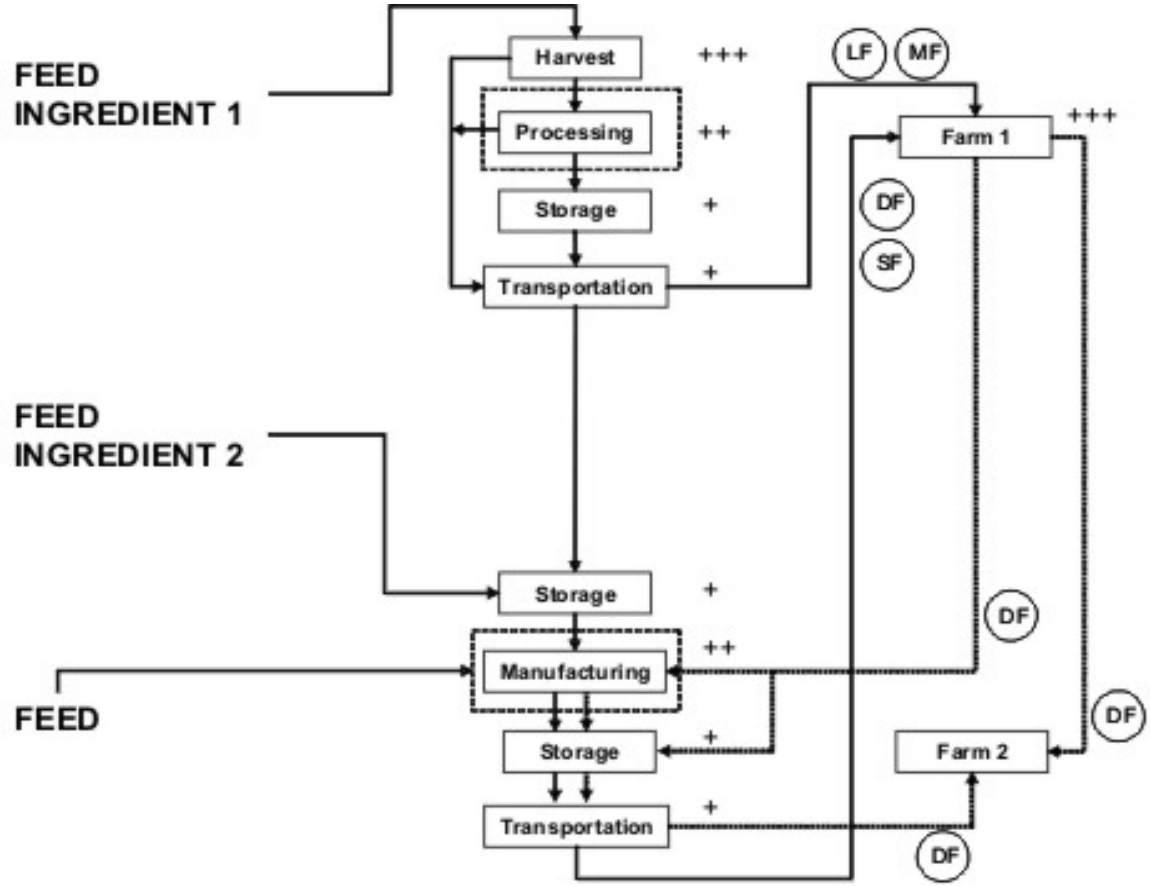
Figure 1 illustrates the possible pathways for transmission of pathogens within the *feed* production and utilisation process.

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 VIII

CHAPTER 6.2.

INTRODUCTION TO THE RECOMMENDATIONS FOR CONTROLLING ANTIMICROBIAL RESISTANCE

EU comment

The EU can support the proposed changes. However, in line with the principles applied by Codex Alimentarius – making transparent references to the cooperation with the OIE - the EU again strongly recommend that the last sentence of paragraph is amended to read:
"Arising from its mandate for the protection of animal health and food safety, and in synergy whith similar activities in Codex Alimentarius, the OIE developed these chapters to provide guidance to Members in regard to risks in the animal sector."

Article 6.2.1.

Objectives

The purpose of this section is to provide guidance for Members to appropriately address the selection and dissemination of resistant micro-organisms and antimicrobial resistance determinants from the use of antimicrobial agents in *aquatic animals*.

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 and controlling ~~and preventing~~ infectious *diseases* in *aquatic animals*. The OIE therefore considers that ensuring continued access to effective antimicrobial agents is important.

The OIE recognises that antimicrobial resistance is a global public and animal health concern that is influenced by the usage of antimicrobial agents in humans, animals and elsewhere. Those working in the human, animal and plant sectors have a shared responsibility to address the risk factors for the selection and dissemination of antimicrobial resistance. 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 *risk analysis* and supported by sound data and information when available. The guidance provided

in these chapters should be consulted as part of the standard approach to reduce the risk associated with the selection and dissemination of antimicrobial resistant micro-organisms and antimicrobial resistance determinants.

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Annexe IX

CHAPTER 7.2.

WELFARE OF FARMED FISH DURING TRANSPORT

EU comment

The EU welcomes the revision of the Chapter on the Welfare of farmed fish and thanks the OIE for having taken into account most of the EU comments previosly submitted.

The EU can support the proposed changes.

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~~ Control of aquatic animal health risks associated with transport of aquatic animals.

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, awareness and training of personnel involved in transport;

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

c) having a *contingency plan* available to enable humane killing of the fish at the start and at the end of the journey, as well as during the journey, if required;

d) ensuring 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:

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a) using a well maintained *vehicle* that is appropriate to the species to be transported;

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

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

d) selecting 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 7.4. 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 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.

Annexe IX (contd)

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. 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).

   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)~~.~~;

      iv) insufficient or excessive length of fasting.

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 *Aquatic Animal Health Service* upon request. Transport logs from previous journeys should be kept after completion of the transport for a period of time as specified by the *Aquatic Animal Health Service*.

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 *contingency plan* (see point 6 of Article 7.2.3.).

b) If the killing of fish is necessary during the transport, it should be carried out humanely in accordance with Chapter 7.4. Killing of farmed fish for disease control purposes (in preparation), and in compliance with relevant legislation.

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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 7.4. Killing of farmed fish for disease control purposes (in preparation).

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 7.4. Killing of farmed 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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Annexe X

CHAPTER 7.3.

WELFARE ASPECTS OF STUNNING AND KILLING OF FARMED FISH FOR HUMAN CONSUMPTION

EU comment
The EU welcomes the revision of the Chapter on Welfare aspects of stunning and killing of farmed fish for human consumption and thanks the OIE for having taken into account most of the EU comments previosly submitted. Regarding point 4 in Article 7.3.6 "Other stunning and killing methods", the EU welcomes the explanation why the OIE does not agree to delete the text, and would propose instead to amend the text in this point.
The EU can support the proposed changes. Furthermore, a specific EU comment is provided in the text for further development of the Chapter.
Moreover, the EU would suggest that a description and assessment of "pharmaccological methods" for stunning are added in the chapter, as such methods also are in use.

Article 7.3.1.

Scope

These recommendations apply to the 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.

This chapter describes general principles that should be applied to ensure the welfare of fish for 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 killing of fish play an important role in their welfare. Personnel handling fish for stunning and 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.

Article 7.3.3.

Transport

If fish are to be transported prior to stunning and killing, this should be done in accordance with OIE recommendations on the welfare of farmed fish during transport (see Chapter 7.2.).

Article 7.3.4.

Design of holding facilities

1. The holding facilities should be designed and specifically constructed to hold a certain fish species or group of fish species.

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.

Annexe X (contd)

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 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 designed and maintained to minimise injury.

Article 7.3.5.

Unloading, transferring and loading

1. Fish should be unloaded, transferred and loaded under conditions that minimise injury and stress to the fish.

2. The following points should be considered:

   a) Water quality (e.g. temperature, oxygen and CO_2 levels, pH and salinity) should be assessed on arrival of fish prior to their unloading, and corrective action taken if required.

   b) Where possible any injured or moribund fish should be separated and killed humanely.

   c) The crowding periods of fish 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.

Article 7.3.6.

Stunning and killing methods

1. General considerations

a) The *Competent Authority* should approve the stunning and killing methods for fish. The choice of method should take account of species-specific information where available.

b) All handling, stunning and killing 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 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 loss of consciousness and insensibility of the fish. The conductivity of fresh and brackish water varies, so it is essential to establish the parameters of the electrical current to ensure proper 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 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.

e) In semi-dry electrical stunning systems, fish should enter the device head first to ensure rapid and efficient stunning.

4. Other killing methods

The following 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, it is preferable to use the methods described in points 2 and 3 of this Article, as appropriate to the fish species.

EU comment

The last sentence of point 4 of Art 7.3.6 should be replaced by: "*Therefore, these methods should not be used if it is feasible to use other methods described in this Chapter*."

Justification: 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.

Article 7.3.7.

~~**Examples of stunning/killing methods for fish groups**~~

~~The following methods enable humane killing for the following fish groups:~~

~~1. Percussive stunning: carp, catfish, salmonids, halibut;~~

~~2. Spiking or coring: salmonids, tuna;~~

~~3. Free bullet: tuna;~~

~~4. Electrical stunning: carp, catfish, eel, salmonids, tilapia.~~

Annex X (contd)

~~Article 7.3.8.~~

Summary table of some stunning/killing methods for fish and their respective welfare issues

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 / kill method.	Immediate loss of consciousness. 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 of a similar size.
Mechanical (contd)	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 / kill method.	Immediate loss of consciousness. 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 / kill method.	Immediate loss of consciousness. Suitable for arge 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 X (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 method. Equipment should be designed and maintained correctly.	Immediate loss of consciousness. 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

Note : the terms small, medium and large fish should be interpreted relative to the species in question.

Article 7.3.8.

Examples of stunning/killing methods for fish groups

The following methods enable humane killing for the following fish groups:

1. percussive stunning: carp, salmonids;
2. spiking or coring: salmonids, tuna;
3. free bullet: tuna;
4. electrical stunning: carp, eel, salmonids.

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— text deleted

Annex XI

CHAPTER 9.4.

TAURA SYNDROME

EU comment

The EU can support the proposed changes.

[…]

Article 9.5.3.

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 9.4.2. intended for any purpose and complying with Article 5.3.1.:

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

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

   c) pasteurised crustacean products that have been subjected to heat treatment at 90°C for 10 minutes (or ~~to~~ any time/temperature ~~pasteurisation~~ equivalent which has been demonstrated to inactivate TSV);

   d) crustacean oil;

   e) crustacean meal; and

   f) chemically extracted chitin.

[…]

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— text deleted

Annex XII

CHAPTER 10.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

EU comment

The EU can support the proposed changes.

[…]

Article 10.1.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from an 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.:

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

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

   c) mechanically dried eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate EHNV);

   d) fish skin leather;

   e) fish oil; and

   f) fish meal.

[…]

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— text deleted

Annex XIII

PRODUCT LISTINGS IN ARTICLES X.X.3 AND X.X.11./12.

CHAPTER 8.1.

INFECTION WITH *BATRACHOCHYTRIUM DENDROBATIDIS*

EU comment

The EU can support the proposed changes. However, it would be valuable also to develop guidelines on *B. dendrobatidis* in relation to the features of the agent, diagnostics etc. as has been done for the Ranavirus.

[…]

Article 8.1.3.

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

1. *Competent Authorities* should not require any *B. dendrobatidis* related conditions, regardless of the *B. dendrobatidis* 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 8.1.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[*commodities* treated in a manner that inactivates the *disease agent* e.g. canned products; leather made from amphibian skin; dried amphibian products (including air dried, flame dried and sun dried)] (under study).~~

   a) heat sterilised hermetically sealed amphibian products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);

   b) cooked amphibian products that have been subjected to heat treatment at 100°C for at least 1 minute (or any time/temperature equivalent which has been demonstrated to inactivate B. dendrobatidis (e.g. 60°C for at least 5 minutes);

c) pasteurised amphibian products that have been subjected to heat treatment at 90°C for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate B. dendrobatidis (e.g. 60°C for at least 5 minutes);

d) mechanically dried amphibian products (i.e. a heat treatment of 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate B. dendrobatidis (e.g. 60°C for at least 5 minutes); and

e) amphibian skin leather.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 8.1.2., other than those referred to in point 1 of Article 8.1.3., Competent Authorities should require the conditions prescribed in Articles 8.1.7.to 8.1.12. relevant to the B. dendrobatidis status of the exporting country, zone or compartment.

Annex XIII (contd)

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 B. dendrobatidis of a species not covered in Article 8.1.2.but which could reasonably be expected to pose a risk of transmission for B. dendrobatidis, *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 8.1.12.

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

1. *Competent Authorities* should not require any *B. dendrobatidis* related conditions, regardless of the *B. dendrobatidis* 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)~~ ~~[skinned frog legs with feet removed;~~

~~ii)~~ ~~skinned amphibian meat or carcasses, with heads, hands and feet removed] (under study).~~

iii) amphibian meat (skin off, fresh 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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 8.1.2. from a country, *zone* or *compartment* not declared free from *B. dendrobatidis*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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– text deleted

Annex XIII (contd)

CHAPTER 8.2.

INFECTION WITH RANAVIRUS

EU comment

The EU can support the proposed changes.

[…]

Article 8.2.3.

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

1. *Competent Authorities* should not require any ranavirus related conditions, regardless of the ranavirus 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 8.2.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[*commodities* treated in a manner that inactivates the *disease agent* e.g. canned products; leather made from amphibian skin; dried amphibian products (including air dried, flame dried and sun dried)] (under study);~~

   a) heat sterilised hermetically sealed amphibian products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);

   b) cooked amphibian products that have been subjected to at 65°C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate all species of the genus Ranavirus in the family Iridoviridae (with the exception of epizootic haematopoietic necrosis virus and European catfish virus);

   c) pasteurised amphibian products that have been subjected to heat treatment at 90°C for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate all virus species of the genus Ranavirus in the family Iridoviridae (with the exception of epizootic haematopoietic necrosis virus and European catfish virus);

   d) mechanically dried amphibian products (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate all virus species of the

genus Ranavirus in the family Iridoviridae (with the exception of epizootic haematopoietic necrosis virus and European catfish virus).

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 8.2.2., other than those referred to in point 1 of Article 8.2.3., *Competent Authorities* should require the conditions prescribed in Articles 8.2.7. to 8.2.12. relevant to the ranavirus 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 ranavirus of a species not covered in Article 8.2.2. but which could reasonably be expected to pose a *risk* of transmission for ranavirus, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Annex XIII (contd)

[…]

Article 8.2.12.

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

1. *Competent Authorities* should not require any ranavirus related conditions, regardless of the ranavirus 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)~~ ~~[skinned frog legs with feet removed;~~

   ~~ii)~~ ~~skinned amphibian meat or carcasses, with heads, hands and feet removed] (under study).~~

   ~~iii)~~ no *commodities* listed.

   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 8.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 9.1.

CRAYFISH PLAGUE (*APHANOMYCES ASTACI*)

EU comment

The EU can support the proposed changes.

[…]

Article 9.1.3.

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

1. *Competent Authorities* should not require any crayfish plague related conditions, regardless of the crayfish plague 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 9.1.2.intended for any purpose and complying with Article 5.3.1.:

   ~~a) [*commodities* treated in a manner that inactivates the *pathogenic agent* e.g. boiled, canned or pasteurised products and some ready-to-eat meals; and crayfish oil and crayfish *meal* intended for use in *feed*;~~

   ~~b) chemically extracted chitin;~~

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

   ~~d) frozen crayfish products that have been subjected to -20°C or lower temperatures for at least 72 hours] under study.~~

   a) heat sterilised hermetically sealed crayfish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time /temperature equivalent);

   b) cooked crayfish products that have been subjected to heat treatment at 100°C for at least 1 minute (or any time/temperature equivalent which has been demonstrated to inactivate A. astaci);

   c) pasteurised crayfish products that have been subjected to heat treatment at 90°C for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate A. astaci);

d) frozen crayfish products that have been subjected to -20°C or lower temperatures for at least 72 hours;

e) crayfish oil;

f) crayfish meal; and

g) chemically extracted chitin;

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.1.2., other than those referred to in point 1 of Article 9.1.3., *Competent Authorities* should require the conditions prescribed in Articles 9.1.7. to 9.1.11. relevant to the crayfish plague status of the *exporting country*, *zone* or *compartment*.

Annex XIII (contd)

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 crayfish plague of a species not covered in Article 9.1.2. but which could reasonably be expected to pose a *risk* of transmission for crayfish plague, *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 9.1.11.

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

1. *Competent Authorities* should not require any crayfish plague related conditions, regardless of the crayfish plague 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.:

   a) ~~[*commodity(ies)*] under study~~.no *commodities* listed.

   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 9.1.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

– text deleted

CHAPTER 9.2.

INFECTIOUS HYPODERMAL AND HAEMATOPOIETIC NECROSIS

EU comment

The EU can support the proposed changes.

[…]

Article 9.2.3.

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

1. *Competent Authorities* should not require any IHHN related conditions, regardless of the IHHN 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.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the pathogenic agent e.g. boiled, canned or pasteurised products and some ready-to-eat meals; and crustacean oil and crustacean meal intended for use in feed;~~

   b) ~~chemically extracted chitin;~~

   ~~c)~~ ~~crustacean products made non-infectious through processing as dry feed (e.g. pelleted or extruded feed)] under study.~~

   a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatmentat 121°C for at least 3.6 minutes or any time/temperature equivalent);

   b) cooked crustacean products that have been subjected to heat treatment at 90°C for at least 20 minutes (or any time/temperature equivalent which has been demonstrated to inactivate IHHNV);

   c) crustacean oil; and

   d) crustacean meal.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.2.2., other than those referred to in point 1 of Article 9.2.3., *Competent Authorities* should require the conditions prescribed in Articles 9.2.7. to 9.2.11. relevant to the IHHN 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 IHHN of a species not covered in Article 9.2.2. but which could reasonably be expected to pose a *risk* of transmission for IHHN, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 9.2.11.

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

1. *Competent Authorities* should not require any IHHN related conditions, regardless of the IHHN 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.:

   ~~a) [commodity(ties)] under study.~~

   a) 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 9.2.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

— text deleted

CHAPTER 9.3.

INFECTIOUS MYONECROSIS

EU comment

The EU can support the proposed changes.

[…]

Article 9.3.3.

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

1. *Competent Authorities* should not require any IMN related conditions, regardless of the IMN 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 9.3.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the disease agent e.g. boiled, canned or pasteurised products and some ready-to-eat meals; and crustacean oil and crustacean meal intended for use in feed;~~

   ~~b)~~ ~~chemically extracted chitin;~~

   ~~c)~~ ~~crustacean products made non-infectious through processing as dry feed (e.g. pelleted or extruded feed)] (under study).~~

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

   b) cooked crustacean products that have been subjected to heat treatment at 100°C for at least 3 minutes (or any time/temperature equivalent which has been demonstrated to inactivate IMNV);

   c) crustacean oil;

   d) crustacean meal; and

   e) chemically extracted chitin.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.3.2., other than those referred to in point 1 of Article 9.3.3., *Competent Authorities* should require the conditions prescribed in Articles 9.3.7. to 9.3.11. relevant to the IMN 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 IMN of a species not covered in Article 9.3.2. but which could reasonably be expected to pose a *risk* of transmission for IMN, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 9.3.11.

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

1. *Competent Authorities* should not require any IMN related conditions, regardless of the IMN 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.:

   ~~a) [commodity(ties)] under study.~~

   a) 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 9.3.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

– text deleted

CHAPTER 9.4.

NECROTISING HEPATOPANCREATITIS

EU comment

The EU can support the proposed changes.

[…]

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 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 9.4.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodity(ies)] under study.~~

   a) heat sterilised hermetically sealed crustacean products (i.e. a heat treatmentat 121˚C for at least 3.6 minutes or any time/temperature equivalent);

   b) cooked crustacean products that have been subjected to heat treatmentat 100˚C for at least 3 minutes (or any time/temperature equivalentwhich has been demonstrated to inactivate the NHPbacterium);

   c) pasteurised crustacean productsthat have been subjected to heat treatmentat 63˚C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate the NHP bacterium);

   d) crustacean oil;

   e) crustacean meal; and

   f) chemically extracted chitin.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.4.2., other than those referred to 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 NHP 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 NHP of a species not covered in Article 9.4.2. but which could reasonably be expected to pose a *risk* of transmission for NHP, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 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 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.:

   ~~a) [commodity(ies)] under study.~~

   a) 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 NHP, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 9.6.

WHITE SPOT DISEASE

EU comment

The EU can support the proposed changes.

[…]

Article 9.6.3.

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

1. *Competent Authorities* should not require any WSD related conditions, regardless of the WSD 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 9.6.2. intended for any purpose and complying with Article 5.3.1.:

~~a) [commodities treated in a manner that inactivates the pathogenic agent e.g. boiled, canned or pasteurised products and some ready-to-eat meals; and crustacean oil and crustacean meal intended for use in feed;~~

~~b) chemically extracted chitin;~~

~~c) crustacean products made non-infectious through processing as dry feed (e.g. pelleted or extruded feed)] (under study).~~

a) heat sterilised hermetically sealed crustacean products (i.e. a heatt reatment at 121°C for at least 3.6 minutes or any time/ temperature equivalent);

b) cooked crustacean products that have been subjected to heat treatment at 60°C for at least 1 minute (or any time/ temperature equivalent which has been demonstrated to inactivate WSSV);

c) pasteurised crustacean products that have been subjected to heat treatmentat 90°C for at least 10 minutes (or any time/ temperature equivalent which has been demonstrated to inactivate WSSV);

d) crustacean oil;

e) crustacean meal; and

f) chemically extracted chitin.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.6.2., other than those referred to in point 1 of Article 9.6.3., *Competent Authorities* should require the conditions prescribed in Articles 9.6.7. to 9.6.11. relevant to the WSD 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 WSD of a species not covered in Article 9.6.2. but which could reasonably be expected to pose a *risk* of transmission for WSD, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 9.6.11.

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

1. *Competent Authorities* should not require any WSD related conditions, regardless of the WSD 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 9.6.2.:

   ~~a) [commodity(ties)] (under study);~~

   a) frozen, peeled shrimp or decapod crustacea (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 9.6.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 9.7.

WHITE TAIL DISEASE

EU comment

The EU can support the proposed changes.

[…]

Article 9.7.3.

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

1. *Competent Authorities* should not require any WTD related conditions, regardless of the WTD 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 9.7.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a) [commodities treated in a manner that inactivates the pathogenic agent e.g. boiled, canned or pasteurised products and some ready-to-eat meals; and crustacean oil and crustacean meal intended for use in feed;~~

   ~~b) chemically extracted chitin;~~

   ~~c) crustacean products made non-infectious through processing as dry feed (e.g. pelleted or extruded feed)] (under study).~~

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

   b) cooked crustacean products that have been subjected to heat treatment at 60°C for at least 60 minutes (or any time/temperature equivalent which has been demonstrated to inactivate MrNV);

   c) pasteurised crustacean productsthat have been subjected to heat treatmentat 90°C for at least 10 minutes (or any time/temperature equivalent that has been shown to inactivate MrNV);

   d) crustacean oil;

   e) crustacean meal; and

f) chemically extracted chitin.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.7.2., other than those referred to in point 1 of Article 9.7.3., *Competent Authorities* should require the conditions prescribed in Articles 9.7.7. to 9.7.11. relevant to the WTD 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 WTD of a species not covered in Article 9.7.2. but which could reasonably be expected to pose a *risk* of transmission for WTD, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Annex XIII (contd)

[…]

Article 9.7.11.

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

1. *Competent Authorities* should not require any WTD related conditions, regardless of the WTD 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 9.7.2.:

   ~~a) [commodity(ties)] (under study).~~

   a) 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 9.7.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 9.8.

YELLOW HEAD DISEASE

EU comment

The EU can support the proposed changes.

[…]

Article 9.8.3.

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

1. *Competent Authorities* should not require any YHD related conditions, regardless of the YHD 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 9.8.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a) [commodities treated in a manner that inactivates the pathogenic agent e.g. boiled, canned or pasteurised products and some ready-to-eat meals; and crustacean oil and crustacean meal intended for use in feed;~~

   ~~b) chemically extracted chitin;~~

   ~~c) crustacean products made non-infectious through processing as dry feed (e.g. pelleted or extruded feed)] under study.~~

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

   b) cooked crustacean products that have been subjected to heat treatment at 60°C for at least 15 minute (or any time/temperature equivalent which has been demonstrated to inactivate YHV);

   c) pasteurised crustacean productsthat have been subjected to heat treatment at 90°C for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate YHV);

   d) crustacean oil;

   e) crustacean meal; and

f) chemically extracted chitin.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 9.8.2., other than those referred to in point 1 of Article 9.8.3., *Competent Authorities* should require the conditions prescribed in Articles 9.8.7. to 9.8.11. relevant to the YHD 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 YHD of a species not covered in Article 9.8.2. but which could reasonably be expected to pose a *risk* of transmission for YHD, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Annex XIII (contd)

[…]

Article 9.8.11.

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

1. *Competent Authorities* should not require any YHD related conditions, regardless of the YHD 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.:

   ~~a) [commodity(ties)] under study.~~

   a) frozen, peeledshrimp or decapodcrustacea (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 9.8.2. from a country, *zone* or *compartment* not declared free from YHD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

Annex XIII (contd)

CHAPTER 10.2.

EPIZOOTIC ULCERATIVE SYNDROME

EU comment

The EU can support the proposed changes.

[…]

Article 10.2.3.

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

1. *Competent Authorities* should not require any EUS related conditions, regardless of the EUS 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 10.2.2. intended for any purpose and complying with Article 5.3.1.:

~~a) [commodities treated in a manner that inactivates the pathogenic agent e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish meal intended for use in feed] (under study).~~

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

b) pasteurised fish products that have been subjected to heat treatmentat 90°C for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate Aphanomyces invadans);

c) mechanically dried eviscerated fish (i.e. a heat treatmentat 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate Aphanomyces invadans);

d) fish oil;

e) fish meal ;

f) frozen eviscerated fish; and

g) frozen fillets or steaks.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.2.2., other than those referred to in point 1 of Article 10.2.3., *Competent Authorities* should require the conditions prescribed in Articles 10.2.7. to 10.2.12. relevant to the EUS 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 EUS of a species not covered in Article 10.2.2. but which could reasonably be expected to pose a *risk* of transmission for EUS, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Annex XIII (contd)

[…]

Article 10.2.12.

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 ulcerative syndrome

1. *Competent Authorities* should not require any EUS related conditions, regardless of the EUS 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.:

   ~~a) [eviscerated fish (chilled or frozen);~~

   ~~b) fillets or cutlets (chilled or frozen);~~

   ~~c) dried eviscerated fish (including air dried, flame dried and sun dried)] (under study).~~

   d) no *commodities* listed.

   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 10.2.2. from a country, *zone* or *compartment* not declared free from EUS, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 10.3.

GYRODACTYLOSIS (*GYRODACTYLUS SALARIS*)

EU comment

The proposed list of safe commodities exclude a wide range of commonly traded products, which in the view of the EU meet the criteria set out in Article 5.3.1, which are listed in the current edition of the Code, but which are not assessed by the Ad hoc group on Safety of products derived from aquatic animals.

The EU would not be able to agree with the proposed changes unless at least the following products are added to the list set out in paragraph 1 of Article 10.3.3:

l) Chilled fish products where the skin, fins and gills have been removed.

m) non-fertilised food-grade fish eggs

Below is an assessment of "chilled fish products where the skin, fins and gills have been removed" and "non-fertilised food-grade fish eggs", using the template used by the Ad hoc group on safety of products derived from aquatic animals, which justifies the listing of these products in Article 10.3.3.

Commodity under consideration		**Chilled fish products where the skin, fins and gills have been removed**	
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*	*Gyrodactylus salaris* is present on the skin, fins and gills of fish living in freshwater (Jensen and Johnsen, 1992). *G. salaris* does not occur in this commodity.	Yes
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*	Potable freshwater is used to process the product (WHO and FAO, 2009). The final product is transported out of water, or on ice made from potable water. In addition, *G. salaris* is readily inactivated by disinfectants (Mo TA, 2010, OIE	Yes

		Reference Laboratory for Gyrodactylosis, personal communication). *G. salaris* does not produce eggs (2009 OIE Aquatic Animal Manual).	
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)*		
AND/OR			
2c.	*Biological (e.g. fermentation).*		
Conclusion	*Gyrodactylus salaris* does not occur on this commodity therefore chilled fish products where the skin, fins and gills have been removed are eligible for inclusion in Article 10.3.3. point 1.		

Commodity under consideration		**non-fertilised food-grade fish eggs**	
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*	*Gyrodactylus salaris* is present on the skin, fins and gills of fish living in freshwater (Jensen and Johnsen, 1992). *G. salaris* does not occur in this commodity.	Yes
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*	Potable freshwater is used to process the product (WHO and FAO, 2009). The final product is transported out of water. In addition, *G. salaris* is readily inactivated by disinfectants (Mo TA, 2010, OIE Reference Laboratory for Gyrodactylosis, personal communication). *G. salaris* does not produce eggs (2009 OIE Aquatic Animal Manual).	Yes
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)*		
AND/OR			
2c.	*Biological (e.g. fermentation).*		
Conclusion	*Gyrodactylus salaris* does not occur on this commodity therefore non-fertilised food-grade fish eggs eligible for inclusion in Article 10.3.3. point 1.		

[…]

Article 10.3.3.

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

1. *Competent Authorities* should not require any gyrodactylosis related conditions, regardless of the gyrodactylosis 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 10.3.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the pathogenic agent e.g. leather made from fish skin, pasteurised products and some ready to eat meals; and fish oil and fish meal intended for use in feed;~~

   ~~b)~~ ~~chilled products of fish, where the head, fins and skin have been removed] (under study).~~

   a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121˚C for at least 3.6 minutes or any time/temperature equivalent);

   b) pasteurised fish products that have been subjected to a heat treatment at 63˚C for at least 30 minutes (or any time/temperature equivalent which has been demonstrated to inactivate G. salaris);

   c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100˚C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate G. salaris);

   d) naturally dried, eviscerated fish (i.e. sun-dried or wind-dried);

   e) frozen, eviscerated fish that have been subjected to -18°C or lower temperatures;

   f) frozen fish fillets or steaks that have been subjected to -18°C or lower temperatures;

   g) chilled, eviscerated fish harvested from seawater of at least 7.5 ppt or higher for at least 50 days;

   h) chilled fish fillets or steaks reared harvested from seawater of at least 7.5 ppt or higher for at least 50 days;

   i) fish oil;

   j) fish meal; and

   k) fish skin leather

Annex XIII (contd)

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.3.2., other than those referred to in point 1 of Article 10.3.3., *Competent Authorities* should require the conditions prescribed in Articles 10.3.7. to 10.3.12. relevant to the gyrodactylosis 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 gyrodactylosis of a species not covered in Article 10.3.2. but which could reasonably be expected to pose a *risk* of transmission for gyrodactylosis, *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 10.3.12.

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

1. *Competent Authorities* should not require any gyrodactylosis related conditions, regardless of the gyrodactylosis 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.:

   ~~a) [fish (chilled or frozen);~~

   ~~b) fillets or cutlets (chilled or frozen);~~

   ~~c) dried fish (including air dried, flame dried and sun dried);~~

   ~~d) smoked salmonids] (under study).~~

   a) no commodities listed.

   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 10.3.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

— text deleted

CHAPTER 10.4.

INFECTIOUS HAEMATOPOIETIC NECROSIS

EU comment

The EU can support the proposed changes.

[…]

Article 10.4.3.

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

1. *Competent Authorities* should not require any IHN related conditions, regardless of the IHN 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 10.4.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a) [commodities treated in a manner that inactivates the disease agent e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish meal intended for use in feed] (under study).~~

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

   b) pasteurised fish products that have been subjected to a heat treatmentat 90°C for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate IHNV);

   c) mechanically dried, eviscerated fish (i.e. a heat treatmentat 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate IHNV);

   d) fish oil ;

   e) fish meal;, and

   f) fish skin leather.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.4.2., other than those referred to in point 1 of Article 10.4.3., *Competent Authorities* should require the conditions prescribed in Articles 10.4.7. to 10.4.12. relevant to the IHN 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 IHN of a species not covered in Article 10.4.2. but which could reasonably be expected to pose a *risk* of transmission for IHN, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 10.4.12.

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

1. *Competent Authorities* should not require any IHN related conditions, regardless of the IHN 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.:

   ~~a) [eviscerated fish (chilled or frozen);~~

   ~~b) fillets or cutlets (chilled or frozen);~~

   ~~c) dried eviscerated fish (including air dried, flame dried and sun dried)] (under study).~~

   a) fish fillets or steaks (frozen or chilled).

   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 10.4.2. from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 10.5.

INFECTIOUS SALMON ANAEMIA

EU comment

The EU can support the proposed changes.

[…]

Article 10.5.3.

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

1. *Competent Authorities* should not require any ISA related conditions, regardless of the ISA 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 10.5.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the disease agent e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish meal intended for use in feed] (under study).~~

   a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121˚C for at least 3.6 minutes or any time/temperature equivalent);

   b) pasteurised fish products that have been subjected to a heat treatment at 90˚C for at least 10 minutes (or to any time/temperature equivalent which has been demonstrated to inactivate ISAV);

   c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100˚C for 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate ISAV);

   d) fish oil;

   e) fish meal; and

   f) fish skin leather.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.5.2., other than those referred to in point 1 of Article 10.5.3., *Competent Authorities* should require the conditions prescribed in Articles 10.5.7. to 10.5.12. relevant to the ISA 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 ISA of a species not covered in Article 10.5.2. but which could reasonably be expected to pose a *risk* of transmission for ISA, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 10.5.12.

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

1. *Competent Authorities* should not require any ISA related conditions, regardless of the ISA 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.:

   ~~a)~~ ~~[eviscerated fish (chilled or frozen);~~

   ~~b)~~ ~~fillets or cutlets (chilled or frozen);~~

   ~~c)~~ ~~dried eviscerated fish (including air dried, flame dried and sun dried)] (under study).~~

   a) fish fillets or steaks (frozen or chilled).

   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 10.5.2. from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 10.6.

KOI HERPESVIRUS DISEASE

EU comment

The EU can support the proposed changes.

[…]

Article 10.6.3.

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

1. *Competent Authorities* should not require any KHVD related conditions, regardless of the KHVD 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 10.6.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the disease agent e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish meal intended for use in feed] (under study).~~

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

   b) pasteurised fish products that have been subjected to heat treatment at 90°C for at least 10 minutes (or to any time/temperature equivalent which has been demonstrated to inactivate KHV);

   c) mechanically dried eviscerated fish (i.e. a heat treatmentat 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate KHV);

   d) fish oil; and

   e) fish meal.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.6.2., other than those referred to in point 1 of Article 10.6.3., *Competent Authorities*

should require the conditions prescribed in Articles 10.6.7. to 10.6.12. relevant to the KHVD 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 KHVD of a species not covered in Article 10.6.2. but which could reasonably be expected to pose a *risk* of transmission for KHVD, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 10.6.12.

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

1. *Competent Authorities* should not require any KHVD related conditions, regardless of the KHVD 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.:

   ~~a) [eviscerated fish (chilled or frozen);~~

   ~~b) fillets or cutlets (chilled or frozen);~~

   ~~c) dried eviscerated fish (including air dried, flame dried and sun dried)] (under study).~~

   a) fish fillets or steaks (frozen or chilled).

   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 10.6.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 10.7.

RED SEA BREAM IRIDOVIRAL DISEASE

EU comment

The EU can support the proposed changes.

[…]

Article 10.7.3.

Importation or transit of aquatic animals and aquatic animal products for any purpose from a country, zone or compartment not declared free from red sea bream iridovirus

1. *Competent Authorities* should not require any RSIVD related conditions, regardless of the RSIVD 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 10.7.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the disease agent e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish meal intended for use in feed](under study).~~

   a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at 121ºC for at least 3.6 minutes or any time/temperature equivalent);

   b) pasteurised fish products that have been subjected to heat treatmentat 90ºC for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate RSIV);

   c) mechanically dried eviscerated fish(i.e. a heat treatmentat 100ºC for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate RSIV)

   d) fish skin leather;

   e) fish oil; and

   f) fish meal.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.7.2., other than those referred to in point 1 of Article 10.7.3., *Competent Authorities* should require the conditions prescribed in Articles 10.7.7. to 10.7.12. relevant to the RSIVD 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 RSIVD of a species not covered in Article 10.7.2. but which could reasonably be expected to pose a *risk* of transmission for RSIVD, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 10.7.12.

Importation of aquatic animals and aquatic animal products for retail trade for human consumption from a country, zone or compartment not declared free from red sea bream iridovirus

1. *Competent Authorities* should not require any RSIVD related conditions, regardless of the RSIVD 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.:

   ~~a)~~ ~~[eviscerated fish (chilled or frozen);~~

   ~~b)~~ ~~fillets or cutlets (chilled or frozen);~~

   ~~c)~~ ~~dried eviscerated fish (including air dried, flame dried and sun dried)] (under study).~~

   a) 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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.7.2. from a country, *zone* or *compartment* not declared free from RSIVD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

— text deleted

CHAPTER 10.8.

SPRING VIRAEMIA OF CARP

EU comment

The EU can support the proposed changes.

[…]

Article 10.8.3.

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

1. *Competent Authorities* should not require any SVC related conditions, regardless of the SVC 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 10.8.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the disease agent e.g. leather made from fish skin, pasteurised products and some ready to eat meals; and fish oil and fish meal intended for use in feed] (under study).~~

   a) heat sterilised hermetically sealed fish products (i.e. a heat treatment at121°C for at least 3.6 minutes or equivalent);

   b) pasteurised fish products that have been subjected to heat treatmentat 90°C for at least 10 minutes (or any time/temperature equivalent which has been demonstrated to inactivate SVCV);

   c) mechanically dried eviscerated fish (i.a. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate SVCV);

   d) fish oil; and

   e) fish meal.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.8.2., other than those referred to in point 1 of Article 10.8.3., *Competent Authorities*

should require the conditions prescribed in Articles 10.8.7. to 10.8.12. relevant to the SVC 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 SVC of a species not covered in Article 10.8.2. but which could reasonably be expected to pose a *risk* of transmission for SVC, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 10.8.12.

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

1. *Competent Authorities* should not require any SVC related conditions, regardless of the SVC 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.:

   a) ~~[eviscerated fish (chilled or frozen);~~

   ~~b) fillets or cutlets (chilled or frozen);~~

   ~~c) dried eviscerated fish (including air dried, flame dried and sun dried)] (under study).~~

   a) 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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.8.2. from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 10.9.

VIRAL HAEMORRHAGIC SEPTICAEMIA

EU comment

The EU can support the proposed changes. Please note that in paragraph 1 it is referred to "RSIVD" instead of VHSV.

[…]

Article 10.9.3.

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

1. *Competent Authorities* should not require any RSIVD related conditions, regardless of the RSIVD 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 10.9.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commodities treated in a manner that inactivates the disease agent e.g. leather made from fish skin, pasteurised products and some ready-to-eat meals; and fish oil and fish meal intended for use in feed] (under study).~~

   a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121oC for at least 3.6 minutes or any time/temperature equivalent);

   b) pasteurised fish products that have been subjected to a heat treatment at 90oC for at least 10 minutes (or to any time/temperature equivalent which has been demonstrated to inactivate VHSV);

   c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate VHSV);

   d) naturally dried, eviscerated fish (i.e. sun-dried or wind-dried);

   e) fish oil;

   f) fish meal; and

g) fish skin leather.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.9.2., other than those referred to in point 1 of Article 10.9.3., *Competent Authorities* should require the conditions prescribed in Articles 10.9.7. to 10.9.12. relevant to the RSIVD 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 RSIVD of a species not covered in Article 10.9.2. but which could reasonably be expected to pose a *risk* of transmission for RSIVD, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex XIII (contd)

Article 10.9.12.

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

1. *Competent Authorities* should not require any VHS related conditions, regardless of the VHS 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.:

   ~~a) [eviscerated fish (chilled or frozen);~~

   ~~b) fillets or cutlets (chilled or frozen);~~

   ~~c) dried eviscerated fish (including air dried, flame dried and sun dried)] (under study).~~

   a) 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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.9.2. from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

— text deleted

CHAPTER 11.1.

INFECTION WITH ABALONE HERPES-LIKE VIRUS

EU comment

The EU can support the proposed changes.

[…]

Article 11.1.3.

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 11.1.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a) [commodity(ties)] under study.~~

   a) heat sterilised hermetically sealed abalone products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);

   b) mechanically dried abalone products (i.e. a heat treatment at 100°C for at least 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate AbHV).

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.1.2., other than those referred to in point 1 of Article 11.1.3., *Competent Authorities* should require the conditions prescribed in Articles 11.1.7. to 11.1.11. 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 of a species not covered in Article 11.1.2. 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.

[…]

Article 11.1.11.

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.:

Annex XIII (contd)

~~a) [commodity(ties)] under study.~~

a) off the shell, eviscerated abalone meat (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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 11.1.2. 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.

- text deleted

Annex XIII (contd)

CHAPTER 11.2.

INFECTION WITH *BONAMIA EXITIOSA*

EU comment

The EU can support the proposed changes.

[…]

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. exitiosa*

1. *Competent Authorities* should not require any *B. exitiosa* related conditions, regardless of the *B. exitiosa* 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.:

   ~~a) [commodities treated in a manner that inactivates the pathogenic agent e.g. canned or pasteurised products] (under study).~~

   a) frozen oyster meat; and

   b) 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. exitiosa* 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 *B. exitiosa* of a species not covered in Article 11.2.2. but which could reasonably be expected to pose a *risk* of transmission for *B. exitiosa*, *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 11.2.11.

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. exitiosa*

1. *Competent Authorities* should not require any *B. exitiosa* related conditions, regardless of the *B. exitiosa* 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.:

   ~~a)~~ ~~[off the shell (chilled or frozen);~~

   ~~b)~~ ~~half-shell (chilled)] (under study).~~

Annex XIII (contd)

   a) chilled oyster meat ; and

   b) 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. exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

- text deleted

CHAPTER 11.4.

INFECTION WITH *MARTEILIA REFRINGENS*

EU comment

The EU can support the proposed changes.

[…]

Article 11.4.3.

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

1. *Competent Authorities* should not require any *M. refringens* related conditions, regardless of the *M. refringens* 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 11.4.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a) [commodities treated in a manner that inactivates the pathogenic agent e.g. canned or pasteurised products] (under study).~~

   a) heat sterilised hermetically sealed mollusc products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time /temperature equivalent).

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.4.2., other than those referred to in point 1 of Article 11.4.3., *Competent Authorities* should require the conditions prescribed in Articles 11.4.7. to 11.4.11. relevant to the *M. refringens* 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 *M. refringens* of a species not covered in Article 11.4.2. but which could reasonably be expected to pose a *risk* of transmission for *M. refringens*, *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 11.4.11.

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

1. *Competent Authorities* should not require any *M. refringens* related conditions, regardless of the *M. refringens* 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.:

Annex XIII (contd)

~~a)~~ ~~[off the shell (chilled or frozen);~~

~~b)~~ ~~half-shell (chilled)] (under study).~~

a) mollusc meat (chilled or frozen); and

b) half-shell oyster (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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 11.4.2. from a country, *zone* or *compartment* not declared free from *M. refringens*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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— text deleted

Annex XIII (contd)

CHAPTER 11.5.

INFECTION WITH *PERKINSUS MARINUS*

EU comment

The EU can support the proposed changes.

[…]

Article 11.5.3.

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

1. *Competent Authorities* should not require any *P. marinus* related conditions, regardless of the *P. marinus* 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 11.5.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a)~~ ~~[commercially sterile canned or other heat treated products] (under study).~~

   a) heat sterilised hermeticallysealed mollusc products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time /temperature equivalent);

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.5.2., other than those referred to in point 1 of Article 11.5.3., *Competent Authorities* should require the conditions prescribed in Articles 11.5.7. to 11.5.11. relevant to the *P. marinus* 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 *P. marinus* of a species not covered in Article 11.5.2. but which could reasonably be expected to pose a *risk* of transmission for *P. marinus*, *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 11.5.11.

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

1. *Competent Authorities* should not require any *P. marinus* related conditions, regardless of the *P. marinus* 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.:

~~a)~~ ~~[chemically preserved products (e.g. smoked, salted, pickled, marinated);~~

~~b)~~ ~~non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite] (under study).~~

Annex XIII (contd)

a) mollusc meat (chilled and frozen); and

b) half-shell oysters (chilled and 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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 11.5.2. from a country, *zone* or *compartment* not declared free from *P. marinus*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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— text deleted

Annex XIII (contd)

CHAPTER 11.6.

INFECTION WITH *PERKINSUS OLSENI*

EU comment

The EU can support the proposed changes.

[…]

Article 11.6.3.

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

1. *Competent Authorities* should not require any *P. olseni* related conditions, regardless of the *P. olseni* 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 11.6.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a) [commercially sterile canned or other heat treated products] (under study).~~

   a) heat sterilised hermetically sealed mollusc products (i.e. a heat treatment at121°C for at least 3.6 minutes or any time/temperature equivalent).

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.6.2., other than those referred to in point 1 of Article 11.6.3., *Competent Authorities* should require the conditions prescribed in Articles 11.6.7. to 11.6.11. relevant to the *P. olseni* 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 *P. olseni* of a species not covered in Article 11.6.2. but which could reasonably be expected to pose a *risk* of transmission for *P. olseni*, *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 11.6.11.

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

1. *Competent Authorities* should not require any *P. olseni* related conditions, regardless of the *P. olseni* 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.:

   ~~a) [chemically preserved products (e.g. smoked, salted, pickled, marinated);~~

   ~~b) non-commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite] (under study).~~

Annex XIII (contd)

   a) mollusc meat (chilled and frozen); and

   b) half-shell molluscs (chilled and 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* or *aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 11.6.2. from a country, *zone* or *compartment* not declared free from *P. olseni*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

— text deleted

CHAPTER 11.7.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

EU comment

The EU can support the proposed changes.

[…]

Article 11.7.3.

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

1. *Competent Authorities* should not require any *X. californiensis* related conditions, regardless of the *X. californiensis* 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 11.7.2. intended for any purpose and complying with Article 5.3.1.:

   ~~a) [commodities treated in a manner that inactivates the disease agent e.g. canned or pasteurised products] (under study).~~

   a) heat sterilised hermetically sealed abalone products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent).

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 11.7.2., other than those referred to in point 1 of Article 11.7.3., *Competent Authorities* should require the conditions prescribed in Articles 11.7.7. to 11.7.11. relevant to the *X. californiensis* 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 *X. californiensis* of a species not covered in Article 11.7.2. but which could reasonably be expected to pose a *risk* of transmission for *X. californiensis*, *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 11.7.11.

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

1. *Competent Authorities* should not require any *X. californiensis* related conditions, regardless of the *X. californiensis* 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.:

   ~~a)~~ ~~[off the shell, eviscerated abalone (chilled or frozen)] (under study).~~

   a) off the shell, eviscerated abalone (chilled or frozen).

Annex XIII (contd)

   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 11.7.2. from a country, *zone* or *compartment* not declared free from *X. californiensis*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

— text deleted

Annex XIV

CHAPTER 7.4.

KILLING OF FARMED FISH FOR DISEASE CONTROL PURPOSES

EU Comment

The EU welcomes the draft chapter on Killing of farmed fish for disease controle purposes.

The EU encourages the OIE to further develop the chapter and to take into consideration the recommendation concerning farmed fish adopted by the Standing Committee of the European Convention for the protection of animals kept for farming purposes, article 19 on emergency killing.

Moreover, the EU would suggest OIE to consider also Annex IV to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes where acceptable methods for euthanisa also applicable in fish production are listed.

Specific EU comments are provided in the text.

Article 7.4.1.

Scope

These recommendations are based on the premise that a decision to kill the farmed fish has been made, and address the need to ensure the welfare of the farmed fish until they are dead.

The killing of individual farmed fish, in the course of farming operations (i.e. sorting, grading, or background morbidity) is out of the scope of this chapter.

Account should also be taken of the guidance given in the following chapters in the *Aquatic Code*: Chapter 4.4. Contingency planning, Chapter 4.6. Handling, disposal and treatment of aquatic animal waste, Chapter 5.4. Control of aquatic animal health risks associated with transport, Chapter 7.2. Welfare of farmed fish during transport and Chapter 7.3. Welfare aspects of stunning and killing of farmed fish for human consumption.

EU comment

In Article 7.4.1 this text should be added after the first sentence: *"If stunning or killing methods refered to in Chapter 7.3. Welfare aspects of stunning and killing of farmed fish for human consumption are used, the requirements in this Chapter should be applied."*

Justification:
It should be more clearly indicated that if methods refered to in Chapter 7.3 are used, the requirements in this Chapter should be applied even if the fish is not used for human consumption.

Article 7.4.2.

General principles

1. Contingency plans for disease control should be in place at a national level and should contain details of disease control strategies, managerial structure, and operational procedures. Fish welfare considerations should be addressed within such contingency plans for disease control;

2. Depending on the situation, emergency killing of fish may be carried on site or fish are transported to an approved killing facility;

EU comment

Point 2 of Article 7.4.2 should read: "*Depending on the situation, emergency killing of fish may be carried out on site or after fish are transported to an approved killing facility or other suitable location; moreover, provisions of Chapter 7.2 should be taken into account.*"

Justification:

The words "*out*" and "*after*" should be added for clarity reasons.

The text "*or other suitable location*" should be added to include other appropriate facilities for killing fish for diagnostic reasons.

3. Fish not suitable for human consumption may be killed by specific methods (e.g. chemical, mechanical), all of which should be included in contingency plans;

4. Fish suitable for human consumption, should be killed following the provisions provided in Chapter 7.3. Welfare aspects of stunning and killing of farmed fish for human consumption.

EU comment

In point 4 of Article 7.4.2 the word "*should* " should be replaced by "*may*"

Justification:

For biosecurity reasons it could be appropriate to kill fish on site even if the fish is suitable for human consumption

Article 7.4.3.

The following principles should apply when killing fish:

1. Operational procedures should be adapted to the specific operating circumstances on the premises and should address biosecurity and fish welfare;

2. killing of fish should be carried out without delay by appropriately qualified personnel with all due consideration made to increased biosecurity protocols;

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Annex XIV (contd)

3. the handling of fish should be minimised and when done, it should be done in accordance with the Articles described below;

4. methods used to kill the fish should result in immediate death or loss of consciousness lasting until death;

5. there should be continuous monitoring of the procedures to ensure they are consistently effective with regard to biosecurity and fish welfare;

6. standard operating procedures should be available and followed at the premises;

Article 7.4.4.

Operational guidelines

A plan for the killing of fish on affected premises due to disease control issues should be developed by the operator and approved by the *Competent Authority*, taking into consideration welfare and biosecurity requirements as well as safety of the personnel. Considerations should include:

1. minimising handling and movement of fish;

2. species, number, age, size of fish to be killed;

3. methods for killing the fish;

4. availability of chemicals/equipment needed to kill the fish;

5. biosecurity issues;

6. any legal issues that may be involved, for example, the use of controlled drugs or chemicals;

7. presence of other nearby aquaculture premises.

EU comment

In Article 7.4.4, the first sentence should be included as first bullet point:

"1. minimising time for fish spent out of water"

Justification:
Being out of water is a welfare issue.

Article 7.3.5.

EU comment

The article should be numbered "Article *7.4.5*"

Justification: Clarity

Competencies and responsibilities of the operational team

The operational team is responsible for the planning, implementation of, and reporting from the killing of the fish.

EU comment

In Article 7.4.5 the term "*operational team*" should be defined or explained

Justification:

Clarity

1. Team leader

    a) Competencies

        i) ability to assess fish welfare, especially relating to the effectiveness of the killing techniques selected and utilised in the fish killing operations, to detect and correct any deficiencies;

EU comment

In point 1. a) i) of Article 7.4.5 the words "*stunning and*" should be added before the word "*killing*"

Justification:

When appropriate, farmed fish should be stunned before killed, and the effectiveness of the

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stunning techniques should then be assessed.

ii) ability to assess biosecurity risks;

iii) skills to manage all activities on premises and deliver outcome on time;

iv) Awareness of the emotional impact on farmers, team members and general public;

v) effective communication skills.

Annex XIV (contd)

b) Responsibilities

i) determine most appropriate killing method(s) to ensure that the fish are killed without avoidable pain and distress which balance biosecurity considerations;

ii) plan overall operations on the affected premises;

iii) determine and address requirements for fish welfare, operator safety and biosecurity;

iv) organise, brief and manage a team of people to facilitate killing of the relevant fish in accordance with national contingency plans for disease control;

v) determine logistics required;

vi) monitor operations to ensure that fish welfare, operator safety and biosecurity requirements are met;

vii) report upwards on progress and problems;

viii) provide a written report summarising the killing, practices utilised in the operation and their effect on aquatic animal welfare and subsequent biosecurity outcomes. The report should be archived and be accessible for a period of time defined by the *Competent Authority*;

ix) review on-site facilities in terms of their appropriateness for mass destruction.

2. On-farm personnel responsible for killing of fish

a) Competencies

i) specific knowledge of fish, and their behaviour and environment;

ii) trained and competent in fish handling and killing procedures;

EU comment

In point 2. a) ii) of Article 7.4.5 the word "*, stunning*" should be added before the words "*and killing*"

Justification:

When appropriate, farmed fish should be stunned before killed.

iii) trained and competent in the maintenance of equipment.

b) Responsibilities

i) ensure humane killing of fish through effective killing techniques;

EU comment

In point 2. b) i) of Article 7.4.5 the words "*stunning and*" should be added before the word "*killing*"

Justification:

When appropriate, farmed fish should be stunned before killed.

i) assist team leader as required;

iii) design and construct temporary fish handling facilities, when required.

Article 7.4.6.

Chemical killing methods

1. Use of chemicals

a) chemicals used for killing fish should kill the fish effectively, not merely have an anaesthetic effect;

b) when using such chemicals, the operating personnel should ensure that the solution has the correct concentration, and that sea water is used for marine fish species and freshwater for freshwater species;

c) fish should be kept in the chemical solution until they are dead. Fish that are merely anaesthetised should be killed by another method such as bleeding, decapitation or another appropriate killing method;

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2. Advantages

   a) Large numbers of fish may be killed in one batch;

   b) handling is not required until fish are anaesthetised or euthanized;

   c) use of chemicals is a non-invasive technique and thus minimises biosecurity risks.

3. Disadvantages

   a) May need to be followed by killing if fish are only anaesthetised;

   b) some chemicals induce a panic reaction in the fish;

   c) care is essential in the preparation and provision of treated water, and in the disposal of water and/or fish carcasses that have been treated with anaesthetic agents.

Article 7.4.7.

Mechanical killing methods

1. Decapitation

   a) Decapitation, using a sharp device such as a guillotine or knife, may be used for killing fish but only following anaesthesia;

   b) the required equipment should be kept in good working order;

   c) contamination of the working area due to bleeding and body fluids may present a biosecurity risk and is the major disadvantage of this method.

2. Maceration

   a) Maceration by a mechanical device with rotating blades or projections causes immediate fragmentation and death in newly hatched *fish* and embryonated eggs, as well as fertilised/unfertilised eggs of *fish*. It is a suitable method for the processing of such material. The procedure results in rapid death and a large number of eggs/newly hatched fry can be killed quickly;

   b) maceration requires specialised equipment which should be kept in good working order. The rate of introducing material into the device should be such that the cutting blades continue to rotate at their fully functional rate and that they do not fall below the defined critical speed defined by the manufacturer;

   c) large fish should be introduced head first into the device;

EU comment

Point 2 c) of Article 7.4.7 are in contradiction to point 2 a), where maceration is told to cause immediate fragmentation and death only for newly hatched fish and eggs, and should be removed.

Justification:

Maceration without prior stunning should be used as a killing method only for newly hatched fish and eggs. Larger fish should be stunned before maceration, and it should be monitored that all fish are macerated before they recover or partially recover conciousness.

d) contamination of the working area due to bleeding and body fluids may present a biosecurity risk and is the major disadvantage of this method.

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Annex XV(A)

CHAPTER 2.1.2.

INFECTION WITH RANAVIRUS

EU comment

The EU can support the proposed chapter. However, the EU would like to draw the attention to point 2.2.1 on susceptible host species, refers to the family of urodele, whereas Article 8.2.2. of the OIE Code refers to caudata. Urodele and caudata appears to be synonyms, but a coherent language should be used to avoid unecessary confusion.

In first paragraph of point 4.3.1.2.1., the EU would propose that a reference is given to the following recent Article in addition to the Articles by Whittington, which both are of an older date:"Propagation and isolation of ranaviruses in cell culture

Aquaculture, Volume 294, Issues 3-4, 16 September 2009, Pages 159-164

Ellen Ariel, Nicole Nicolajsen, Maj-Britt Christophersen, Riikka Holopainen, Hannele Tapiovaara, Britt Bang Jensen"

1. Scope

For the purpose of this chapter, ranavirus disease is considered to be systemic clinical or subclinical infection with a member of the genus *Ranavirus.*

2. Disease information

2.1. Agent factors

2.1.1. Aetiological agent, agent strains

The genus *Ranavirus* in the Family Iridoviridae. The type species is Frog virus 3 (FV3) (Chinchar *et al.,* 2005). Other species include Bohle virus (BIV), Epizootic haematopoietic necrosis virus (EHNV), European catfish virus (ECV), European sheatfish virus (ESV) and Santee-Cooper ranavirus. There are many other tentative species in this genus. Since the recognition of disease due to EHNV in finfish in Australia in 1986, similar systemic necrotising iridovirus syndromes have been reported in amphibians. Ranaviruses have been isolated from healthy or diseased frogs, salamanders and reptiles in America, Europe and Australia (Chinchar, 2002; Drury *et al.,* 1995; Fijan *et al.,* 1991; Hyatt *et al.,* 2002; Speare & Smith, 1992; Wolf *et al.,* 1968; Zupanovic *et al.,* 1998b). Ranaviruses have large (150–180 nm), icosahedral virions, a double-

stranded DNA genome 150–170 kb, and replicate in both the nucleus and cytoplasm with cytoplasmic assembly (Chinchar *et al.,* 2005). They possess common antigens that can be detected by several techniques.

Species	*No. of isolates*	*Examples*	*Geographic source*
Ambystoma tigrinum virus	*2*	*Ambystoma tigrinum virus, Regina ranavirus*	*North America*
Bohle iridovirus	*1*	*Bohle iridovirus*	*Australia*
Frog virus 3	*12*	*Frog virus 3*	*Europe, North & South America*
		Box turtle virus 3	*Europe, North & South America*
		Bufo bufo United Kingdom virus	*Europe, North & South America*
		Bufo marinus Venezuelan iridovirus 1	*Europe, North & South America*
		Lucké triturus virus 1	*Europe, North & South America*
		Rana temporaria United Kingdom virus	*Europe, North & South America*
		Redwood Park virus	*Europe, North & South America*
		Stickleback virus	*Europe, North & South America*
		Tadpole edema virus	*Europe, North & South America*
		Tadpole virus 2	*Europe, North & South America*
		Tiger frog virus	*Europe, North & South America*
		Tortoise virus 5	*Europe, North & South America*
Tentative species	*3*	*Rana esculenta iridovirus*	*Europe, North & South America*
		Testudo iridovirus	*Europe, North & South America*

2.1.2. Survival outside the host

All ranaviruses are probably extremely resistant to drying; EHNV can survive for months in water, in frozen fish tissues for more than 2 years (Langdon, 1989), and in frozen fish carcases for at least a year (Whittington *et al.,* 1996). Santee-Cooper ranavirus remains viable in frozen fish tissues for at least 155 days (Plumb & Zilbert, 1999). Less is known about other ranaviruses, but given their similarity to EHNV they are presumed to have comparable stability. ATV was infectious for salamanders if present in moist but not dry pond sediment, but the duration of infectivity is unknown.

2.1.3. Stability of the agent (effective inactivation methods)

Ranaviruses (as exemplified via EHNV) are susceptible to 70% ethanol, 200 mg litre^{-1} sodium hypochlorite or heating to 60°C for 15 minutes (19). If desiccated first, EHNV may survive heating to 60°C for 15 minutes (unpublished observations). 10^7 plaque-forming units per ml of a ranavirus of amphibian origin was inactivated within 1 minute in a solution of 150 mg litre^{-1} chlorhexidine (0.75% Nolvasan ®), 180 mg litre^{-1} sodium hypochlorite (3% bleach) or 200 mg litre^{-1} potassium peroxymonosulfate (1% Virkon ®) (Bryan *et al.,* 2009).

2.1.4. Life cycle

The route of infection is unknown but amphibians are susceptible experimentally following bath exposure injection and or exposure following laboratory induced abrasions. (Cunningham *et al.,* 2007; 2008).

2.2. Host factors

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2.2.1. Susceptible host species
Natural ranavirus infections are known from most of the major families of Anura and Urodele (Carey *et al.* 2003a; 2003b; Cullen & Owens, 2002; Daszak *et al.,* 2003).

2.2.2. Susceptible stages of the host
Susceptible stages of the host are all age classes, larvae, metamorphs and adults.

2.2.3. Species or sub-population predilection (probability of detection)
Not known.

2.2.4. Target organs and infected tissue
Amphibian target organs and tissues infected with ranaviruses may vary. Three examples are given: i) BIV: liver, kidney, spleen, lung and other parenchymal tissues (Cullen & Owens, 2002). ii) FV-3 infects proximal tubular epithelial cells in the kidney, the liver, and the gastrointestinal tract (Robert *et al.,* 2005). iii) United Kingdom ranavirus (RUK) infects epithelial cells, fibroblasts, lymphocytes, melanomacrophages and a small proportion of endothelial cells in many tissues, as well as hepatocytes and Kuppfer cells in the liver, the epidermis and dermis (Cunningham *et al.,* 2008). *Ambystoma tigrinum virus* is found in skin, spleen, liver, renal tubular epithelial cells, and lymphoid and haematopoietic tissues of salmanders.

2.2.5. Persistent infection with lifelong carriers
Not known.

2.2.6. Vectors
Amphibians can become infected in the same way as fish and, as such, details associated with EHNV are included here. Possible vectors include nets, boats and other equipment, or in amphibians used for bait by recreational fishers. Birds are potential mechanical vectors, as ranaviruses can be carried in the gut, on feathers, feet and the bill. It should be noted that ranaviruses are likely to be inactivated at typical avian body temperatures (40–44°C). Nevertheless, it is possible that ranaviruses (as evidenced by EHNV) can be spread by regurgitation of ingested material within a few hours of feeding is possible (Whittington *et al.,* 1996). In addition amphibians have been shown to be infected by exposure to sediment from sites where ranavirus die-offs have occurred.

2.2.7. Known or suspected wild aquatic animal carriers
Not known.

2.3. Disease pattern

2.3.1. Transmission mechanisms
Ranavirus infections can occur from animal-to-animal contact, ingestion of infected, dying and dead individuals. Viruses can be spread between widely separated river systems and impoundments. Transmission is understood to occur by means other than water (refer above); mechanisms include translocation of live fish or bait by recreational fishers.

2.3.2. Prevalence
Ranavirus infections have been reported on five continents (Gray *et al.*, 2009); its prevalence, based on intensive widespread serosurveillance, antigen detection, is not known.

2.3.3. Geographical distribution

Ranaviruses have been recovered from free-living or farmed, healthy or diseased frogs in America, continental Europe, the United Kingdom and Asia (Chinchar, 2002; Cunningham *et al.*, 1996; Drury *et al.*, 1995; Fijan *et al.*, 1991; Fox *et al.*, 2006; He *et al.*, 2002; Wolf *et al.*, 1968; Zhan *et al.*, 2001; Zupanovic *et al.*, 1998b) as well as diseased free-living spotted salamanders Ambystoma maculatum in North America (Docherty *et al.*, 2003; Jancovich *et al.*, 2003). Bohle iridovirus (BIV), which is distinct from FV-3, was isolated originally from diseased ornate burrowing frog *Limnodynastes ornatus* tadpoles in far north Queensland, Australia (Speare & Smith, 1992). It has not been isolated since, although there is serological evidence of ranavirus infection in cane toads *Bufo bufo* in that region (Whittington *et al.*, 1996). Another distinct species of ranavirus, Ambystoma tigrinum virus (ATV), is responsible for die-offs in the tiger salamander *A. tigrinum* (Jancovich *et al.*, 2005). Viruses closely related to FV-3 have also been recovered from reptiles. Wamena iridovirus (WIV) was isolated in Australia from diseased green pythons *Chondropython viridis* smuggled from West Papua (Irian Jaya) while THIV (TV-CH8) was recovered from diseased Hermann's tortoises *Testudo hermanni* in Europe. Both WIV and THIV had >97% nucleotide sequence homology with FV-3 in the regions of MCP that were examined (Hyatt *et al.*, 2002; Marshang *et al.*, 1999).

2.3.4. Mortality and morbidity

Mortality and morbidity vary from species to species. Laboratory infections show that >75–100% of infected animals of an experimental group following short infection times (Harp & Petranka, 2006; Pearman *et al.*, 2004) However other experiments involving different host species and ranaviruses gave variable results (Brunner *et al.*, 2004; 2007; Cunningham *et al.*, 2007).

2.3.5. Environmental factors

Natural epizootics of amphibian ranaviruses appear to be similar for piscinine iranaviruses (e.g. EHNV). Epizootics appears to be seasonal and can be related to poor husbandry (captive populations) and overcrowding (wild and captive). It has been assumed that for some amphibians such as salamanders (references) disease is related to the annual appearance of large numbers of non-immune young animals and their subsequent exposure to the virus in shallow waters (Brunner *et al.*, 2004; 2007; Greer & Collins, 2008; Greer *et al.*, 2008; Jancovich *et al.*, 1997; 2001; Rojas *et al.*, 2005).

2.4. Control and prevention

2.4.1. Vaccination

None available.

2.4.2. Chemotherapy

None available.

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2.4.3. Immunostimulation
Not tested.

2.4.4. Resistance breeding
Not tested.

2.4.5. Restocking with resistant species
Not tested.

2.4.6. Blocking agents
Not tested.

Annex XV(A) (contd)

2.4.7. Disinfection of eggs and larvae
Not tested.

2.4.8. General husbandry practices
Not tested.

3. Sampling

3.1. Selection of individual specimens

A simple method for preparation of tissues for cell culture and enzyme-linked immunosorbent assay (ELISA) has been validated in fish (Whittington & Steiner, 1993; Whittington *et al.*, 1999).

Bath large amphibians for 30 seconds in 70% ethanol; bath small amphibians for 5 seconds in 70% ethanol then rinse in sterile water. Dissect aseptically in a Class II biosafety cabinet.

Large amphibians: (*>60 mm length*) remove 0.1 g liver, kidney, spleen (± other organs in specific situations) and place in sterile 1.5 ml tubes. Tubes suitable for use with pestles for grinding tissues (see below) are available, but standard 1.5 ml tubes may be suitable. In some situations liver, kidney and spleen may be pooled in a single tube (see section 3.3).

Medium amphibian (*30–60 mm length*): scrape all viscera into the tube.

Small amphibian (*<30 mm length*): remove head and tail, place rest of animal into the tube.

3.2. Preservation of samples for submission

For cell culture and ELISA, freeze tubes containing tissues at from –20°C to –80°C until needed.

For light microscopic examination, fix tissues in 10% neutral buffered formalin.

3.3. Pooling of samples

The effect of pooling tissues from multiple animals on the sensitivity of diagnostic tests has not been evaluated. However, tissues for virus isolation are commonly pooled in lots of 5 or 10 individuals per test.

3.4. Best organs or tissues

Liver, kidney, spleen, lung, skin.

3.5. Samples/tissues that are not appropriate

Inappropriate tissues include gonads, gonadal fluids, milt and ova, since there is no evidence of reproductive tract infection and broodstock are not known to participate in an infection cycle.

4. Diagnostic methods

4.1. Field diagnostic methods

4.1.1. Clinical signs

There are two syndromes in frogs associated with ranavirus infection: a chronic ulcerative syndrome and an acute haemorrhagic syndrome (Cunningham *et al.*, 1996). Salmanders infected with *Ambystoma tigrinum* virus develop ulcerative dermatitis and enteritis. Affected larvae have small multifocal haemorrhages affecting subcutaneous tissue on the plantar surface of feet, the inguinal area, and the vent area, with ventral oedema and the skin may contain pale foci (Bollinger *et al.*, 1999; Docherty *et al.*, 2003).

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4.1.2. Behavioural changes

Field and behaviour changes differ between species, life stage and severity of disease. Changes include lordosis, erratic swimming, lethargy and loss of equilibrium (Gray *et al.*, 2009).

4.2. Clinical methods

4.2.1. Gross pathology

There may be no gross lesions or nonspecific lesions. There are two syndromes in frogs associated with ranavirus infection: ulcerative syndrome and haemorrhagic syndrome (Cunningham *et al.*, 1996). In salmanders infected with *Ambystoma tigrinum* virus there may be ulcerative dermatitis, pale foci in the skin, small multifocal haemorrhages affecting subcutaneous tissue on the plantar surface of feet, the inguinal area, the vent, the subserosal surface of the intestine, and the liver may be pale and swollen; there may be ventral oedema (Bollinger *et al.*, 1999; Docherty *et al.*, 2003).

4.2.2. Clinical chemistry

Not applicable.

4.2.3. Microscopic pathology

BIV and FV3 cause multifocal multi-organ haemorrhage and necrosis (Cullen & Owens, 2002; Robert *et al.*, 2005). Salmanders infected with *Ambystoma tigrinum* virus develop necrosis in many tissues including spleen, liver, renal tubular epithelial cells, and lymphoid and haematopoietic tissues (Bollinger *et al.*, 1999). Amphophilic intracytoplasmic inclusion bodies may be present in cells in many organs together with single cell or variable sized areas of focal necrosis (Bollinger *et al.*, 1999; Docherty *et al.*, 2003). In skin there may be foci of spongiosis and ballooning degeneration, erosion and ulceration and hyperplasia of epidermal epithelial cells which may have intracytoplasmic inclusion bodies (Bollinger *et al.*, 1999).

4.2.4. Wet mounts

Not applicable.

4.2.5. Smears

Not tested.

4.2.6. Fixed sections

Text

4.2.7. Electron microscopy/cytopathology

Affected tissues (e.g. kidney liver and spleen) contain cells exhibiting necrosis. Cells contain conspicuous cytoplasmic inclusions that are rarefied areas of the cytoplasm in which the viruses are assembled. Within the cytoplasm, aggregates (paracrystalline arrays) of large (175 nm ± 6 nm) non-enveloped icosahedral viruses are apparent; single viruses are also present. Complete viruses (containing electron-dense cores) bud/egress from the infected cells through the plasma membrane. The nuclei of infected cells are frequently located peripherally and are distorted in shape.

4.3. Agent detection and identification methods

4.3.1. Direct detection methods

4.3.1.1. Microscopic methods

Light microscopy: routine methods can be used for tissue fixation in 10% buffered neutral formalin, paraffin embedding, preparation of 10 µm sections and staining with H&E to demonstrate tissue necrosis and basophilic intracytoplasmic inclusion bodies. These inclusion bodies are indicative but not confirmatory for ranavirus. Formalin-fixed paraffin-embedded sections can also be stained using an immunoperoxidase method (see below) to identify ranavirus antigen associated with necrotic lesions.

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Electron microscopy: Ultrathin routine sectioning methods can be used for preparation of tissues and cell cultures (Eaton *et al.*, 1991) to demonstrate tissue necrosis, presence of viruses and virus inclusion bodies. Tissues and cells fixed with an alternative fixation and embedding regime can be used for antigen detection (Hyatt, 1991).

Negative contrast electron microscopy: supernatants from dounce homogenised tissues (10% [w/v]) and cell cultures can be used to detect viruses. Ranaviruses have a definitive appearance. They vary in diameter (150–180 nm) and have a limiting cell-derived (plasma membrane) envelope that surrounds a capsid of skewed symmetry. Underlying the capsid is a *de novo* membrane that itself surrounds a core containing the double-stranded (ds) DNA and minor proteins. These preparations can also be used to confirm ranavirus antigenicity (Eaton *et al.*, 1991).

4.3.1.1.1. Wet mounts

Not applicable.

4.3.1.1.2. Smears

Not applicable.

4.3.1.1.3. Fixed sections

See Section 4.3.1.1 on microscopic methods.

4.3.1.2. Agent isolation and identification

4.3.1.2.1. Cell culture/artificial media

Preparation of amphibian tissues for virus isolation and ELISA

A simple method for preparation of tissues for cell culture and ELISA has been described (Whittington & Steiner, 1993; Whittington *et al.*, 1999) (see sampling Section 3.1).

i) Freeze tubes containing tissues at –80°C until needed.

ii) Add 0.5 ml of homogenising medium (minimal essential medium Eagle, with Earle's salts with glutamine [MEM] with 200 International Units [IU] ml^{-1} penicillin, 200 µg ml^{-1} streptomycin and 4 µg ml^{-1} amphotericin B) to each tube. Grind tissue to a fine mulch with a sterile fitted pestle.

iii) Add another 0.5 ml of homogenising medium to each tube and mix with a pestle.

iv) Add three sterile glass beads to each tube (3 mm diameter) and close the lid of the tube.

v) Vortex the suspension vigorously for 20–30 seconds and place at 4°C for 2 hours.

vi) Vortex the suspension again as above and centrifuge for 10 minutes at 2500 ***g*** in a benchtop microcentrifuge.

vii) Transfer the supernatant, now called clarified tissue homogenate, to a fresh sterile tube. Homogenates may be frozen at –80°C until required for virus isolation and ELISA.

Cell culture/artificial media

Cell culture is the gold-standard test but is costly and time consuming. Ranaviruses grow well in many fish cell lines including BF-2 (bluegill fry ATCC CCL 91), FHM (fathead minnow; ATCC CCL 42), EPC (e*pithelioma papulosum cyprini* [Fijan *et al.*, 1983]), and CHSE-214 (Chinook salmon embryo cell line; ATCC CRL 1681) at temperatures ranging from 15 to 22°C (Crane *et al.*, 2005), but BF-2 are preferred by the Reference Laboratory where an incubation temperature of 22°C both before and after inoculation with virus is used. The procedure for BF-2 cells is provided below. A procedure for CHSE-214 cells is provided under immunoperoxidase staining below (see Section 4.3.1.2.2). *Ambystoma tigrinum* virus produces CPE like that of EHNV in FHM, RTG and bullfrog tongue cells at 25°C (Docherty *et al.*, 2003). Others have used frog embryo fibroblasts at 27°C or FHM cells to isolate or propagate the United Kingdom isolates of FV-3 (Cunningham *et al.*, 1996, 2007).

The identity of viruses in cell culture is determined by immunostaining, ELISA, immuno-electron microscopy, polymerase chain reaction (PCR) or other methods.

Samples: tissue homogenates.

Cell culture technical procedure: cells are cultured (in flasks, tubes or multi-well plates) with growth medium (MEM + 10% fetal calf serum [FCS] with 100 IU ml^{-1} penicillin, 100 µg ml^{-1} streptomycin and 2 µg ml^{-1} amphotericin B). The cells are incubated until almost confluent at 22°C, which can take up to 4 days depending on the seeding rate. Medium is changed to a maintenance medium (MEM with 2% FCS and 100 IU ml^{-1} penicillin, 100 µg ml^{-1} streptomycin and 2 µg ml^{-1} amphotericin B) on the day of inoculation. A 1/10 dilution using homogenising medium is made of single or pooled homogenates. Each culture is inoculated with 100 µl of sample per ml of culture medium. This represents a 1/100 dilution of a 0.1 mg ml^{-1} tissue homogenate. One culture is inoculated with undiluted homogenate, and two with 1/10 homogenate. No adsorption step is used. As an alternative, two to three cultures can be inoculated directly with 10 µl undiluted homogenate per ml of culture medium. Note that a high rate of cell toxicity or contamination often accompanies the use of a large undiluted inoculum. The cultures are incubated at 22°C in an incubator for 6 days. Cultures are read at day 3 and day 6. Cultures are passed at least once to detect samples with low levels of virus. On day 6, the primary cultures (P1) are frozen overnight at –20°C, thawed, gently mixed and then the culture supernatant is inoculated onto fresh cells as before (P2), i.e. 100 µl P1 supernatant per ml culture medium. Remaining P1 supernatants are transferred to sterile 5 ml tubes and placed at 4°C for testing by ELISA or PCR or another means to confirm the cause of cytopathic effect (CPE) as EHNV. P2 is incubated as above, and a third pass is conducted if necessary.

Interpretation of results

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CPE is well developed and consists of focal lysis surrounded by rounded granular cells. This change extends rapidly to involve the entire monolayer, which detaches and disintegrates.

4.3.1.2.2. Antibody-based antigen detection methods

It should be noted that antibodies used in all related methods (immunoperoxidase, antigen-capture ELISA and immunoelectron microscopy) cross-react with all known ranaviruses (Hyatt *et al.*, 2000).

4.3.1.2.2.1. Detection of ranaviruses using immunoperoxidase staining of infected cell cultures

Principle of the test: ranaviruses replicate within cultured cells. The addition of a mild detergent permeabilises the cells allowing an affinity purified rabbit antibody to bind to intracellular viral proteins. Raanvirus is detected by a biotinylated anti-species antibody and a streptavidin–peroxidase conjugate. The addition of a substrate results in 'brick-red' staining in areas labelled with antibodies.

Samples: tissue homogenates.

Operating characteristics: when performed as described in this protocol, the staining is conspicuous and specific. However, the test has not been validated with respect to sensitivity or reproducibility.

Preparation of cells: the procedure described below is for CHSE-214 cells. Other recommended cell lines can also be used.

i) CHSE-214, 24-well plates are seeded the day before use with 250,000 cells/well (or 4 million cells in 40 ml of growth medium per plate) in 1.5 ml of growth medium (Earle's MEM with non-essential amino acids [EMEM], 10% FCS, 10 mM N-2-hydroxyethyl-piperazine-N-2-ethanesulfonic acid [HEPES], 2 mM glutamine, 100 IU penicillin and 100 µg streptomycin) and incubated in 5% CO_2 at 22°C overnight. (Note: cultures must be nearly confluent and have healthy dividing cells prior to use.)

ii) Discard the medium, inoculate each well with 150 µl of a 10% suspension of ground tissue (e.g. liver, kidney or spleen), incubate for 1 hour (22°C) then add 1.5 ml of fresh maintenance medium (as for growth medium except 2% FCS) and return to the incubator (22°C).

iii) Observe cultures for CPE. If no CPE occurs by day 10, pass the cultures on to fresh CHSE cells by collecting the cells and medium and adding 150 µl to the cells of the fresh plate; note that cells are not freeze–thawed. There is no need to discard the existing medium, just return the new plate to the incubator (22°C). Again, observe daily for CPE.

iv) Fix cells (add 50 µl for 96-well plate cultures with 200 µl culture medium/well or 400 µl (for 24-well plate cultures with 1.6 ml culture medium/well) of a 20% formalin solution to each well), without discarding the culture medium when CPE is first observed. After incubation (22°C) for 1 hour at room temperature (RT), the medium/formalin mixture is discarded and the wells are rinsed twice with PBS-A (phosphate buffered saline, Ca^{++} and Mg^{++} free) to remove the formalin. More PBS-A is added if the plates are to be stored at 4°C.

Protocol

i) Dilute primary anti-EHNV antibody and normal serum to working strength as described below (fixation protocol for immunocytochemistry) for the relevant agent in 1% skim milk (SM) solution (PBS-A (SM)) to the volume required for the test.

ii) Remove PBS-A from wells (with fixed cell cultures) and wash wells twice with 0.05% (v/v) PBS/Tween 20 (PBST). Add 50 µl of primary antibody solutions to each well in a 96-well plate well or 200 µl in a 24-well plate well. Incubate on a plate shaker at 100–200 rpm at RT (22–24°C) for 15–30 minutes or without shaking at 37°C for 1 hour.

iii) Dilute biotinylated anti-species serum (secondary antibody) in 0.1% SM solution as described in the fixation protocol (below) for the relevant agent to the volume required for the test.

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iv) Remove primary antibody solution and wash wells three times with PBST. Add secondary antibody to all wells. Incubate on a plate shaker at 100–200 rpm at RT for 15–30 minutes or without shaking at 37°C for 1 hour.

v) Dilute streptavidin–peroxidase conjugate in 0.1% SM solution for the relevant agent to the volume required for the test.

vi) Remove secondary antibody from wells and wash wells three times with PBST. Add conjugate to each well. Incubate on a plate shaker at 100–200 rpm at RT for 15–30 minutes or without shaking at 37°C for 1 hour.

vii) Prepare stock substrate of 3-amino-9-ethylcarbazole (AEC) solution: dissolve one AEC tablet (20 mg) in 2.5 ml of dimethyl formamide.

viii) Remove conjugate from wells. Wash (three times) with PBST.

ix) Dilute dissolved AEC stock in 47.5 ml of acetate buffer (4.1 ml anhydrous sodium acetate in 1 litre of de-ionised water; the pH is adjusted to 5.0 with glacial acetic acid). Just before use, add 25 µl 30% hydrogen peroxide to AEC solution then add to each well. Incubate at RT for 20 minutes.

x) Remove substrate solution and wash wells twice with deionised water to stop reaction.

xi) To visulise all cells counterstain with Mayer's haematoxylin (50 µl/well or 200 µl/well) for 1 minute and rinse with deionised water.

xii) Add 50 µl Scott's tap water and rinse with deionised water and air dry.

Interpretation of the results

Positive reaction: granular-like, focal, brick-red staining of cells indicates presence of virus identified by the diagnostic antibody.

Negative reaction: no red staining apparent – all cells should be stained pale blue due to counterstain.

Background staining: non-granular, non-focal, more generalised, pale, pinkish staining may occur throughout the culture. This background staining could be caused by any number of reasons, e.g. non-specific antibody reaction with non-viral components, inefficient washing, and expiration of other reagents.

Reagents for immunocytochemistry tests

20% Formaldehyde (*PBS-A*) *saline*

Formalin (36–38% formaldehyde)	54 ml
Distilled water	36 ml
10 × PBS-A	10 ml

10 × PBS-A

To make up 1 litre of 10 × PBS-A use:

NaCl	80.0 g
Na_2HPO_4	11.5 g
KCl	2.0 g
KH_2PO_4	2.0 g
Distilled water	1.0 litre

NOTE: some salts are supplied with extra water groups. If using these reagents adjust the masses to ensure the appropriate mass of salt is added, e.g. for $Na_2HPO_4.2H_2O$ add 15 g instead of 11.5 g (156 mw/120 mw × 11.5 g = 14.95 g) to remove the effect of the water molecules.

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4.3.1.2.2.2 Detection of ranavirus using antigen-capture ELISA

Antigen-capture ELISA has been validated to detect EHNV in cell cultures and directly in fish tissue homogenates. The same assay can be applied to amphibian tissues. The analytical sensitivity is 10^3 to 10^4 $TCID_{50}$ ml^{-1}. Specificity approaches 100% and sensitivity for direct detection in fish tissues is 60% relative to the gold standard of virus isolation in BF-2 cells (Drury *et al.*, 1995; Marsh *et al.*, 2002; and unpublished data). ELISA is useful for both diagnosis and certification. Neutralisation tests cannot be used to identify EHNV because neutralising antibodies are not produced following immunisation of mammals or fish. Mouse monoclonal antibodies produced against EHNV are directed against major capsid protein (MCP) epitopes and are non-neutralising (unpublished data). Rabbit-anti-EHNV antibodies have been developed for use in antigen-capture ELISA, immunoperoxidase staining and immunoelectron microscopy (Hengstberger *et al.*, 1993; Hyatt *et al.*, 1991; Reddacliff & Whittington, 1996). Reagents and protocols are available from the reference laboratory.

Samples: tissue homogenate samples prepared using a validated protocol (see below), and cell cultures.

Principle of the test: EHNV particles are captured from the sample by an affinity purified rabbit antibody that is coated to the plate. EHNV is detected by a second antibody and a peroxidase-labelled conjugate using the chromogen ABTS (2,2'-azino-di-[3-ethyl-benzthiazoline]-6-sulphonic acid). The enzyme is inactivated after 20 minutes and the resulting optical density (OD) is compared with standards.

Test components and preparation of reagents

i) Flat bottom microtitre plates are required.

ii) Affinity purified rabbit anti-EHNV immunoglobulin and sheep anti-EHNV antiserum reagents are supplied in freeze-dried form. Reconstitute using 1 ml of purified water and allow the vial to stand at RT for 2 minutes. Mix the vial very gently. These reagents are stable when stored at –20°C for at least 4 years. For routine use in ELISA, it is recommended that working stocks of both antibodies be prepared as a 1/10 dilution in tris saline glycerol merthiolate TSGM (formula at end of this section). These are stable at –20°C for at least 5 years and do not solidify at this temperature.

iii) The peroxidise labelled anti-sheep immunoglobulin conjugate (commercial reagent, KPL #14-23-06; 0.5 mg) is supplied as a freeze-dried powder. This reagent has displayed remarkable consistency in activity between different lots over a period of 15 years. The product should be reconstituted in sterile 50% glycerol water, dispensed in 150 µl aliquots and stored at –20°C as undiluted stock. A working stock is prepared by adding 900 µl of TSGM to 100 µl of undiluted stock. The working stock is also stored at –20°C and is stable for at least 1 year. New batches of this conjugate should be titrated against an older batch using standard protocols.

iv) EHNV control antigen, heat-inactivated, is supplied as freeze-dried powder. Reconstitute in 1 ml sterile water and store in small aliquots at –20°C. Prepare dilutions using PBSTG (PBS + Tween + gelatin) on the same day the test is performed. Control EHNV antigen dilutions (A, B, D and F) cover the range of the signal response of the assay and enable a normalisation procedure to be undertaken.

Equipment

An automatic plate washer is recommended although plates can be washed by hand. The assay is sensitive to plate washing conditions. If the OD of the controls is unexpectedly low, and the conjugate and other reagents are within date, the plate washer should be adjusted so that washing pressure during filling of wells and aspiration of wells is minimised.

An automatic plate reader is recommended although plates can be read by eye.

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Precision calibrated pipettes (e.g. Gilson) should be used to prepare dilutions of all reagents and to load reagents into microtitre plate wells.

Protocol

i) Coat a 96-well ELISA plate (100 µl well^{-1}) with affinity purified rabbit-anti-EHNV diluted 1/12,800 in borate coating buffer. Incubate overnight at 4°C.

ii) Wash plate five times with wash buffer (Milli-Q (MQ) purified water plus 0.05% Tween 20). Note that distilled and deionised water can also be used in this and all other steps.

iii) Prepare a blocking solution: warm the solutions in a microwave oven or water bath to dissolve the gelatin, then cool to RT.

iv) Block remaining binding sites using blocking solution (100 µl well^{-1}) (1% [w/v] gelatin in PBSTG diluent [PBS, 0.05% (v/v) Tween 20, 0.1% (w/v) gelatin]). Incubate at RT for 30 minutes.

v) Wash plate five times as above.

vi) Work in a Class II biological safety cabinet. Dilute the control antigen (see below) in PBSTG and add to the lower right-hand corner of the plate. Add tissue homogenate samples or culture supernatant samples and control antigens at 100 µl/well. All samples and controls are added to duplicate wells. Incubate for 90 minutes at RT.

The control antigens are dilutions of a heat killed cell culture supernatant of EHNV 86/8774. The controls are expected to give the following OD, although there will be some variation from laboratory to laboratory and ±10% variation should therefore be allowed:

Control	Dilution in PBS*	OD (405 nm)*
A	1/5	>2.0
B	1/40	1.90
D	1/200	0.68
F	1/3000	0.16

* These dilutions and OD values are determined by the OIE Reference Laboratory for EHNV and will vary with the batch of control antigen. The values above are for batch 86/8774-4-5-01. The positive-negative cut-off for clarified tissue homogenate samples from redfin perch and rainbow trout in this ELISA is approximated by the OD value of control D on each plate.

vii) Wash the plate by hand to avoid contamination of the plate washer. Work in a Class II cabinet. Aspirate wells using a multichannel pipette. Rinse the plate twice.

viii) Wash the plate five times on the plate washer, as above.

ix) Add the second antibody sheep-anti-EHNV diluted 1/32,000 in PBSTG (100 µl well^{-1}). Incubate for 90 minutes at RT.

x) Wash the plate five times on the plate washer.

xi) Add the conjugate diluted 1/1500 in PBSTG (100 µl well^{-1}). Incubate for 90 minutes at RT.

xii) Wash the plate five times on the plate washer.

xiii) Add ABTS substrate (22 ml ABTS + 10 µl H_2O_2) (100 µl well^{-1}) and place the plate on a plate shaker. Time this step from the moment substrate is added to the first wells of plate 1. Incubate for 20 minutes.

xiv) Immediately add ABTS stop solution (50 µl well^{-1}), shake the plate briefly and read OD at 405 nm. Calculate mean ELISA OD of duplicate wells. Calculate the coefficient of variation of the

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duplicates: samples with CV >15% should be retested if the mean OD lies near the positive–negative cut-off.

Normalisation of data and decision limit quality control

If it is desired to normalise data from plate to plate and over time, or to undertake decision limit quality control, the following procedure can be followed. Run control antigens in ELISA on at least five occasions over a period of 3 weeks (a total of 20 separate ELISA plates). Calculate the mean OD for each control antigen. Then, for each plate subsequently used, calculate a plate correction factor (PCF) as follows:

PCF = (mean OD control A/actual OD + mean OD control B/actual OD + mean OD control D/actual OD + mean OD control F/actual OD)/4. Multiply the actual mean OD of each sample by the PCF for that plate and report these values.

PCF is allowed to vary between 0.8 and 1.2, which approximates to a coefficient of variation of 10%. Values outside this range suggest that a plate needs to be retested. Plots of PCF over time provide a ready means for monitoring the stability of reagents, procedural variations and operator errors. This QC method has been validated for antigen capture ELISA.

Buffers and other reagents

Borate coating buffer

Boric acid	6.18 g
Disodium tetraborate ($Na_2B_4O_7.10H_2O$)	9.54 g
NaCl	4.38 g
MQ water to	1 litre

Autoclave

10 × phosphate buffered saline

NaCl	80.00 g
KCl	2.00 g
Na_2HPO_4	11.50 g
KH_2PO_4	2.00 g
MQ water to	900 ml

Adjust pH to 7.2 with HCl or NaOH; make up to 1 litre
Autoclave

For working strength dilute 1/10 and recheck pH.
For storage of powder in jars, make up twice the above quantity of powder; store; to make up add 1.8 litres MQW, pH, make up to 2 litres.

ABTS

Citrate phosphate buffer

Citric acid	21.00 g
Na_2HPO_4	14.00 g

MQ water to 800 ml; adjust pH to 4.2; make up to 1 litre

ABTS	0.55 g
Citrate phosphate buffer to	1 litre

Dispense in 22-ml aliquots and freeze.
Immediately prior to use add 10 µl H_2O_2 per 22-ml aliquot.

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ABTS stop solution (0.01% NaN_3 in 0.1 M citric acid)

Citric acid	10.5 g
MQW to	500 ml
Add 50 mg sodium azide or 1 ml of 5% solution.	

KPL Conjugate #14-23-06[1]

TSGM cryoprotectant

10 × Tris/saline, pH 7.4	50 ml
Glycerol	250 ml
Sterile purified water to	500 ml
Autoclave	
Add 10% Merthiolate	1 ml
Store in dark bottle at 4°C.	

1 Reagent Supplier: Bio-Mediq DPC Australia, P.O. Box 106, Doncaster, Victoria 3108, Australia; Tel.: (+61-3) 9840 2767; Fax: (+61-3) 9840 2767. Visit: www.kpl.com for links to worldwide network distributors

10 × Tris/saline (250 mM Tris, 1.5 M NaCl)

Tris	15.14 g
NaCl	43.83 g
Sterile purified water	500 ml
pH adjust to	7.4

4.3.1.2.2.3. Immunoelectron microscopy

Gold-labelling of sections containing tissues or cell cultures

Principle of the test: cell cultures, tissues and/or tissue homogenates can be used for examination by electron microscopy. Conventional electron microscopy (examination of ultra-thin sections) will generate data on virus structure and morphogenesis. Negative contrast electron microscopy will produce images that can be used to examine the particulate structure of the virus. The use of ranavirus-specific antibodies and conjugated gold with these preparations permits both ultrastructure and antigenicity to be examined (Hyatt, 1991). These collective data enable classification to the genus Ranavirus.

Cell cultures and tissues

i) Fix tissues or cell cultures as described in Hyatt (1991). Briefly, 2.5% (v/v) buffered glutaraldehyde (cacodylate or phosphate) is used to fix cells for 40 minutes. Following primary fixation the cells are rinsed in the same buffer (3 × 20 minutes), post-fixed in 1% (w/v) buffered osmium tetroxide (1 hour), washed (3 × 5 minutes) in double-distilled/reverse osmosis (RO) water, dehydrated through graded alcohol (70–100%) and infiltrated and embedded in an epoxy resin (e.g. Spurrs or epon). For gold labelling of ultra-thin resin sections, attention must be given to fixation and embedding regimes. For example, cells should be fixed in 0.25% (v/v) glutaraldehyde with 2–4% paraformaldehyde. No secondary fixation is used and the cells are infiltrated and embedded in an acrylic resin such as LR White.

ii) Following fixation and embedding, cut and transfer ultrathin sections onto filmed nickel grids.

iii) Cut sections from the appropriate blocks.

iv) Block in 2% (w/v) skim milk powder in PBS-A (10 minutes).

v) Block free aldehydes with 0.1 M glycine in PBS-A (20 minutes).

vi) Wash in PBS-A (3 × 1 minutes). This is an optional step used only if there is an excess of free aldehydes (a high background may be indicative of this).

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vii) If protein A-gold is not being used then block in normal species serum – this serum should be homologous to that complexed to gold. Recommended dilution is approximately 1/40 (10 minutes).

viii) Incubate in primary antibody. If incubation details are unknown then perform initial reactions with 1/100 to 1/2700 dilutions (with three-fold dilutions). Dilute antibodies in 1% (v/v) cold water fish gelatin in PBS-A, (60 minutes, RT).

ix) Rinse in 1% (v/v) coldwater fish gelatin in PBS-A, (6 × 3 minutes).

x) Incubate in gold-labelled secondary antibody or protein A-gold or protein G-gold. Suggested dilution 1/40 in a PBS-A containing 1% (w/v) bovine serum albumin (BSA), 0.1% (v/v) Tween 20 and 0.1% (v/v) Triton X, 60 minutes, RT.

xi) Rinse in PBS-A (6 × 3minutes, RT).

xii) Post-fix in 2.5% (v/v) glutaraldehyde in PBS-A (5 minutes, RT).

xiii) Rinse in water (RO) (3 × 3 minutes, RT).

xiv) Dry on filter paper (type not critical).

xv) Stain in uranyl acetate and lead acetate.

Interpretation of results

Viruses within the cytoplasm of infected cells will be specifically gold-labelled. Viruses will be located singularly, within assembly bodies (inclusion bodies) and within paracrystalline arrays.

Gold-labelling of virus particles (*viruses adsorbed to grids*)

i) Dounce homogenise 10% (w/v) liver, kidney or spleen and clarify (5 minutes, 2500 ***g***).

ii) Adsorb the supernatant (from homogenate or cell cultures) to grid substrate.

iii) Use carbon-coated 200 mesh gold grids.

iv) Fix the sample with 0.1% (v/v) glutaraldehyde and 1% (v/v) Nonidet P40 (NP40) in PBS (2 minutes).

v) Wash in PBS (3 × 3 minutes).

vi) Block with 5% (v/v) cold water fish gelatin (Sigma) in PBS (10 minutes) followed with incubation buffer (PBS/0.1% cold water fish gelatin).

vii) Incubate with antibody (affinity purified rabbit anti-EHNV, Lot No. M708; supplied by the OIE Reference Laboratory; suggested dilution 1/500) for 1 hour, at RT.

viii) Wash grids (6 × 3 minutes) in incubation buffer.

ix) Incubate with 10 nm protein A-gold (for dilution, refer to suppliers recommendation) for 1 hour, at RT.

x) Wash (6 × 3 minutes).

xi) Fix with 2.5% glutaraldehyde (5 minutes).

xii) Wash with distilled water (3 × 3 minutes) and stain with 2% phosphotungstic acid (pH 6.8) for 1 minute.

Interpretation of results

The inclusion of NP40 will permit antibodies and protein A-gold to penetrate the outer membrane and react with the underlying capsid. Labelling should be specific for the virus. Non-EHNV affinity purified rabbit serum (1/500) should be included as a negative control.

4.3.1.2.2.4. Immunohistochemistry (*immunoperoxidase stain*)

Samples: formalin-fixed paraffin-embedded tissue sections.

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Technical procedure

The following protocol is intended for the qualitative demonstration of ranavirus antigens in formalin-fixed paraffin-embedded tissue sections (He *et al.*, 2002). It assumes that antigens may have become cross linked and therefore includes a protease digestion step that may be omitted if unfixed samples are examined. A commercial kit (DAKO® LSAB K0679) with peroxidase-labelled streptavidin and a mixture of biotinylated anti-rabbit/anti-mouse/anti-goat immunoglobulins as link antibodies is used for staining. Other commercially supplied reagents are also used. For convenience these are also supplied by DAKO[2]. The primary affinity purified rabbit anti-EHNV antibody (Lot No. M708) is supplied freeze-dried by the OIE Reference Laboratory.

2 Dako Cytomation California Inc., 6392 via Real, Carpinteria, CA 93013, USA, Tel.: (+1-805) 566 6655, Fax: (+1-805) 566 6688; Dako Cytomation Pty Ltd, Unit 4, 13 Lord Street, Botany, NSW 2019, Australia, Fax: (+61-2) 9316 4773; Visit www.dakocytomation.com for links to other countries.

i) Cut 5 µm sections and mount on SuperFrost® Plus G/Edge slides (Menzel-Glaser, HD Scientific Cat. No. HD 041300 72P3). Mark around the section with a diamond pencil to limit the spread of reagents.

ii) De-paraffinise the section:

Pre-heat slides in a 60°C incubator for 30 minutes.

Place slides in a xylene bath and incubate for 5 minutes. Repeat once. Note that xylene replacements can be used without deleterious effects.

Tap off excess liquid and place slides in absolute ethanol for 3 minutes. Repeat once.

Tap off excess liquid and place slides in 95% ethanol for 3 minutes. Repeat once.

Tap off excess liquid and place slides in distilled or deionised water for 30 seconds.

iii) Expose antigens using a protease treatment. Flood slide with proteinase K (5–7 µg ml^{-1}) and incubate for 20 minutes (ready-to-use solution, DakoCytomation Cat. No. S3020). Rinse slide by immersing three times in water. Place in a PBST bath for 5 minutes (PBS pH 7.2, 0.05% [v/v] Tween 20). Tap off the excess wash solution and carefully wipe around the section.

iv) Perform the immunostaining reaction using the Universal DAKO LSAB®+ Kit, Peroxidase (DakoCytomation Cat No. K0679). Ensuring the tissue section is completely covered, add the following reagents to the slide. Avoid drying out.

v) 3% hydrogen peroxide: cover the section and incubate for 5 minutes. Rinse gently with PBST and place in a fresh wash bath.

vi) Primary antibody (affinity purified rabbit anti-EHNV 1:/1500 Lot No. M708) and negative control reagent (non-immune rabbit serum at a dilution of 1/1500) on a second slide. Cover the section and incubate for 15 minutes. Rinse slides.

vii) Link: cover the section and incubate for 15 minutes. Rinse slides.

viii) Streptavidin peroxidase: cover the section and incubate for 15 minutes. Rinse slides.

ix) Substrate–chromogen solution: cover the section and incubate for 5 minutes. Rinse slides gently with distilled water.

x) Counterstain by placing slides in a bath of DAKO® Mayer's Haematoxylin for 1 minute (Lillie's Modification, Cat. No. S3309). Rinse gently with distilled water. Immerse 10 times into a water bath. Place in distilled or deionised water for 2 minutes.

xi) Mount and cover-slip samples with an aqueous-based mounting medium (DAKO® Faramount Aqueous Mounting Medium Cat. No. S3025).

Interpretation of results

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Ranavirus antigen appears as a brown stain in the areas surrounding degenerate and necrotic areas in parenchymal areas. There should be no staining with negative control rabbit serum on the same section.

Availability of test and reagents: antibody reagents and test protocols are available from the OIE Reference Laboratory.

4.3.1.2.3. Molecular techniques

Identification of ranavirus at genus and species level is possible using two PCR methods based on the MCP gene. In the first method, two PCR assays using MCP primers are used with restriction analysis to detect and rapidly differentiate fish ranaviruses (EHNV, ECV) from amphibian ranaviruses (FV3, BIV) (Harp & Petranka, 2006). This can be completed in less than 24 hours at relatively low cost. In the second method, a single MCP PCR assay is used to generate a 580 bp product, which is then sequenced to identify the type of ranavirus.

Samples: virus from cell culture or direct analysis of tissue homogenate.

4.3.1.2.3.1. PCR and restriction endonuclease analysis (REA): technical procedure

Amplified product from PCR assay MCP-1 digested with PflM I enables differentiation of Australian iridoviruses (EHNV and BIV) from non-Australian iridoviruses (FV3, Americas; and ECV, Europe). Amplified product from PCR assay MCP-2 digested with Hinc II, Acc I and Fnu4H I (individually) enables differentiation of EHNV and BIV (Australia) from each other and from FV3 (Americas) and ECV (Europe).

Preparation of reagents

EHNV-purified DNA and BIV-purified DNA PCR control reagents are supplied by the reference laboratory in freeze-dried form. Reconstitute using 0.5 ml of Tris-EDTA (TE) buffer (10 mM Tris/HCl, 1 mM EDTA, pH 8.0) and allow the vial to stand at RT for 2 minutes. Mix the vial very gently. For routine use, as a PCR control, it is recommended that working stocks be prepared as a 1/10 dilution in TE buffer (pH 8.0). Aliquots of 250 µl should be stored at –20°C. Each aliquot is sufficient for at least 50 reactions (1 to 5 µl added to cocktail) and has a minimum shelf life of 6 months from date of diluting.

Primers M151 and M152 (MCP-1, 321 bp), M153 and M154 (MCP-2, 625 bp) are supplied in working strength and should be stored at –20°C. Primers can also be ordered from commercial suppliers. For primer sequences, refer to Table 4.1.

Table 4.1. MCP-1 and MCP-2 primer sequences

PCR assay	Primer	Sequence	Product size	Gene location
MCP-1	M151	AAC-CCG-GCT-TTC-GGG-CAG-CA	321 bp	266–586
	M152	CGG-GGC-GGG-GTT-GAT-GAG-AT		
MCP-2	M153	ATG-ACC-GTC-GCC-CTC-ATC-AC	625 bp	842–1466
	M154	CCA-TCG-AGC-CGT-TCA-TGA-TG		

PCR cocktail

Amplification reactions in a final volume of 50 µl (including 5 µl DNA sample) contain 2.5 µl of each working primer, 200 µM of each of the nucleotides dATP, dTTP, dGTP and dCTP, 10 × PCR

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buffer (66.6 mM Tris/HCl, 16.6 mM $(NH_4)_2SO_4$, 2.5 mM $MgCl_2$, 1.65 mg ml^{-1} BSA, 10 mM beta-mercaptoethanol) and 2 U Taq polymerase. Instructions on preparation of 10 × PCR buffer are included in Table 4.2.

Table 4.2. 10 × PCR buffer preparation

Ingredients	**Amount**	**Final concentration in 50 µl PCR mix**
Tris	4.050 g	66.6 mM
Ammonium sulphate	1.100 g	16.6 mM
BSA (albumin bovine fraction V fatty acid free)	0.825 g	1.65 mg ml^{-1}
Magnesium chloride	1.25 ml	2.5 mM
TE buffer (sterile)	50 ml	

NOTE: alternative commercial buffers may also be used.

Two negative controls are included, one comprising PCR cocktail only and the second containing 5 µl TE buffer.

The MCP-1 and MCP-2 reactions have the following profile: 1 cycle of denaturation at 94°C for 3 minutes, followed by 35 cycles of denaturation at 94°C for 30 seconds, annealing at 50°C for 30 seconds and extension at 72°C for 1 minute; a final extension of 72°C for 5 minutes, and cooling to 4°C.

NOTE: the annealing temperature may be increased to 60 or 62°C to reduce non-specific amplification when the assay is used to test fish tissues.

PCR results are assessed by electrophoresis in 2% agarose gels stained with ethidium bromide. EHNV PCR control DNA (1/10 working stock) should give a result similar in intensity to the 10–3 band in both cases.

Restriction endonuclease analysis (*REA*)

PCR amplicons are subjected to REA with the enzymes described in Table 4.3. All endonucleases should be used according to the manufacturers' instructions. REA reactions are prepared by adding 1–4 µl of PCR product, 2 U of the appropriate restriction endonuclease, 1.6 µl of buffer (supplied with each restriction endonuclease), 1.6 µl of 100 µg ml^{-1} BSA (for PflM I and Hinc II) and made up to a final volume of 16 µl with sterile purified water. Restriction digests are incubated for 2–4 hours at the recommended temperatures and assessed by agarose gel electrophoresis in 3% gels. The predicted band sizes after restriction are given in Table 4.4.

Table 4.3. Restriction endonuclease analysis of ranavirus MCP amplicons

PCR Assay	Restriction enzyme	Predicted band sizes after restriction (bp)	Pattern applies to
MCP-1 (321bp)	*Pfl*M I	321	EHNV, BIV
		131, 190	FV3, WV
MCP-2 (625bp)	*Hinc* II	100, 138, 387	EHNV
		100, 525	BIV, FV3
		100, 240, 285	WV
	Acc I	238, 387	EHNV
		625	BIV, ESV, ECV, WV
		164, 461	FV3, GV

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*Fnu*4H I	33, 38, 44, 239, 271	EHNV
	3, 33, 38, 44, 108, 399	BIV
	3, 38, 44, 108, 432	FV3, GV
	3, 9, 38, 44, 108, 151, 272	ESV, ECV
	3, 44, 71, 108, 399	WV

Aliquot into 500 µl volumes and store at –20°C. For a working solution, add 3.5 µl of beta-mercaptoethanol per 500 µl 10 × buffer. Any remaining buffer should be discarded after preparing the PCR cocktail.

The sensitivity of PCR in diagnostic applications directly on fish tissues is being evaluated.

Detailed protocols to enable completion of the test, worksheets and purified control EHNV DNA are available from the OIE Reference Laboratory.

4.3.1.2.3.2. Alternative PCR and sequencing for viral identification

In this assay two primers, a reverse primer (5'-AAA-GAC-CCG-TTT-TGC-AGC-AAA-C-3') and a forward primer (5'-CGC-AGT-CAA-GGC-CTT-GAT-GT-3'), are used for amplification of the target MCP sequence (580 base pairs [bp]) of EHNV DNA by PCR. This PCR procedure can be used for the specific detection of ranaviruses from redfin perch, rainbow trout, sheatfish, catfish, guppy fish (*Poecilia reticulata*), doctor fish (*Labroides dimidatus*) and a range of amphibian ranaviruses (Eaton *et al.*, 1991). Nucleic acid (1 µl) is added to Taq polymerase buffer containing 0.1 µM of each primer, 2.5 U Taq polymerase (Promega) and 2.5 mM $MgCl_2$. The mixture is incubated in an automatic thermal cycler programmed for 35 cycles at 95°C for 60 seconds, 55°C for 60 seconds, and 72°C for 60 seconds, and finally held at 72°C for 15 minutes. Amplified DNA (580 bp) is analysed by agarose gel electrophoresis, excised and sequenced using a range of standard technologies). Each viral species is identified by its unique DNA sequence available from GenBank. Samples can be submitted to the OIE reference laboratory for specific identification.

4.3.1.2.4. Agent purification

Purification of EHNV has been described (Drury *et al.*, 1995; Hyatt *et al.*, 2000) and a protocol is available from the reference laboratory.

4.3.2. Serological methods

Neutralising antibodies have not been detected in fish or mammals exposed to ranaviruses Indirect ELISA for detection of antibodies induced following exposure to ranavirus has been described for *Bufo marinus* Protocols and specific anti-immunoglobulin reagents required to conduct these tests are available from the reference laboratory.

5. Rating of tests against purpose of use

The methods currently available for surveillance, detection, and diagnosis of ranavirus are listed in Table 5.1. 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; d = the method is presently not recommended for this purpose; and NA = not applicable. 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 (see Chapter 1.1.2 of this *Aquatic Manual*), their routine nature and the fact that they have been used widely without dubious results, makes them acceptable.

Table 5.1. Methods for targeted surveillance and diagnosis

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Method	Targeted surveillance				Presumptive diagnosis	Confirmatory diagnosis
	Ova/milt	Tadpoles	Metamorphs	Adults		
Gross signs	na	d	d	d	d	d
Histopathology	na	d	d	d	b	d
Immunoperoxidase stain	na	c	c	c	b	b
Transmission EM	na	d	d	d	c	c
Immuno-EM	na	d	d	d	c	c

Table 5.1 cont. Methods for targeted surveillance and diagnosis

Method	Targeted surveillance				Presumptive diagnosis	Confirmatory diagnosis
	Ova/milt	Tadpoles	Metamorphs	Adults		
Cell culture	na	a	a	a	a	a
Antigen-capture ELISA	na	a	a	a	b	b
Antibody-capture ELISA	na	d	d	c	c	d
PCR-REA	na	d	a	d	c	a
PCR sequence analysis	na	d	d	d	c	a

EM = electron microscopy; ELISA = enzyme-linked immunosorbent assay; PCR = polymerase chain reaction; REA: restriction endonuclease analysis; na: not applicable

6. Test(s) recommended for targeted surveillance to declare freedom from ranavirus

Statistically valid sampling practices need to be used but these cannot presently be defined for amphibians.

Correct organs/samples need to be collected.

Standardised tests of specified sensitivity and specificity should be used. This restricts certification testing to cell culture, the gold standard test.

Serology might also play a useful role in surveys to identify infected amphibian populations. Further research is required to confirm the validity of this approach.

7. Corroborative diagnostic criteria

7.1. Definition of suspect case

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Amphibian, apparently healthy, moribund or dead in which skin and or parenchymal tissues contain histological evidence of focal, multifocal or locally extensive liquefactive or coagulative necrosis with or without intracytoplasmic basophilic inclusion bodies.

7.2. Definition of confirmed case

Amphibian, apparently healthy, moribund or dead in which skin and or parenchymal tissues contain histological evidence of focal, multifocal or locally extensive liquefactive or coagulative necrosis with or without intracytoplasmic basophilic inclusion bodies and/or in which ranavirus is demonstrated by the following means:

1. Characteristic CPE in cell culture and cell culture is positive for ranavirus in immunoperoxidase test or antigen-capture ELISA or PCR,

   or

2. Tissues positive in antigen-capture ELISA or immunoperoxidase stain or immunoelectron microscopy or PCR

   And for both 1 and 2, where PCR is used

3. Sequence consistent with ranavirus is demonstrated by PCR-REA or PCR-sequencing.

Annex XV(A) (contd)

8. References

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Annex XV(B) (contd)

CHAPTER 1.1.3.

METHODS FOR DISINFECTION OF AQUACULTURE ESTABLISHMENTS

[…]

EU comments

1. The EU proposes that point 4.1.2 is amended to read:

"There are a number of protocols regularly used to disinfect eyed eggs. In general, the pH of the solutions of the iodophor product must be between 6 and 8. At a pH of 6 or less, the toxicity for eyed and newly fertilised eggs increases, and at 8 or more, the disinfection efficacy decreases. It is therefore essential to control the pH, and 100 mg litre^{-1} $NaHCO_3$ must be added to the water. It is recommended that the eggs be rinsed in clean fresh water~~, or 0.9% saline,~~ before and after disinfection and that an iodophor solution giving 100 ppm (parts per million) free iodine in 0.9% saline free of organic matter be used as the disinfectant solution. The contact time for a 100 ppm iodophor solution should not be less than 10 minutes (with occasional gentle agitation) and the solution should be used only once."

Justification: Using a solution of neutral pH to wash the eggs increases the contact between the eggs and the disinfectant.

2. The EU proposes the following amendments in point 4.1.3:

a) First bullet point is amended to read: "Eggs should be stripped and separated from ovarian fluid, rinsed in 0.9% saline (30–60 seconds), sperm added and fertilisation allowed to proceed for one minute ~~5–15 minutes~~,"

Justification: Sperm are only active for 15 seconds and die within 60 seconds. It therefore seems excessive to allow 5-15 minutes for fertilisation.

b) Third bullet point is amended to read as follows:

"The eggs should then be rinsed in a 100 ppm iodophor solution for 1 minute. Then the solution should be discarded and replaced with a fresh 100 ppm solution and the eggs disinfected for a further 30 minutes, during which time hardening occurs and so they should be left undisturbed. This solution, and the rinsing solutions, should be used only once. The ratio of eggs to iodophor solution should be a minimum of 1:4."

c) Fifth bullet point is deleted.

d) A new third paragraph is added which would read: "It is also acceptable to harden newly fertilised eggs before disinfection."

Justification for proposals b), c), and d):
It appears from the prescribed procedure that the saline solution is washed from the eggs prior to disinfection (and the iodophor solution is not in 0.9% saline) hence egg hardening will occur as they are disinfected. As eggs are delicate during the hardening process they should be left undisturbed (agitation can lead to death). This needs to be made clear, see proposed amendment in 3rd bullet point. For the same reason, the fifth bullet point referring to water hardening after disinfection is superfluous (and possibly misleading) and is proposed deleted. Finally, for the sake of clarity it should be highlighted that eggs also may be hardened prior to disinfection, see proposed new third paragraph.

e) A new fourth paragraph is added in the end which would read: "Once the eggs are disinfected it should be ensured that they do not become contaminated. Thus they should not come in contact with water which has not been disinfected and the containers in which they are kept should be thoroughly disinfected."

Justification: To avoid the spread of the disease agent in question it is essential that the eggs are not contaminated after disinfection. This should be emphasised in this chapter of the OIE Aquatic Manual.

4. Routine sanitation and biosecurity

Many aquaculture establishments, especially those cultivating early stages of aquatic animals, employ [~~measures that use~~] a number of disinfection methods for disease prevention and control. These measures may be part of [~~a~~] on-farm[~~s~~] routine biosecurity programmes [~~that may be~~] designed for exclusion of specific diseases [~~as well as serving as~~] or for general pest and disease exclusion purposes [~~measures~~].

4.1. Disinfection of fish eggs [and larvae]

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4.1.1. Principles and limitations of [~~Guidelines for~~] disinfection of fish egg[~~s~~] surfaces

Disinfection of eggs with iodine can be carried out for various fish species, but it is most commonly used for eggs of salmonid fish [~~of the Salmonidae family~~] (salmon, trout and char). Disinfection is [~~Although~~] generally effective for decontamination of surfaces of eyed and newly fertilised eggs. [~~,~~] T[~~t~~]he use of disinfectants, such as iodophors, may prevent transmission of egg surface associated diseases; disinfection for the decontamination of surfaces of eggs can [~~should~~] not [~~be relied upon to~~] prevent true vertical transmission [~~of some bacterial pathogens (e.g. *Renibacterium salmoninarum*) and viral pathogens (e.g. infectious pancreatic necrosis virus) that may be present within the eyed and newly fertilised egg~~]. Epidemiological studies and laboratory tests have shown that disinfection of eggs with iodophor may not always be effective in preventing transmission of Infectious pancreatic necrosis (IPN) virus, *Renibacterium salmoninarum* and Infectious haematopoietic necrosis (IHN) virus, for which this method was developed initially.

The amount of viral particles in the water to be used during the disinfection of the eggs, the level of infection with the virus in the broodstock (ovarian fluid and milt), and the temperature and pH of the water to be used for disinfection are among the main parameters that may affect the efficacy of the disinfection procedure.

4.1.2. Eyed eggs of salmonid fish

There are a number of protocols regularly used to disinfect eyed eggs. In general, the pH of the solutions of the iodophor product must be between 6 and 8. At a pH of 6 or less, the toxicity for eyed and newly fertilised eggs increases, and at 8 or more, the disinfection efficacy decreases. It is therefore essential to control the pH, and 100 mg litre^{-1} $NaHCO_3$ must be added to the water. It is recommended that the eggs be rinsed in clean fresh water, or 0.9% saline, before and after disinfection and that an iodophor solution giving 100 ppm (parts per million) free iodine in 0.9% saline free of organic matter be used as the disinfectant solution. The contact time for a 100 ppm iodophor solution should not be less than 10 minutes and the solution should be used only once.

4.1.3. Newly fertilised salmonid eggs via a water-hardening process

For disinfecting newly fertilised salmonid eggs via a water-hardening process with iodophors, the active iodine concentration should be 100 ppm. One such procedure is as follows:

- Eggs should be stripped and separated from ovarian fluid, rinsed in 0.9% saline (30–60 seconds), sperm added and fertilisation allowed to proceed for 5–15 minutes,
- The eggs should then be rinsed in 0.9% saline (30–60 seconds) to remove excess sperm and other organic materials,
- The eggs should then be rinsed in a 100 ppm iodophor solution for 1 minute. Then the solution should be discarded and replaced with a fresh 100 ppm solution and the eggs disinfected for a further 30 minutes. This solution, and the rinsing solutions, should be used only once. The ratio of eggs to iodophor solution should be a minimum of 1:4,
- The eggs should be rinsed again in fresh or treated (filtered/UV) [~~sterile~~] hatchery water for 30–60 seconds,
- Water-hardening should be finished using clean water.

It is important that eggs are not fertilised in the presence of the iodophor solution as this will kill sperm cells.

4.1.4. Eggs of other fish species

There is limited information on the disinfection of egg surface for non-salmonid [~~other~~] species. For such species, preliminary tests should be conducted to determine at what egg stage and at which iodophor concentration, disinfection can be carried out safely. Disinfection of eggs of marine species, such as plaice, cod and Atlantic halibut, for which some adverse effects of iodophors have been documented, may be achieved with 400–600 mg litre^{-1} glutaraldehyde and a contact time of 5–10 minutes. However, the iodophor method [~~this~~] is not effective against nodaviruses for which the use of ozone at 1 mg O_3 litre^{-1} for 30 seconds is recommended. An ozone concentration of 0.1–0.2 mg O_3 litre^{-1} for 3 minutes inactivates most pathogenic fish bacteria as well.

~~[4.1.5. Efficacy limits~~

~~Disinfection of eggs with iodophor may not always be effective in preventing vertical transmission of infectious pancreatic necrosis virus, *Renibacterium salmoninarum* and infectious haematopoietic necrosis virus, for which this method was developed initially. The ineffectiveness of iodophor disinfection in some instances has been proven by epidemiological studies and laboratory tests.~~]

4.1.6. Mollusc eggs and larvae

Disinfection of eggs and larval stages is not considered practical for most molluscan culture systems. In addition, there is little information on specific disinfection procedures for pathogens of molluscs (i.e. *Marteilia* spp., *Haplosporidium* spp., *Bonamia* spp., *Perkinsus* spp., iridovirus and pathogenic levels of marine microbes) or seawater. Therefore, disinfectants and concentrations are based on related pathogens or seawater sterilisation. Three stages of disinfection can be applied to hatcheries:

a) pretreatment of influent water, e.g. filters (1.0 and 0.22 µm) or chemical disinfection for protection of mollusc stocks;

b) treatment within the facilities (especially recycling systems) = protection of mollusc stocks;

c) treatment of effluent water = protection of the environment.

4.1.7. Disinfection of eggs and larvae in penaeid shrimp hatcheries

Certain penaeid shrimp viral diseases (i.e. spherical baculovirosis, tetrahedral baculovirosis, and hepatopancreatic parvovirus infections) are transmitted by faecal contamination of spawned eggs. These diseases, as well as infections due to certain other shrimp viruses such as white spot disease virus, and certain bacterial and fungal disease agents, can be eliminated or have their incidence reduced through the routine use of disinfection protocols when used to surface disinfect eggs and/or recently hatched nauplii. A widely used method is given below:

For fertilised eggs[3]

Collect fertilised eggs. Rinse with running seawater for 1–2 minutes. Fully immerse eggs in 100 ppm formalin for 1 minute. Fully immerse eggs in iodophor (0.1 ppm iodine) for 1 minute. Rinse in running seawater 3–5 minutes. Transfer to disinfected larval rearing tanks.

For nauplii[4]

Using phototaxic response to light, collect nauplii with netting or screen. Rinse with running seawater for 1–2 minutes. Fully immerse nauplii in 400 ppm formalin for 30–60 seconds. Fully immerse nauplii in iodophor (0.1 ppm iodine) for 1 minute. Rinse in running seawater 3–5 minutes. Transfer to disinfected larval rearing tanks.

3 Fertilised eggs are more sensitive than nauplii to formalin.

4 Nauplii are much easier to collect than fertilised eggs in hatcheries.

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