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

Paris, 13–17 October 2008

The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 13 to 17 October 2008.

Dr Vallat addressed the Aquatic Animals Commission and expressed his great appreciation of the outstanding achievements of the Aquatic Animals Commission under the Presidency of Dr Bernoth who is standing down as President after the end of this meeting because of a career change. He also thanked Dr Hill as Vice-President for standing in for Dr Bernoth until the 77th General Session in May 2009 when Commission elections are due. Dr Vallat thanked Dr Bernoth for her contribution to the work of the OIE and wished her well in her new career in terrestrial animal health.

Dr Bernoth then opened the meeting and welcomed participants.

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

The Aquatic Animals Commission recognised the contribution of the following Members in providing comments: Australia, Chinese Taipei, Croatia, European Union (EU), Japan and the United States of America (USA).

The Aquatic Animals Commission reviewed the agenda papers, addressed comments that Members had submitted by 12 September 2008 and amended texts in the OIE *Aquatic Animal Health Code* (*Aquatic Code*) where appropriate. The amendments are shown in the usual manner by double underline and strikeout and are presented in the Annexes to this report.

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 Aquatic Animals Commission's working documents.

Comments on this report's Annexes III to XVI must reach OIE Headquarters by **6 February 2009** to be considered at the March 2009 meeting of the Aquatic Animals Commission. Comments should be sent to the International Trade Department at: **trade.dept@oie.int**

The table below summarises the texts as presented in the Annexes. Part I: Annexes III to XVI are presented for Members' comment, with a view to proposing the text for adoption at the 77th General Session in May 2009; Part II: Annexes XVII to XXI are presented for Members' information. At the bottom of the table, Part III lists Report Items where Members' comments are invited (but no Annex is provided).

Part I - Annexes for Members' comments (deadline 6 February 2009)	**Annex number**
Definitions (Ch. 1.1.1.)	Annex III
Diseases listed by the OIE (Ch. 1.2.3.)	Annex IV
General obligations related to certification (Ch. 1.3.1.)	Annex V
Certification procedures (Ch 1.3.2)	Annex VI
Quality and Evaluation of Competent Authorities (Ch 1.4.3.)	Annex VII
Crayfish plague (Ch 2.3.7.)	Annex VIII
Example Article X.X.X.3; X.X.X.9; X.X.X.12	Annex IX
Necrotising hepatopancreatitis (Ch 2.3.X.)	Annex X
Milky haemolymph disease of spiny lobsters (*Panulirus* spp.) (Ch 2.3.X.)	Annex XI
Model international aquatic animal health certificates	Annex XII
Criteria to assess the safety of aquatic animal commodities (X.X.X.)	Annex XIII
Criteria to assess the safety of aquatic animal products destined for human consumption (X.X.X.)	Annex XIV
Welfare of farmed fish during transport (App 3.4.2.)	Annex XV
Handling and disposal of carcasses and wastes of aquatic animals (App X.X.X.)	Annex XVI
Part II - Annexes for Members' information	**Annex number**
Report of the ad hoc Group on the OIE List of Aquatic Animal Diseases – Crustacean Team (June 2008)	Annex XVII
Reports of the ad hoc Group on Aquatic Animal Health Surveillance (April 2008 and July 2008)	Annex XVIII
Report of the ad hoc Group on Safety of Products Derived From Aquatic Animals (August 2008)	Annex XIX
Annex to the OIE PVS Tool	Annex XX
Work Plan	Annex XXI
Part III - Report items where Members' comments are invited (no Annex)	**Report Item number**
Call for nominations for Reference Laboratories	11.1., 11.2., 11.4.
De-listed diseases	13.1
Second OIE Global Conference on Aquatic Animal Health	13.2

1. Activities and progress of *ad hoc* Groups

1.1. Report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases – Crustacean Team – June 2008

Dr Lightner reported on the meeting of the *ad hoc* Group. The *ad hoc* Group had considered crustacean diseases under study, diseases suggested for deletion and a new disease for listing, and made recommendations accordingly. The *ad hoc* Group had also provided draft chapters for the *Aquatic Code* for the 2 diseases recommended by them for listing. Details are provided under Agenda Items 3.2 and 3.3.

The President thanked Dr Lightner and the *ad hoc* Group for their excellent work. The Aquatic Animals Commission noted the report and endorsed the Group's recommendations.

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

1.2. Report of the *ad hoc* Group on Aquatic Animal Health Surveillance – April 2008 and July 2008

Dr Hill reported on the two meetings of the *ad hoc* Group. Whilst the majority of work was the drafting of the Handbook on Aquatic Animal Health Surveillance, the *ad hoc* Group discussed the issue of surveillance periods for demonstrating freedom of a disease in wild populations of aquatic animals. It was concluded that because diseases in wild aquatic animal populations are more difficult to detect than in farmed populations, the self declaration of freedom should in general be based on historical freedom for at least 25 years or targeted surveillance for at least 5 years (compared to 10 years and 2 years as the default figures, respectively). The Aquatic Animals Commission agreed with this conclusion.

Dr Hill then provided an update on the status of the draft Handbook on Aquatic Animal Health Surveillance prepared by the *ad hoc* Group. He reported that the work of drafting the text has been completed and the draft manuscript sent to three experts for review. Dr Hill indicated that the reviewers' comments would be considered by the *ad hoc* Group at its meeting on 19-21 January 2009.

The OIE plans to publish the Handbook in 2009.

The President thanked Dr Hill for the significant outputs from this *ad hoc* Group and noted that the Aquatic Animals Commission is looking forward to the publication of the Handbook.

The Aquatic Animals Commission wishes to remind Members that once the OIE Handbook on Aquatic Animal Health Surveillance is published, the Aquatic Animals Commission will revise the *Aquatic Code* Appendix on surveillance (3.3.1.) to reduce the amount of technical information in that Appendix, thereby rendering the text more consistent with other chapters in the *Aquatic Code*.

The two meeting reports of the *ad hoc* Group are provided for information at Annex XVIII.

1.3. Report of the *ad hoc* Group on Safety of Products Derived From Aquatic Animals – August 2008

Dr Berthe reported on the meeting of the *ad hoc* Group and highlighted the main points of discussion. Detail is provided under Agenda Item 3.3.

The President thanked Dr Berthe and the *ad hoc* Group for the excellent work. The Aquatic Animals Commission noted the report and endorsed the Group's recommendations.

The Aquatic Animals Commission recommended that the *ad hoc* Group be reconvened to continue work on safe aquatic animal products.

The meeting report of the *ad hoc* Group is provided for information at Annex XIX

2. *Aquatic Animal Health Code* – Member comments

2.1. General comments

At the 76th General Session, the EU had asked that it be noted that several comments had been sent to the Aquatic Animals Commission and no explanation had been given as to why they had not been accepted. In her reply at the 76th General Session, Dr Bernoth had noted that if the Aquatic Animals Commission were to provide a rationale for each comment received but not-accepted, this would be very time consuming. However, the Aquatic Animals Commission undertook to review its approach.

The Aquatic Animals Commission discussed this item and confirmed that it considers all comments received but provides a specific response to individual comments only if an explanation is required, for example when other Members would benefit from that explanation. This is irrespective of whether the original comment is accepted or rejected.

2.2. Listing of the sabellid worm (*Terebrasabella heterouncinata*)

The Aquatic Animals Commission (March 2008 Report) had asked for comments on the Report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases – Mollusc Team (January 2008) and its recommendation on the listing of the sabellid worm *Terebrasabella heterouncinata*. Comments were received from Australia, Chinese Taipei and the USA.

The Aquatic Animals Commission reviewed Member comments. The listing of the sabellid worm will be proposed for adoption at the 77th General Session in May 2009 (refer to AnnexIV).

The Aquatic Animals Commission requested that the *ad hoc* Group prepare a Disease card to be posted on the OIE website to provide information for reporting purposes.

2.3. Case definition for abalone viral mortality

The Aquatic Animals Commission (March 2008 Report) had asked for comments on the Report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases – Mollusc Team (January 2008) and its recommendation on the case definition of the abalone viral mortality (AVM) complex. Comments were received from Australia, Chinese Taipei, Japan, and the USA.

The Aquatic Animals Commission reviewed Member comments and decided to focus the scope of the AVM complex to the herpes-like virus associated manifestations.

The Aquatic Animals Commission requested that the *ad hoc* Group prepare a revised case definition for the March 2009 meeting of the Aquatic Animals Commission with a view to proposing the revision of the scope of the AVM complex and the consequential replacement of the name 'AVM' with 'Abalone herpes-like virus disease' in Chapter 1.2.3. for adoption at the 77th General Session in May 2009.

The Aquatic Animals Commission also requested that the *ad hoc* Group revise the Disease card on the OIE website accordingly.

2.4. Crayfish plague (Chapter 2.3.7.)

Comments had previously been received from Australia, the EU, and two OIE experts on the draft chapter sent out for comment as part of the March 2007 Report of the Aquatic Animals Commission.

The Aquatic Animals Commission reviewed comments, amended the text accordingly and has prepared a clean text because of the extensive nature of the comments.

Regarding the timeframe for surveillance for declaration of freedom from crayfish plague (Articles 2.3.7.4 and 2.3.7.5.), the Aquatic Animals Commission considered advice received from the OIE experts. While the default periods in the *Aquatic Code* Appendix on surveillance is 10 years for no observed occurrence of the disease, and is 10 years for basic biosecurity conditions, the Aquatic Animals Commission modified these to 25 and 10 years respectively, in Articles 2.3.7.4. and 2.3.7.5., for this chapter, based on expert advice, because crayfish plague is primarily a disease of wild populations. Likewise, the periods for targeted surveillance and basic biosecurity conditions (in Articles 2.3.7.4. and 2.3.7.5.) were increased from 2 years to 5 years.

The updated Chapter on crayfish plague that will be proposed for adoption at the 77th General Session in May 2009 is presented at Annex VIII, for Member comment.

2.5. Guidelines on the control of aquatic animal health hazards in aquatic animal feed

The Aquatic Animals Commission, in its March 2008 meeting report, had invited the EU to provide more detail on the EU's suggested additional wording on the authorisation to use terrestrial animal by-products in aquaculture. The Aquatic Animals Commission reviewed the information subsequently provided by the EU.

The Aquatic Animals Commission understands the concern about terrestrial by-products in aquatic animal feed being diverted to other terrestrial animal species. However, this would present a terrestrial animal health issue and therefore is outside the scope of the *Aquatic Code*.

2.6. Handling and disposal of carcasses and wastes of aquatic animals (New Appendix)

Comments had previously been received from Australia, Canada, Chinese Taipei, the EU, New Zealand, and the USA on the draft text sent out for comment as part of the October 2007 Report of the Aquatic Animals Commission. The Aquatic Animals Commission resumed its review of the draft text and was appreciative of the many constructive comments received.

The Aquatic Animals Commission amended the chapter considerably taking into account Members' comments.

The new appendix on Handling and disposal of carcasses and wastes of aquatic animals that will be proposed for adoption at the 77th General Session in May 2009 is presented at Annex XVI, for Member comment.

3. *Aquatic Animal Health Code* – other items

3.1. Definitions (Chapter 1.1.1.)

The Aquatic Animals Commission reviewed the *Aquatic Code* Chapter 1.1.1. Definitions. A number of definitions have been proposed for deletion because they are not used at all in the *Aquatic Code*, used only in other definitions, or used only once or twice in the text of the *Aquatic Code*.

Modifications to some definitions as well as new definitions are suggested for inclusion as a result of harmonising of the *Aquatic* and *Terrestrial Codes* (see Item 4.).

The updated Chapter on Definitions that will be proposed for adoption at the 77th General Session in May 2009 is presented at Annex III, for Member comment.

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

The Aquatic Animals Commission endorsed the Crustacean *ad hoc* Group recommendations to:

i) De-list Tetrahedral baculovirosis (*Baculovirus penaei*) and Spherical baculovirosis (*Penaeus monodon*-type baculovirus);

ii) De-list Hepatopancreatic parvovirus disease, and Mourilyan virus disease (currently listed as under study);

iii) List Necrotising hepatopancreatitis (currently listed as under study);

iv) List Milky haemolymph disease of spiny lobsters (*Panulirus* spp.) as an emerging disease.

Full justification is provided in the Crustacean *ad hoc* Group Report (Annex XVII).

For proposed changes to the list of mollusc diseases see items 2.2. and 2.3.

The updated Chapter on Diseases listed by the OIE that will be proposed for adoption at the 77th General Session in May 2009 is presented at Annex IV, for Member comment.

3.3. Disease chapters

The Crustacean *ad hoc* Group had prepared draft disease chapters for the two diseases they recommended for listing, i.e. Necrotising hepatopancreatitis and Milky haemolymph disease of spiny lobsters (*Panulirus* spp.).

The Aquatic Animals Commission endorsed these draft chapters that will be proposed for adoption at the 77th General Session in May 2009 provided the International Committee adopts the listing of these diseases. The draft chapters are presented at Annexes X and XI, for Member comment.

The *ad hoc* Group on Safety of Aquatic Animal Products pointed out that in two chapters (Chapters 2.2.1. Infection with *Bonamia ostreae* and 2.2.4. Infection with *Marteilia refringens*), the *Aquatic Code* lists species considered not to be susceptible in point 1b) of Article X.X.X.3. on commodities. The *ad hoc* Group recommended those provisions be moved to Article X.X.X.2. on scope. The Aquatic Animals Commission agreed to this amendment which will be made in the 2009 edition of the *Aquatic Code*.

The Aquatic Animals Commission also endorsed the *ad hoc* Group's advice that biological samples preserved for diagnostic applications are not commodities subject to international trade and that the subject is more appropriately addressed in Chapter 1.5.6. on 'Measures concerning international transport of aquatic animal disease agents and pathological material'. The Aquatic Animals Commission requested that the *ad hoc* Group develop a new article for inclusion in Chapter 1.5.6. that specifies fixation treatments to inactivate all OIE-listed disease agents.

The *ad hoc* Group also developed criteria for assessing the safety of aquatic animal commodities irrespective of country disease status. The criteria are based on the absence of the disease agent in the traded commodity or inactivation of the disease agent through processing the product. The Aquatic Animals Commission endorsed the criteria and recommended that these be included in the *Aquatic Code.*

The *ad hoc* Group also developed criteria for assessing the aquatic animal health implications of aquatic animal products destined for human consumption. The criteria for considering products to be safe are based on the expected volume of waste and absence of the pathogen in the waste tissue. The Aquatic Animals Commission modified the criteria and recommended that these also be included in the *Aquatic Code*.

The Aquatic Animals Commission discussed its recommendations on aquatic animal commodities with Dr Vallat, in particular the development of criteria to be used in assessing products as safe (from an aquatic animal disease perspective) for trade. Dr Vallat agreed that this was a useful approach and again emphasized the importance to the OIE of facilitating safe trade in commodities.

The Criteria that will be proposed for adoption at the 77th General Session in May 2009 are presented at Annex XIII and Annex XIV, for Member comment.

The *ad hoc* Group also noted that the listing of commodities for human consumption based on mitigation measures (in point 1 of Article X.X.X.3.) is related to relevant provisions in Article X.X.X.12. The Aquatic Animals Commission agreed that the current structure of the disease chapters in the *Aquatic Code* could be modified in a way that would significantly clarify the recommendations. The Aquatic Animals Commission endorsed the *ad hoc* Group's modification of Article X.X.X.12 and agreed that it should be applied to all disease chapters. As a consequence changes would also be made to Articles X.X.X.3. and X.X.X.9.

An example of amendments to Articles X.X.X.3., X.X.X.9. and X.X.X.12 that will be proposed for adoption with application to all disease chapters, at the 77th General Session in May 2009, is presented at Annex IX, for Member comment.

The *ad hoc* Group had also been asked to consider whether mollusc larvae, spat and juvenile stages should be listed in Article 2.2.X.3. (point 1a) of all mollusc disease chapters. The *ad hoc* Group applied the criteria developed to assess the safety of aquatic animal commodities irrespective of country disease status and concluded that mollusc larvae, spat and juvenile stages could not be considered as a safe commodity. The Aquatic Animals Commission agreed that Article 2.2.X.3. (point 1a) in all mollusc disease chapters should therefore remain unchanged.

3.4. Welfare of farmed fish during transport (New Appendix)

As indicated at the 76th General Session, the Aquatic Animals Commission has developed text on the Welfare of farmed fish during transport that is based on text drafted previously by an *ad hoc* Group convened under the auspices of the Animal Welfare Working Group (AWWG). The current text takes into account Member comments received on previous draft texts.

The Aquatic Animals Commission requested the International Trade Department to forward a copy of the revised draft chapter to the AWWG with a request for the Group to provide comment to the Aquatic Animals Commission.

The Aquatic Animals Commission encourages Members to provide comments on this draft chapter as that will provide useful guidance to the Commission in future work on other chapters dealing with welfare of farmed fish (i.e. a chapter on the humane slaughter of fish and a chapter on the humane killing of fish for disease control).

The draft Appendix on welfare of farmed fish during transport, which will be proposed for adoption at the 77th General Session in May 2009, is presented at Annex XV for Member comment.

3.5. Disease specific surveillance chapters and Model for authors

In response to the call made in the Aquatic Animals Commission's March 2008 Report, Australia and the EU provided a prioritised list of diseases for which a specific surveillance chapter should be developed.

The EU recommended: for fish: viral haemorrhagic septicaemia, Infectious haematopoietic necrosis, Koi herpesvirus disease, infectious salmon anaemia, epizootic ulcerative syndrome and epizootic haematopoietic necrosis; for molluscs: Infection with *Marteilia refringens*, *Bonamia ostreae*, *Bonamia exitiosa*, *Perkinsus marinus*, *Mikrocytos mackini*; for crustaceans: white spot disease, Taura syndrome and yellowhead disease.

Australia recommended: white spot syndrome; viral haemorrhagic septicaemia; Red Sea bream iridoviral disease; Koi herpesvirus disease; crayfish plague.

The Aquatic Animals Commission agreed that these chapters should provide guidance on surveillance to underpin the declaration of freedom but should not address other types of surveillance. The Aquatic Animals Commission requested that the *ad hoc* Group on Surveillance, at its November 2008 meeting, draft a chapter on viral haemorrhagic septicaemia for consideration at the Aquatic Animals Commission March 2009 meeting. This chapter would serve as a model for the development of other disease chapters.

3.6. Model international aquatic animal health certificates

Following the adoption of the model veterinary certificates in the *Terrestrial Code* at the 76th General Session in May 2008, the Aquatic Animals Commission reviewed the model international aquatic animal health certificates in the *Aquatic Code* with the view to harmonising them with the *Terrestrial Code* model certificates.

The Aquatic Animals Commission agreed to replace the current five model certificates with two new ones:

i) Model aquatic animal health certificate for international trade in live aquatic animals including gametes; and

ii) Model aquatic animal health certificate for international trade in aquatic animal products. These will also include an Article on Notes for guidance.

The new chapters on model international aquatic animal health certificates, which will be proposed for adoption at the 77th General Session in May 2009 are presented at Annex XII for Member comment.

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

The Aquatic Animals Commission was joined by Dr Thiermann, President of the Terrestrial Animal Health Standards Commission. Dr Thiermann provided an update on the new structure of the *Terrestrial Code* which is now published in two volumes. The separation into two volumes required reordering of chapters and renumbering of articles throughout. The Aquatic Animals Commission agreed that a similar reordering should be applied to the *Aquatic Code* but that the *Aquatic Code* should remain as a single volume. The Aquatic Animals Commission agreed to remove the current Section 3.1 'Blood Sampling and Vaccination', because of its limited relevance to international trade, and Appendix 3.2.2. 'Disinfection of Aquaculture Establishments', because this topic will be addressed in the revised edition of the *Aquatic Manual*.

The Aquatic Animals Commission was joined by Ms Zampaglione, Head of the OIE Communications Unit, who updated the Commission on the recent meeting of the *ad hoc* Group on Communication. Ms Zampaglione informed the Aquatic Animals Commission that, in 2001, OIE Delegates had voted for the inclusion of recommendations on communication as an element of veterinary services' activities. Based on that Resolution, the OIE is developing strategies and has implemented capacity building activities relevant to communication. The OIE has held seminars on communication in several regions, with participation of chief veterinary officers and their communications officers. From these meetings it has become clear that 'communication' for veterinary services needed to be defined. The first meeting of the *ad hoc* Group on Communication was held in Paris, 11-12 September 2008. Members included professional communicators and veterinarians. The *ad hoc* Group reviewed the areas where communication is currently referenced in the *Terrestrial Code* (general definitions and risk analysis) and concluded that the broader context of communication is not adequately addressed. The *ad hoc* Group proposed a tentative framework for the development of a *Terrestrial Code* Chapter on communication and appropriate definitions. Dr Thiermann reported that the Code Commission at its recent meeting had considered the *ad hoc* Group Report and the proposed definitions and had made some minor modifications.

The Aquatic Animals Commission appreciated the development of recommendations to OIE Members on communication and agreed to adopt a parallel approach in the *Aquatic Code*. The Aquatic Animals Commission reviewed the proposed definitions and adapted them for use in the *Aquatic Code* (See Agenda Item 3.1.). However, the definitions would not be used in the *Aquatic Code* until an appropriate text on communication has been developed for the *Aquatic Code*.

The Aquatic Animals Commission and Dr Thiermann agreed to continue to work together to ensure ongoing harmonisation of the two *Codes*.

As a further step towards harmonisation of the two *Codes*, the Aquatic Animals Commission reviewed and amended Chapter 1.3.1 (General Obligations) and Chapter 1.3.2 (Certification Procedures). These amendments take into account equivalent *Terrestrial Code* chapters and amendments recommended by the Code Commission at its meeting in September 2008.

The amended chapters, which will be proposed for adoption at the 77th General Session in May 2009, are presented at Annex V (Chapter 1.3.1 General Obligations) and Annex VI (Chapter 1.3.2 Certification procedures) for Member comment.

5. OIE PVS Tool

The Aquatic Animals Commission noted the Annex to the OIE PVS Tool on Modifications in Approach when Evaluating the Performance of Competent Authorities Responsible for Aquatic Animal Health (presented at Annex XX, for information). The Aquatic Animals Commission acknowledged this Annex as a good working document.

The Aquatic Animals Commission discussed with Dr Vallat a proposal to evaluate the PVS Tool and the Aquatic Annex prior to its application at a Member's request. The Aquatic Animals Commission recommended that the OIE conduct a simulation exercise in collaboration with the Competent Authority of a country willing to assist the OIE with this process. This simulation would generate useful practical information that could be used to refine the PVS Tool and its Aquatic Annex. Dr Vallat agreed that this would be a useful approach.

The Aquatic Animals Commission also proposed new text for inclusion in the *Aquatic Code* that will provide the legal base relevant to performance and evaluation of Competent Authorities for aquatic animal health. This new text would replace the current Chapter 1.4.3. 'Evaluation of Competent Authorities'.

The new chapter on Quality and Evaluation of Competent Authorities, which will be proposed for adoption at the 77th General Session in May 2009, is presented at Annex VII, for Member comment.

6. Regional Commission Conferences

6.1. 23rd Conference of the OIE Regional Commission for Europe (16 - 19 September 2008, Vilnius, Lithuania)

Dr Berthe reported on his attendance and presentation at this conference on behalf of the Aquatic Animals Commission. His presentation provided a summary of progress made regarding aquatic animal health since the adoption of the Aquatic Resolutions by the International Committee during the 72nd General Session. Dr Berthe stressed some of the most significant changes in the *Aquatic Code* that were adopted during the 76th General Session and provided an outlook of expected future developments in light of the economic importance of aquatic animals and products for the region.

6.2. Upcoming Conferences

The following Commission members will attend the upcoming Conferences on behalf of the Aquatic Animals Commission:

– 19th Conference of the OIE Regional Commission for the Americas (17-21 November 2008, Havana, Cuba): Dr Enriquez

– 18th Conference of the OIE Regional Commission for Africa (February 2009, N'Djamena, Chad): Prof. Katunguka-Rwakishaya.

7. OIE meetings

7.1. OIE/ NACA Regional Workshop on Aquatic Animal Health (Thailand, 25-28 March 2008)

Dr Bernoth represented the Aquatic Animals Commission at a workshop held jointly by the OIE and the Network of Aquaculture Centres in Asia-Pacific (NACA) for senior aquatic animal health officers from countries in the region. The workshop built awareness about OIE aquatic animal health standards, the OIE standard setting process, OIE disease reporting, and responsibilities of governments including cooperation between veterinary and other competent authorities. Dr Bernoth gave three presentations:

a) An introduction to the OIE standards for aquatic animal health

b) How to use the OIE aquatic animal health standards within the WTO-SPS Agreement framework

c) The OIE standard setting process; roles of Member Countries and Territories

The workshop recommended that activities of aquatic focal points should include active participation in providing inputs to the OIE international standards setting process through the OIE Delegates.

Staff from the OIE Animal Health Information Department provided hands-on, on-line training, on the various aspects of the World Animal Health Information System (WAHIS), including immediate notifications, follow-up reports, six-monthly reports and annual questionnaires. They also explained the various avenues to interrogate the output side of WAHIS, the World Animal Health Information Database (WAHID) that is freely available on the OIE web site.

During the workshop, officers from the OIE Animal Health Information Department, the OIE Regional Representation for Asia and the Pacific, officers from NACA, and Dr Bernoth, explored the next steps in setting up a WAHIS/OIE-NACA Regional Core for Aquatic Animal Health. Information on OIE-listed diseases would be entered into WAHIS and be searchable in WAHID. However, the creation of a WAHIS/OIE-NACA Regional Core for Aquatic Animal Health would also allow entering information on non OIE-listed diseases. Such information would not be displayed or searchable in WAHID globally, but would appear on the websites of NACA and OIE Asia-Pacific.

The Directors General of the OIE and NACA subsequently signed a Memorandum of Understanding (MoU) on cooperation between these two organisations on aquatic animal health issues. The Regional Core is a specific part of this MoU.

7.2. OIE Regional Seminar on 'OIE international standards, a lever for growth in the fisheries and aquaculture sector in Southern Africa' (10 – 12 June 2008, Mozambique)

Professor Katunguka Rwakishaya attended and presented a paper at this Regional Seminar. His presentation highlighted the increasing contribution of aquaculture to global supplies of fish, crustaceans, and molluscs, and the role of Aquatic Animals Commission in setting standards for international trade in aquatic animals. Seminar participants were informed that the OIE International health standards are periodically reviewed and updated by the Aquatic Animals Commission with the assistance of international experts, and that they need to be aware of these standards and of their obligations to report the occurrence of listed (and emerging) aquatic animal diseases to the OIE. Participants were encouraged to continue efforts to increase cooperation between veterinary and other authorities with competence for aquatic animal health. Broad discussions were held after the presentation and it was generally agreed that there was a lack of communication between the veterinary authorities and fisheries officers leading to uncoordinated approaches to the reporting and control of aquatic animal diseases. It was recommended that the OIE Regional office should convene regular meetings to discuss aquatic animal health issues in the region.

7.3. Third Meeting of the OIE Inter-American Aquatic Animal Health Committee (11-13 November 2008, Mazatlan, Mexico)

Dr Enriquez will attend this meeting and provide an update on activities of the Aquatic Animals Commission.

8. Other meetings

Dr Bernoth informed the Aquatic Animals Commission that the 7th Annual General Meeting of the NACA Regional Advisory Group on Aquatic Animal Health is scheduled to take place from 15-17 December 2008 in Bangkok, Thailand. Dr Hill will represent the Aquatic Animals Commission at that meeting.

Dr Hill will also attend the XV Conference of the Italian Society of Fish Pathologists (22-24 October 2008, Sicily, Italy) to give an invited presentation on: 'The role of OIE in setting international standards for preventing the spread of aquatic animal diseases'.

Dr Hill will also attend the 96th Indian Science Congress (3-7 January 2009, Shillong, India) following an invitation from Dr Vallat to represent the OIE at this conference and give a presentation on: 'The potential impact of climate change on aquatic animal health'.

9. Cooperation with FAO

The Aquatic Animals Commission noted the report, recommendations and follow-up activities of the FAO Workshop on Development of an Aquatic Biosecurity Framework for Southern Africa that was held in April 2008 in Malawi. The Aquatic Animals Commission agreed this is an important initiative and will continue to provide support, as appropriate.

Dr Berthe attended the FAO Western Balkan Regional Seminar/Workshop on Aquatic Animal Health, 20-22 May 2008, Sarajevo, on behalf of the OIE. He gave a presentation on OIE activities in aquatic animal health. A main recommendation from this workshop was the development of a program and proposal for regional cooperation on aquaculture and trade of aquatic products among countries of the Western Balkan region and their trading partners.

10. *Manual of Diagnostic Tests for Aquatic Animals*

10.1. Sixth edition 2009

10.1.1. Update on progress and timelines

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

Work on the sixth edition of the *Aquatic Manual* had met with some problems, which have been resolved. Draft chapters have been received for all but three diseases, and these chapters have been reviewed by the Consultant Editor. It is hoped to send all the draft chapters to Members in November for review and comment by disease experts. The *Aquatic Manual* is still on schedule for publication in the third quarter of 2009.

The Commission reviewed comments from the Consultant Editor on generic issues with the disease chapter template. It was also decided that he should remove generic text from the three introductory chapters to create one chapter on general information on aquatic animal health management, leaving specific information in the fish, mollusc and crustacean chapters.

The Commission will update the chapter on disinfection in a similar way, i.e. have an introductory part on disinfection followed by specific information on fish, molluscs and crustaceans. This will include an expanded section on disinfection of salmonid and non salmonid eggs.

10.1.2. Diseases of amphibians

In May this year, the International Committee adopted two diseases of amphibians for inclusion in chapter 1.2.3 of the *Aquatic Code*. These are: Infection with *Batrachochytrium dendrobatidis and* Infection with ranavirus. Although disease cards have been prepared and are available on the Commission's web site, in the absence of OIE Reference Laboratories and designated experts for these diseases, *Aquatic Manual* chapters have not yet been prepared. The Commission would encourage nominations (see item 11.2. below). If a nomination is approved and adopted in May 2009, draft chapters could be presented for adoption in May 2010 and inclusion in the web version of the *Aquatic Manual*.

11. OIE Reference Laboratories

11.1. Abalone viral mortality complex

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

11.2. Amphibian diseases

Following the listing of Infection with *Batrachochytrium dendrobatidis* and Infection with ranavirus in May 2008, there is now a need for OIE Reference Laboratories for these two diseases. The Aquatic Animals Commission encourages interested countries with expertise to submit applications for OIE Reference Laboratory status through the OIE Delegate.

11.3. New application for Reference Laboratory status

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

OIE Reference Laboratory for crayfish plague (*Aphanomyces astaci*):

Finnish Food Safety Authority, Evira Kuopio, Neulaniementie 4, FIN-70210 Kuopio, FINLAND. Tel.: (+358) 2077.24962; Fax: (+358) 2077.24970; E-mail: satu.viljamaa-dirks@evira.fi; Designated Reference Expert: Dr Satu Viljamaa-Dirks

11.4. New diseases proposed for listing

The Aquatic Animals Commission is calling for nominations for OIE Reference laboratories for Necrotising hepatopancreatitis, Milky haemolymph disease of spiny lobsters (*Panulirus* spp.), and the sabellid worm *Terebrasabella heterouncinata*. These would be assessed should the listing of these diseases be adopted at the 77th General Session in May 2009.

11.5. Twinning application

The Commission was pleased that there had been an application for a twinning project for an aquatic animal disease. The Commission reviewed the application and suggested some modifications in its scope.

11.6. OIE Seminar to be held during the WAVLD Conference, Madrid, 19 June 2009

The Commission was informed that the title of the OIE Seminar to be held in Madrid during the WAVLD Conference will be 'Veterinary Laboratory Networks and Networking', and was asked to identify a suitable aquatic animal topic and speaker. The Commission agreed that Dr Berthe should represent the Commission and give a presentation on the Commission's position paper on pathogen strain differentiation that has been updated and expanded since the Reference Laboratory Conference in Brazil in 2006. Pathogen strain differentiation is a problem encountered by many laboratories and would benefit from information sharing. This topic will also be a theme at the Second OIE Reference Laboratory and Collaborating Centre Conference that will be held in Paris in 2010.

12. Disease cards

Disease cards for Necrotising hepatopancreatitis and Milky haemolymph disease of spiny lobsters (*Panulirus* spp.) have been posted on the Aquatic Animals Commission pages of the OIE website.

Amphibian disease cards, prepared by the *ad hoc* Group on Amphibian Diseases, for Infection with ranavirus and Infection with *Batrachochytrium dendrobatidis* have also been posted on the Aquatic Animals Commission pages of the OIE website.

13. Other business

13.1. De-listed diseases

The Aquatic Animals Commission discussed problems that have arisen from the retention of disease-specific chapters for 11 de-listed diseases in the *Aquatic Code* and *Aquatic Manual*: Problems include:

a) Members may consider that having a list of diseases for notification purposes and a larger list of diseases for which trade recommendations are made – but which are not necessarily notifiable – effectively re-instates two different categories of diseases and therefore is in breach of the International Committee's resolution (2001) to have a single list of diseases.

b) As the chapters on de-listed diseases in the *Aquatic Code* have generally not been updated, some of the information is out of date. Obtaining updates of chapters of de-listed diseases for the *Aquatic Manual* has proven difficult.

c) Members have requested clarification regarding certification of freedom from de-listed diseases.

The Aquatic Animals Commission agreed that text on de-listed diseases should be removed from the *Aquatic Code* because those diseases have been assessed against the OIE Criteria for Listing, and found not to meet the requirements.

For the next edition of the *Aquatic Manual* (2009), chapters on de-listed diseases will be retained in the *Aquatic Manual* as an interim arrangement but will be moved to a separate section within the *Aquatic Manual* with the view to deleting them from future editions.

The Aquatic Animals Commission will formally propose these arrangements for adoption at the 77th General Session in May 2009. The Aquatic Animals Commission encourages Members to comment on this proposal.

13.2. Second OIE Global Conference on Aquatic Animal Health

The Aquatic Animals Commission recalled the success of the first OIE Global Conference on Aquatic Animal Health held in Bergen, Norway in 2006 and discussed whether there would be benefit in organising a second conference. The Aquatic Animals Commission considered possible key issues that could be the focus of a second conference and identified two suitable topics:

i) Safety of trade in aquatic animal commodities, and

ii) Problems associated with availability and use of antimicrobials in aquaculture.

The Aquatic Animals Commission encourages Members to indicate their support for a second conference and to comment on the suggested topics or to identify alternative topics.

13.3. Update of the Commission's web pages

Dr Hill reported that the Commission's web pages are up to date. The Aquatic Animals Commission decided it would be useful to add a link to the Aquatic Animal Health Standards Commission Report from the 76th General Session of the International Committee to the Commissions web pages for users' convenience.

13.4. Review of Aquatic Animals Commission mandate regarding food safety

The Aquatic Animals Commission discussed with Dr Vallat the possibility of the OIE extending the Aquatic Animals Commission's mandate to cover the food safety implications of aquatic animals and aquatic animal products. Issues for current or future consideration include: aquatic animal feeds, traceability of aquatic animals and products, antimicrobial resistance, and biotechnology related issues.

The first priority is for the OIE to develop recommendations on the food safety implications of aquatic animal feeds. This could be done via an *ad hoc* Group reporting to the Animal Production Food Safety Working Group and then to the Aquatic Animals Commission if the revised mandate is approved by the International Committee.

Dr Vallat agreed in principle to the approach proposed by the Aquatic Animals Commission.

13.5 Review of the Aquatic Animals Commission's work plan for 2009

The updated Aquatic Animals Commission's work plan for 2009/2010 is presented at Annex XXI for information.

14. Date of the next meeting

9-13 March 2009.

.../Annexes

Annex I

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13–17 October 2008

_____

List of participants

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Annex I (contd)

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Annex II

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 13–17 October 2008

Adopted Agenda

Welcome from the Director General

Adoption of the Agenda

1. Activities and progress of *ad hoc* Groups

1.1. Report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases – Crustacean Team – June 2008

1.2. Report of the *ad hoc* Group on Aquatic Animal Health Surveillance – April 2008 and July 2008

1.3. Report of the *ad hoc* Group on Safety of Products Derived from Aquatic Animals – August 2008

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

2.1. General comments

2.2. Listing of sabellid worm (*Terebrasabella heterouncinata)*

2.3. Case definition for abalone viral mortality

2.4. Crayfish plague

2.5. Guidelines for the control of aquatic animal health hazards in aquatic animal feed

2.6. Handling and disposal of carcasses and wastes of aquatic animals (New Chapter)

3. *Aquatic Animal Health Code* – other items

3.1. Definitions (Chapter 1.1.1.)

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

3.3. Disease chapters

3.4. Welfare of farmed fish during transport (New Chapter)

Annex II (contd)

3.5. Disease specific surveillance chapters and Model for authors

3.6. Model international aquatic animal health certificates

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

5. OIE PVS Tool

6. Regional Commissions Conferences

6.1. 23rd Conference of the OIE Regional Commission for Europe

6.2. Upcoming Conferences

7. OIE Meetings

7.1. OIE/NACA Regional Workshop on Aquatic Animal Health

7.2. OIE Regional Seminar on 'OIE international standards, a lever for growth in the fisheries and aquaculture sector in Southern Africa'

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

8. Other Meetings

9. Cooperation with FAO

10. *Manual of Diagnostic Tests for Aquatic Animals*

10.1. Sixth edition (2009)

10.1.1. Update on progress and timelines

10.1.2. Diseases of amphibians

11. OIE Reference Laboratories

11.1. Abalone viral mortality complex

11.2. Amphibian diseases

11.3. New applications for Reference Laboratory status

11.4. New diseases proposed for listing

11.5. Twinning application

11.6. OIE seminar to be held during WAVLD Conference, Madrid, 19 June 2009

12. Disease cards

13. Other business

13.1. De-listed diseases

13.2. Second OIE Global Conference on Aquatic Animal Health

13.3. Update of the Commission's web pages

13.4. Review of Aquatic Animals Commission mandate regarding food safety

13.5. Review of the Aquatic Animals Commission's work plan for 2009

14. Date of the next meeting

Annex III

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1.

For the purpose of the *Aquatic Code*:

~~*Acceptable risk*~~

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

~~*Approved laboratory*~~

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

~~*Aquatic Animal Health Standards Commission*~~

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

~~*Aquatic animal import unit*~~

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

~~*Breeding station*~~

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

~~*Broodstock*~~

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

Communication

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

Crisis

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

Crisis Communication

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

~~*Compartmentalisation*~~

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

Annex III (contd)

~~*Crustacean products*~~

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

~~*Discharge*~~

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

~~*Fish products*~~

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

~~*Fish slaughtering premises*~~

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

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

~~*Food hygiene*~~

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

~~*Free aquaculture establishment*~~

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

~~*Fresh crustaceans*~~

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

~~*Fresh fish*~~

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

~~*Fresh molluscs*~~

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

~~*Hatcheries*~~

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

~~*Imported outbreak*~~

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

~~*Infected aquaculture establishment*~~

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

~~*Laboratory*~~

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

~~*Lot*~~

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

~~*Marketing*~~

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

~~*Mollusc nurseries*~~

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

Outbreak ~~*of disease*~~

means the sudden ~~an~~ occurrence of *disease* in an *aquatic animal population.*

Outbreak communication

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

~~*Ova*~~

~~see *eggs* and *gametes*.~~

~~*Partial stamping out policy*~~

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

~~*Place of shipment*~~

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

~~*Population*~~

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

~~*Processing*~~

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

~~*Products of animal origin destined for use in aquatic animal feeding*~~

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

~~*Products of aquatic animal origin destined for human consumption*~~

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

~~*Qualitative risk assessment*~~

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

Annex III (contd)

~~*Quantitative risk assessment*~~

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

Risk

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

Risk assessment

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

Risk communication

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

~~*Sanitary measure*~~

~~means measures such as those described in each chapter of the *Aquatic Code* that are used for *risk* reduction and are appropriate for particular *diseases*.~~

~~*Sanitary slaughtering*~~

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

~~*Screening method*~~

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

~~*Sealed vehicle*~~

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

~~*Sensitivity analysis*~~

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

~~*Sexual products*~~

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

~~*Shellfish*~~

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

~~*Shipment*~~

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

~~*Sperm*~~

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

Annex III (contd)

~~*Subclinical*~~

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

~~*Surveillance zone*~~

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

~~*Transparency*~~

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

~~*Transport*~~

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

~~*Uncertainty*~~

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

~~*Variability*~~

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

~~*Vertical transmission*~~

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

~~*Zoning*~~

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

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~~—~~ text deleted

Annex IV

CHAPTER 1.2.3.

DISEASES LISTED BY THE OIE

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

Article 1.2.3.1.

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

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

Article 1.2.3.2.

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

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*
- Abalone herpes-like virus disease ~~viral mortality~~[1]
- Infection with *Terabrasabella heterouncinata.*

Article 1.2.3.3.

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

- Taura syndrome
- White spot disease
- Yellowhead disease
- ~~Tetrahedral baculovirosis (*Baculovirus penaei*)~~
- ~~Spherical baculovirosis (*Penaeus monodon*-type baculovirus)~~
- Infectious hypodermal and haematopoietic necrosis
- Crayfish plague (*Aphanomyces astaci*)
- Necrotising hepatopancreatitis~~[2]~~
- Infectious myonecrosis
- White tail disease[1]
- ~~Hepatopancreatic parvovirus disease[2]~~
- ~~Mourilyan virus disease[2]~~
- Milky haemolymph disease of spiny lobsters (*Panulirus* spp.)[1]

Annex IV (contd)

Article 1.2.3.4.

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

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

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— text deleted

1 Listed according to Article 1.2.2.2.

2 Listing of this disease is under study.

Annex V

CHAPTER 1.3.1.

GENERAL OBLIGATIONS RELATED TO CERTIFICATION

Article 1.3.1.1.

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

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

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

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

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

Article 1.3.1.2.

Responsibilities of the importing country

1. The import requirements included in the *international aquatic animal health certificate* should assure that *commodities* introduced into the *importing country* comply with OIE standards ~~the national level of protection~~. *Importing countries* should restrict their requirements to those ~~justified for such~~ necessary to achieve the national appropriate ~~a~~ level of protection. If these are ~~more~~ stricter than the OIE standards, ~~guidelines and recommendations, then~~ they should be based on an import *risk analysis*.

2. The *international aquatic animal health certificate* should not include requirements for the exclusion of *disease agents* or *aquatic animal diseases* that are present ~~within the *territory* of~~ in the *importing country* and are not subject to any official control programme, except when the strain of the *disease agent* in the *exporting country* is of significantly higher pathogenicity and/or has a larger host range. ~~The requirements applying to *disease agents* or *diseases* subject to official control programmes in a country or *zone* should not provide a higher level of protection on imports than that provided for the same *disease agents* or *diseases* by the measures applied within that country or *zone*.~~ The measures imposed on imports to manage the *risks* posed by a *disease agent* or *aquatic animal disease* should not require a higher level of protection than that provided by measures applied as part of the official control programme operating within the *importing country*.

Annex V (contd)

3. The *international aquatic animal health certificate* should not include ~~requirements for~~ measures against *disease agents* or *diseases* that ~~which~~ are not OIE listed, unless the *importing country* has ~~identified the *disease agent* as presenting a significant *risk* for that country, after conducting a scientifically based import *risk analysis* according to the guidelines in Section 1.4.~~ demonstrated through an import *risk analysis*, carried out in accordance with Section 1.4., that the *disease agent* or *disease* poses a significant *risk* to the *importing country*.

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

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

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

Article 1.3.1.3.

Responsibilities of the exporting country

1. An *exporting country* should, on request, supply the following to *importing countries*:

   a) information on the *aquatic animal* health situation and national *aquatic animal* health information systems to determine whether that country is free or has *zones* or *compartments* ~~that are~~ free from *OIE-listed diseases* including the regulations and procedures in force to maintain ~~it's~~ the free status;

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

   ~~c) for *diseases* not listed, information on new findings that are of potential epidemiological significance to other countries;~~

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

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

   f) technical information, particularly on biological tests and vaccines applied in all or part of the country ~~national *territory*;~~,

   ~~g) identification of the country or location of harvest or production of the product being exported.~~

2. *Competent Authorities* of *exporting countries* should:

   a) have official procedures for the authorisation of *certifying officials*, defining their functions and duties as well as conditions covering possible suspension and termination of the~~ir appointment~~ authorisation;

   b) ensure that relevant instructions and training are provided to *certifying officials*;

   c) monitor the activities of the *certifying officials* to verify their integrity and impartiality.

3. The ~~Head of the~~ *Competent Authority* of the *exporting country* is ultimately accountable for certification ~~the *certifying official*~~ used in *international trade*.

Article 1.3.1.4.

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

1. *International trade* involves a continuing ethical responsibility. Therefore, if within a reasonable period subsequent to an export taking place, the *Competent Authority* becomes aware of the appearance or reappearance of a *disease* that has been specifically included in the *international aquatic animal health certificate* or other *disease* of potential epidemiological importance to the *importing country* there is an obligation for the *Competent Authority* to notify the *importing country*, so that the imported ~~*aquatic animals*~~ *commodities* may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.

2. ~~Equally, i~~If a *disease* condition appears in imported *aquatic animals* within a reasonable period after importation, the *Competent Authority* of the *exporting country* should be informed so as to enable an investigation to be made, because this may be the first available information on the occurrence of the *disease* in a previously free *aquatic animal* population. The *Competent Authority* of the *importing country* should be informed of the result of the investigation because the source of *infection* may not be in the *exporting country*.

3. If a *disease* condition appears in *aquatic animals* in the *importing country* within a reasonable period after importation of *commodities*, the *Competent Authority* of the *exporting country* should be informed so as to enable an investigation to be made, because this may be the first available information on the occurrence of the *disease* in a previously free *aquatic animal* population. The *Competent Authority* of the *importing country* should conduct trace back investigations because the source of *disease* may not be in the *exporting country*.

4. In case of suspicion, on reasonable grounds, that an *international aquatic animal health certificate* may be fraudulent, the *Competent Authority* of the *importing country* and *exporting country* should conduct an investigation. Consideration should also be given to notifying any third country(ies) that may have been implicated. All associated *consignments* should be kept under official control, pending the outcome of the investigation. The *Competent Authorities* of all countries involved should fully cooperate with the investigation. If the *international aquatic animal health certificate* is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

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Annex VI

CHAPTER 1.3.2.

CERTIFICATION PROCEDURES

Article 1.3.2.1.

Protection of the professional integrity of the certifying official

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

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

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

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

Article 1.3.2.2.

Certifying officials

Certifying officials should:

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

2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party authorised by the *Competent Authority*;

3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the *certifying official* should be in possession of that documentation before signing;

4. have no conflict of interest in the commercial aspects of the *aquatic animals* or *aquatic animal products* being certified and be independent from the commercial parties.

Article 1.3.2.~~2~~3.

~~Procedures for the p~~Preparation of international aquatic animal health certificates

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

Annex VI (contd)

1. Certificates should be designed so as to minimise the potential for fraud including use of a unique identification number, or other appropriate means to ensure security. Paper certificates should ~~be pre-printed, if possible on one sheet of paper, serially numbered, and issued by the *Competent Authority* on officially headed notepaper and, if possible, printed using techniques that prevent forgery.~~ bear the official identifier of the issuing *Competent Authority*. Each page of a multiple page certificate should bear the unique certificate number and a number indicating the number of the page out of the total number of pages. Electronic certification procedures should include equivalent safeguards.

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

3. If so required, they should be written in the language of the *importing country*. In such circumstances, they should also be written in a language understood by the *certifying official*.

4. They should require appropriate identification of *aquatic animals* and *aquatic animal products* except where this is impractical (e.g. eyed eggs).

5. They should not require a *certifying official* to certify matters that are outside his/her knowledge or that he/she cannot ascertain and verify.

6. Where appropriate, they should be accompanied, when presented to the *certifying official*, by notes of guidance indicating the extent of enquiries, tests or examinations expected to be carried out before the certificate is signed.

7. Their text should not be amended except by deletions that must be signed and stamped by the *certifying official*. The signature and stamp must be in a colour different to that of the printing of the certificate.

8. Only original certificates should be ~~are~~ accepted ~~able~~ by the *importing country*.

9. Replacement certificates may be issued by a *Competent Authority* to replace original certificates that have been, for example, lost, damaged, contain errors, or where the original information is no longer correct. These duplicates should be provided by the issuing authority and ~~These must~~ be clearly marked to indicate that they are replacing the original certificate. A replacement certificate should reference the number and the issue date of the certificate that it supersedes. The superseded certificate should be cancelled and where possible, returned to the issuing authority.

~~Article 1.3.2.3.~~

~~Certifying officials~~

~~*Certifying officials* should:~~

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

~~2. only certify matters that are within their own knowledge at the time of signing the certificate, or that have been separately attested by another competent party approved by the *Competent Authority*;~~

~~3. sign only at the appropriate time certificates that have been completed fully and correctly; where a certificate is signed on the basis of supporting documentation, the *certifying official* should be in possession of that documentation before signing;~~

~~4. have no conflict of interest in the commercial aspects of the *aquatic animals* or *aquatic animal products* being certified and be independent from the commercial parties.~~

Article 1.3.2.4.

Electronic certification

1. Certification may be provided by electronic documentation sent directly from the *Competent Authority* of the *exporting country* to the *Competent Authority* of the *importing country*. Normally, such systems also provide an interface with the commercial organisation marketing the *commodity* for provision of information to the certifying authority. The *certifying official* must have access to all information such as laboratory results and *aquatic animal* identification data.

2. Electronic certificates should carry the same information as conventional certificates.

3. The *Competent Authority* must have in place systems for the security of electronic certificates against access by unauthorised persons or organisations.

4. The *certifying official* must be officially responsible for the secure use of his/her electronic signature. ~~This may be by a personal identification number or a similar secure mechanism.~~

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Annex VII

CHAPTER 1.4.3.

QUALITY AND EVALUATION OF COMPETENT AUTHORITIES

Article 1.4.3.1.

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

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

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

The quality of *Competent Authorities* can be measured through an evaluation, the general principles of which are described in Article 1.4.4.3. and in Article 1.4.4.4.

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

Article 1.4.3.2.

Fundamental principles of quality

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

1. Professional judgement

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

2. Independence

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

3. Impartiality

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

4. Integrity

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

Annex VII (contd)

5. Objectivity

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

6. General organisation

The *Competent Authorities* must be able to demonstrate by means of appropriate legislation, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of *aquatic animal* health measures, and of international *aquatic animal* health certification activities. Legislation 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 the control of *aquatic animal* movements, *aquatic animal* disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

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

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

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

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

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

7. Quality policy

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

8. Procedures and standards

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

a) programming and management of activities, including international *aquatic animal* health certification activities;

b) prevention, control and *notification* of disease *outbreaks*;

c) *risk analysis*, epidemiological *surveillance* and *zoning*;

d) inspection and sampling techniques;

e) diagnostic tests for *aquatic animal diseases*;

f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;

g) border controls and import regulations;

h) *disinfection*;

i) treatments intended to destroy, if appropriate, pathogens in *aquatic animal* products.

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

9. Information, complaints and appeals

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

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

10. Documentation

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

11. Self-evaluation

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

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

12. Communication

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

13. Human and financial resources

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

Annex VII (contd)

Article 1.4.3.3.

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

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

Article 1.4.3.4.

A Member that intends to conduct an evaluation of another Member's *Competent Authorities* should give them notice in writing. This notice should define the purpose of the evaluation and details of the information required.

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

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

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

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

Article 1.4.3.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of the *Competent Authorities* of Members, upon request by Members.

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

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

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

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

Annex VIII

CHAPTER 2.3.7.

CRAYFISH PLAGUE

Article 2.3.7.1.

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

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

Article 2.3.7.2.

Scope

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

Article 2.3.7.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any crayfish plague related conditions, regardless of the crayfish plague status of the *exporting country*, *zone* or *compartment*.

    a) For the species referred to in Article 2.3.7.2. intended for any purpose:

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

        ii) chemically extracted chitin;

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

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

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

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

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

Annex VIII (contd)

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.7.2., other than those listed in point 1 of Article 2.3.7.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.7.7. to 2.3.7.11. relevant to the crayfish plague status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation / transit from an *exporting country*, *zone* or *compartment* not declared free of crayfish plague of a *commodity* of a species not covered in Article 2.3.7.2. but which could reasonably be expected to be a potential mechanical vector for *A. astaci*, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.7.4.

Crayfish plague free country

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

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

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

OR

2. A country where the *susceptible species* referred to in Article 2.3.7.2 are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been met continuously in the country for at least the past 10 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 25 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual*) may make a *self-declaration of freedom* from crayfish plague when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 5 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *A. astaci*.

OR

4. A country that has previously made a *self-declaration of freedom* from crayfish plague but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from crayfish plague again until the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 5 years without detection of *A. astaci*; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 5 years.

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

Article 2.3.7.5.

Crayfish plague free zone or free compartment

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

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

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

OR

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

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 25 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual*) may be declared free from crayfish plague when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 5 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 5 years without detection of *A. astaci*.

Annex VIII (contd)

OR

4. A *zone* previously declared free from crayfish plague but in which the *disease* is detected may not be declared free from crayfish plague again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 5 years without detection of *A. astaci*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 5 years.

Article 2.3.7.6.

Maintenance of free status

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

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of point 3 of Articles 2.3.7.4. or 2.3.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as crayfish plague free provided that conditions that are conducive to clinical expression of crayfish plague, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.7.7.

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

When importing live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from crayfish plague.

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

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

Article 2.3.7.8.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures:

    a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

    b) the treatment of all effluent and waste materials in a manner that ensures inactivation of *A. astaci*.

2. If the intention of the introduction is the establishment of a new stock, the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: http://www.ices.dk/indexfla.asp) may be summarised to the following main points:

    a) identify stock of interest (cultured or wild) in its current location;

    b) evaluate stock health/disease history;

    c) take and test samples for *A. astaci*, pests and general health/disease status;

    d) import and quarantine in a secure facility a founder (F-0) population;

    e) produce F-1 generation from the F-0 stock in *quarantine*;

    f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *A. astaci* and perform general examinations for pests and general health/disease status;

    g) if *A. astaci* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as crayfish plague free or specific pathogen free (SPF) for *A. astaci*;

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

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

Article 2.3.7.9.

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

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

Annex VIII (contd)

1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the *processing* be treated in a manner that ensures inactivation of *A. astaci*.

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

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

Article 2.3.7.10.

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

When importing *aquatic animal products* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from crayfish plague.

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

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

Article 2.3.7.11.

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

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

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

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Annex IX

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

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

Article 2.1.4.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any SVC related conditions, regardless of the SVC status of the *exporting country*, *zone* or *compartment*:

   a) From the species referred to in Article 2.1.4.2. intended for any purpose:

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

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

   ~~b) The following *commodities* destined for human consumption from the species referred to in Article 2.1.4.2. which have been prepared and packaged for direct retail trade:~~

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

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

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

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

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.1.4.2., other than those referred to in point 1 of Article 2.1.4.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.1.4.7. to 2.1.4.12. relevant to the SVC status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation~~/~~ or transit of a *commodity* from an *exporting country*, *zone* or *compartment* not declared free of SVC ~~of a live *commodity*~~ from a species not covered in Article 2.1.4.2. but which could reasonably be expected to be a ~~potential~~ mechanical vector/fomite for SVC, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

[…]

Annex IX (contd)

Article 2.1.4.9.

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

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

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.4.3., or products described in point 1 ~~2~~ of Article 2.1.4.12., or other products authorised by the *Competent Authority*; and

2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of SVCV.

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

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

[…]

Article 2.1.4.12.

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

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

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

   ii) fillets or cutlets (chilled or frozen);

   iii) dried *eviscerated fish* (including air dried, flame dried and sun dried);

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

2. When importing *aquatic animal products*, other than those referred to in point 1. above, of the species referred to in Article 2.1.4.2. from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

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

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

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

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Annex X

CHAPTER 2.3.X.

NECROTISING HEPATOPANCREATITIS

Article 2.3.X.1.

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

Methods for conducting surveillance and diagnosis of NHP are provided in the *Aquatic Manual* (under development).

Article 2.3.X.2.

Scope

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

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

Article 2.3.X.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any NHP related conditions, regardless of the NHP status of the *exporting country*, *zone* or *compartment*.

    a) For the species referred to in Article 2.3.X.2. intended for any purpose:

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

        ii) chemically extracted chitin;

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

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

    b) [The following products destined for human consumption from species referred to in Article 2.3.X.2. which have been prepared and packaged for direct retail trade:

        i) de-headed and “de-veined” (intestine removed) shrimp tails.

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

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.X.2., other than those listed in point 1 of Article 2.3.X.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.X.7. to 2.3.X.11. relevant to the NHP status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation / transit from an *exporting country*, *zone* or *compartment* not declared free of NHP of a *commodity* of a species not covered in Article 2.3.10.2. but which could reasonably be expected to be a potential mechanical vector for NHP-B, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.X.4.

Necrotising hepatopancreatitis free country

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from NHP if all the areas covered by the shared water are declared NHP free countries or *zones* (see Article 2.3.x.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.X.2. is present may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.X.2. are present but there has been no observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual)*, may make a *self-declaration of freedom* from NHP when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of NHP-B.

OR

4. A country that has previously made a *self-declaration of freedom* from NHP but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from NHP again when the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of NHP-B and;

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 2.3.X.5.

Article 2.3.X.5.

Necrotising hepatopancreatitis free zone or free compartment

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a NHP free *zone* or *compartment* if all the relevant *Competent Authorit(ies)* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.X.2. is present may be declared free from NHP when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.x.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from NHP when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual)*, may be declared free from NHP when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of NHP-B.

Annex X (contd)

OR

4. A *zone* previously declared free from NHP but in which the *disease* is detected may be declared free from NHP again when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of NHP-B and;

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.X.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from NHP following the provisions of points 1 or 2 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may maintain its status as NHP free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from NHP following the provisions of point 3 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as NHP free provided that conditions that are conducive to clinical expression of NHP, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.X.7.

Importation of live aquatic animals from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing live *aquatic animals* of the species referred to in Article 2.3.x.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.x.4. or 2.3.x.5. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from NHP.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.8.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:

    a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

    b) the treatment of all effluent and waste materials in a manner that ensures inactivation of NHP-B.

2. If the intention of the introduction is the establishment of a new stock, Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: http://www.ices.dk/indexfla.asp) may be summarised to the following main points:

    a) identify stock of interest (cultured or wild) in its current location;

    b) evaluate stock health/*disease* history;

    c) take and test samples for NHP-B, pests and general health/*disease* status;

    d) import and quarantine in a secure facility a founder (F-0) population;

    e) produce F-1 generation from the F-0 stock in *quarantine*;

    f) culture F-1 stock and at critical times in its development (life cycle) sample and test for NHP-B and perform general examinations for pests and general health/*disease* status;

    g) if NHP-B is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet *basic biosecurity conditions* of the *importing country*, *zone*, or *compartment*, the F-1 stock may be defined as NHP free or specific pathogen free (SPF) for NHP-B;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.9.

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

When importing, for human consumption, live *aquatic animals* of the species referred to in Article 2.3.x.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Annex X (contd)

1. the consignment be delivered directly to and held in isolation until *processing* and/or consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the *processing* be treated in a manner that ensures inactivation of NHP-B.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.10.

Importation of aquatic animal products from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing *aquatic animal products* of the species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.X.4. or 2.3.X.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from NHP.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from necrotising hepatopancreatitis

When importing *aquatic animal products* of the species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Annex XI

CHAPTER 2.3.X.

MILKY HAEMOLYMPH DISEASE OF SPINY LOBSTERS

Article 2.3.X.1.

For the purposes of the *Aquatic Code*, milky haemolymph disease of spiny lobsters (*Panulirus* spp.) (MHD) means *infection* with an unclassified rickettsial-like bacteria.

Methods for conducting surveillance and diagnosis of MHD are provided in the *Aquatic Manual* (under development).

Article 2.3.X.2.

Scope

The recommendations in this Chapter apply to: tropical spiny lobsters in the genus *Panulirus* spp., especially *Panulirus ornatus*, *P. homarus* and *P. stimpsoni.* Common names for these and other potential *susceptible species* are listed in the *Aquatic Manual.* These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

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

Article 2.3.X.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any MHD related conditions, regardless of the MHD status of the *exporting country*, *zone* or *compartment*.

    a) For the species referred to in Article 2.3.X.2. intended for any purpose:

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

        ii) chemically extracted chitin;

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

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

    b) [The following products destined for human consumption from species referred to in Article 2.3.X.2. which have been prepared and packaged for direct retail trade:

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

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.X.2., other than those listed in point 1 of Article 2.3.X.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.X.7. to 2.3.X.11. relevant to the MHD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of MHD of a *commodity* of a species not covered in Article 2.3.X.2. but which could reasonably be expected to be a potential mechanical vector for MHD, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.X.4.

Milky haemolymph disease free country

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from MHD if all the areas covered by the shared water are declared MHD free countries or *zones* (see Article 2.3.X.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.X.2. is present may make a *self-declaration of freedom* from MHD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.X.2. are present but there has been no observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from MHD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual*) may make a *self-declaration of freedom* from MHD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of the bacterial agent of MHD.

OR

4. A country that has previously made a *self-declaration of freedom* from MHD but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from MHD again when the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimize the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of the agent of MHD; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 2.3.X.5.

Article 2.3.X.5.

Milky haemolymph disease free zone or free compartment

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

If a *zone* or *compartment* extends over more than one country, it can only be declared an MHD free *zone* or *compartment* if all the relevant *Competent Authority(ies)* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.X.2. is present may be declared free from MHD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.X.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from MHD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual*) may be declared free from MHD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *AquaticManual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of the agent of MHD.

Annex XI (contd)

OR

4. A *zone* previously declared free from MHD but in which the *disease* is subsequently detected may be declared free from MHD again when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimize the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of the agent of MHD; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.X.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from MHD following the provisions of points 1 or 2 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may maintain its status as MHD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from MHD following the provisions of point 3 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as MHD free provided that conditions that are conducive to clinical expression of MHD, as described in Chapter X.X.X.. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.X.7.

Importation of live aquatic animals from a country, zone or compartment declared free from milky haemolymph disease

When importing live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* declared free from MHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.X.4. or 2.3.X.5. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from MHD.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from milky haemolymph disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from MHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:

   a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

   b) the treatment of all effluent and waste materials in a manner that ensures inactivation of the agent of MHD.

2. If the intention of the introduction is the establishment of a new stock, the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: http://www.ices.dk/indexfla.asp) may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

   c) take and test samples for the agent of MHD, pests and general health/disease status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for MHD and perform general examinations for pests and general health/disease status;

   g) if the agent of MHD is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as MHD free or specific pathogen free (SPF) for the agent of MHD;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from milky haemolymph disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from MHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Annex XI (contd)

1. the consignment be delivered directly to and held in isolation until *processing* and/or consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the *processing* be treated in a manner that ensures inactivation of the agent of MHD.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.10.

Importation of aquatic animal products from a country, zone or compartment declared free from milky haemolymph disease

When importing *aquatic animal products* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* declared free from MHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.X.4. or 2.3.X.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from MHD.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from milky haemolymph disease

When importing *aquatic animal products* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from MHD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Annex XII

APPENDIX 4.1.

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

Article 4.1.1.

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

1. General

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

2. Part I. Details of dispatched consignment

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

Annex XII (contd)

Box I.10.	Name of the place from which the live aquatic animals or aquatic animal products are being shipped (this will be a land, sea or airport).
Box I.11.	Date of departure. For live aquatic animals include the expected time of departure.
Box I.12.	Details of the means of transport. Identification of the means of transport at the time the certificate is issued: for air transport, the flight number; for maritime transport, the name of the vessel; for rail transport, the number of the train and the wagon and for road transport, the registration number of the road vehicle and the number of the trailer where used.
Box I.13.	Name of expected border post and, if available, its UN/LOCODE (refer to the United Nations Code for Trade and Transport Locations).
Box I.14.	CITES permit number(s) if the commodity concerns species listed in the Convention on International Trade in Endangered Species of Wild Fauna and Flora.
Box I.15.	Describe the commodity or use the titles as they appear in the Harmonised System of the World Customs Organization.
Box I.16.	Heading or HS Code of the Harmonized System set up by the World Customs Organization.
Box I.17.	Total quantity or weight of the commodity. For live aquatic animals give the total count of aquatic animals or weight. For live aquatic animals products and gametes give the gross weight and the net weight in kg of the whole consignment.
Box I.18.	Temperature of products for transport and storage.
Box I.19.	For live aquatic animals or gametes give the total number of containers in which they are being transported. For aquatic animal products give the total number of packages.
Box I.20.	Identify the containers/seal numbers where required.
Box I.21.	Identify the type of packaging of aquatic animal products as defined in Recommendation No. 21 – Code of Passengers, Type of Cargo, Package and Packaging Materials of UN/CEFACT (United Nation Centre for Trade Facilitation and Electronic Business).
Box I.22.	Intended use of the imported live aquatic animals or aquatic animal products. Breeding: applies to gametes and broodstock. Grow out: applies to live aquatic animals, aquatic eggs and aquatic larvae Slaughter: applies to live aquatic animals for slaughter. Restocking: applies to live aquatic animals for the purpose of rebuilding stocks. Ornamental: applies to live aquatic animals kept for companionship or enjoyment. Competition/Exhibition: applies to live aquatic animals used in an exhibition. Human consumption: applies to aquatic animals or aquatic animals products intended for human consumption.

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

3. Part II. Zoosanitary information

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

Annex XII (contd)

Article 4.1.2.

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

COUNTRY :

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

* Optional and ** If referenced in Part II.

Annex XII (contd)

COUNTRY :

Part II. Zoosanitary information

	II.a. Certificate reference number:

II. The undersigned Certifying Official certifies that the animal(s)/hatching eggs described above satisfy(ies) the following requirements:

Certifying Official:

Name and address (in capital letters):

Official position:

Date:

Signature:

Stamp:

Annex XII (contd)

Article 4.1.3.

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

COUNTRY :

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

* Optional and ** If referenced in Part II.

Annex XII (contd)

COUNTRY :

Part II. Zoosanitary information

II.a. Certificate reference number

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

Certifying Official:

Name and address (in capital letters):

Official position:

Date:

Signature:

Stamp:

Annex XIII

CRITERIA TO ASSESS THE SAFETY OF AQUATIC ANIMAL COMMODITIES IRRESPECTIVE OF COUNTRY DISEASE STATUS

1. Absence of disease agent in the traded commodity:

   1a. There is strong evidence that the disease agent does not occur in the tissues from which the commodity is derived;

   AND

   1b. The water used to rear or process the commodity is not contaminated with the disease agent and the processing prevents cross contamination of the final product.

OR

2. Even if the disease agent does occur in the tissues from which the commodity was derived, the processing to produce the final commodity involves processes known to inactivate the disease agent:

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

   AND/OR

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

   AND/OR

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

Annex XIV

CRITERIA TO ASSESS THE SAFETY OF AQUATIC ANIMAL PRODUCTS DESTINED FOR HUMAN CONSUMPTION

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

AND

2. Includes only a small amount of waste tissues;

AND

3a. The disease agent is unlikely to be present in the waste tissues;

OR

3b. The disease agent does occur in the waste tissues but the processing (i.e. post importation such as cooking) to produce the final consumable product involves processes known to inactivate and/or reduce the load of disease agent:

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

AND/OR

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

AND/OR

iii) Biological (e.g. fermentation).

Annex XV

APPENDIX 3.4.2.

WELFARE OF FARMED FISH DURING TRANSPORT

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

Article 3.4.2.1.

Responsibilities

The welfare of farmed fish during their transport is the joint responsibility of all personnel involved. All parties handling fish prior to loading as well as during loading and unloading have a personal responsibility for the welfare of the fish being handled.

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

1. The responsibilities of the *Competent Authority* for the exporting and importing jurisdiction include:

    a) establishing minimum standards for fish welfare during transport, including examination before, during and after their transport, appropriate certification and record keeping;

    b) ensuring appropriate awareness and training of personnel involved in transport;

    c) ensuring implementation of the standards, including possible accreditation of transport companies.

2. Owners and managers of farmed fish at the start and at the end of the journey are responsible for:

    a) the general health of the fish and their fitness for transport at the start of the journey and to ensure the overall welfare of the fish during the transport regardless of whether these duties are subcontracted to other parties;

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

    c) having a contingency plan available to enable humane killing of the fish at the start and at the end of the journey, if required.

3. Transport companies, in cooperation with the *Competent Authority* and farm owner/manager, are responsible for planning the transport to ensure that the transport can be carried out according to fish health and welfare standards including:

    a) choosing an appropriate, well maintained *vehicle*;

    b) ensuring that competent staff are available for loading and unloading;

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

d) selecting appropriate technology for loading and unloading of the *vehicle*.

4. The person in charge of supervising the transport is responsible for all documentation relevant to the transport, and practical implementation of guidelines for welfare of fish during transport.

Article 3.4.2.2.

Competence

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

1. All persons handling live fish, or who are otherwise responsible for live fish during transport, should be competent according to their responsibilities listed in Article 3.4.2.1.

2. *Competent Authority*, farm owners/managers, and transport companies have a responsibility in providing appropriate training to their staff and personnel.

3. Any necessary training should address species-specific knowledge and may include practical experience on:

a) fish behaviour, physiology, general signs of disease and poor welfare;

b) operation and maintenance of equipment relevant to fish health and welfare;

c) water quality;

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 adverse weather conditions, and emergencies;

g) appropriate logbooks and record keeping.

Article 3.4.2.3.

Planning the transport

1. General considerations

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

a) type of *vehicle* and transport equipment required;

b) route – such as distance, expected weather and/or sea conditions;

c) nature and duration of the transport;

d) need for care of the fish during the transport;

e) emergency response procedures related to fish welfare;

f) assessment of the necessary biosecurity level (e.g. washing and *disinfection* practices, safe places for changing water, treatment of transport water (refer to Chapter 1.5.1.).

2. Contingency plans

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

3. Vehicle design and maintenance

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

b) *Vehicles* and *containers* should be maintained in good mechanical and structural condition to prevent predictable and avoidable damage of the *vehicle* that may directly or indirectly affect the welfare of transported fish.

c) *Vehicles* (if relevant) and *containers* should have adequate circulation of water and equipment for oxygenation to meet variations in the conditions during the journey.

d) The fish should be accessible to inspection en route to ensure that fish welfare standards can be assessed and shortcomings appropriately addressed.

e) Documentation that focuses on fish welfare and thus carried with the *vehicle* should include a transport logbook of stocks received, contact information, mortalities and disposal/storage logs.

4. Water

a) Water quality (e.g. oxygen, pH, temperature, salinity) should be adequate for the species being transported.

b) Equipment to maintain adequate water quality (e.g. oxygen, pH, temperature, salinity) and to monitor water quality may be required depending on the length of the transport.

5. Documentation

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

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

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

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

c) The transport log should be made available to the dispatcher and the receiver of the consignment as well as to the *Competent Authority* upon request. Transport logs from previous journeys should be kept after completion of the transport for a period of time as specified by the *Competent Authority*.

6. Preparation of fish for the transport

a) Prior to transport, feed should be withheld from the fish, taking into consideration the fish species and life stage to be transported.

b) The ability of the fish to cope with the stress of transport should be assessed based on health status, previous handling and recent transport history of the fish. Except for disease control purposes, only fish that are fit for transport should be loaded.

c) Signs of unfitness for transport includes:

i) significant physical injuries or abnormal behaviour, such as rapid ventilation or abnormal swimming;

ii) recent exposure to stressors;

iii) history of exposure to disease agents.

7. 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 feed deprivation or osmotic acclimatisation.

Article 3.4.2.5.

Loading the fish

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

a) overcrowding;

b) improperly constructed or operated equipment (such as nets, pumps, pipes and fittings);

c) water quality - some species of fish should be acclimatised if there is a likelihood of the fish being transported in water of a significantly different temperature or other water parameters;

d) air temperature, tide level and time of the day.

2. The density of fish in a *vehicle* and/or *container* should not exceed what is generally accepted for a given species and a given situation.

3. Loading should be carried out, or supervised, by operators with knowledge and experience of the behaviour and other characteristics of the fish species being loaded to ensure that the welfare of the fish is maintained.

Article 3.4.2.6.

Transporting the fish

1. General considerations

   a) Where necessary, periodic inspections should take place during the transport to verify that acceptable welfare is being maintained.

   b) Where necessary, the person in charge should ensure that water quality is monitored and the necessary adjustments made to avoid extreme conditions.

   c) The *vehicle* operator should travel in a manner that minimises uncontrolled movements of the fish.

2. Emergency procedures

   a) In the event of a fish health emergency during transport, the *vehicle* operator should initiate the procedure to implement the contingency plan (see point 2 of Article 3.4.2.3.).

   b) If the killing of fish is necessary during the transport, the person in charge should ensure that the killing is carried out humanely in accordance with the Chapter on the Humane Killing of Fish for Disease Control Purposes (in preparation), and in compliance with relevant legislation.

Article 3.4.2.7.

Unloading the fish

1. The principles of good fish handling during loading apply equally during unloading.

2. Fish should be unloaded as soon as possible after arrival at the destination, allowing sufficient time to ensure that the unloading procedure does not cause harm to the fish. Some species of fish should be acclimatised if there is a likelihood of the fish being unloaded into water of a significantly different quality (such as temperature, salinity, pH).

3. Moribund or seriously injured fish should be removed and humanely killed in accordance with the Chapter on the Humane Killing of Fish for Disease Control Purposes (in preparation).

Article 3.4.2.8.

Post-transport activities

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

2. Fish showing abnormal clinical signs should be humanely killed in accordance with the Chapter on the Humane Killing of Fish for Disease Control Purposes (in preparation) or isolated and examined by a veterinarian or other qualified personnel, who may recommend treatment.

3. Significant problems associated with transport should be evaluated to prevent recurrence of such problems.

Article 3.4.2.9.

Actions in the event of an extreme situation

1. Extreme weather conditions are hazards for fish transport and require appropriate *vehicle* and *container* design to minimise risks. Fish should not be transported in extreme weather conditions that threaten fish welfare.

2. If fish cannot be unloaded, temporarily or permanently, the welfare of the fish should be given due consideration while attempts are undertaken to rectify such situations. Fish whose welfare may be irrevocably impacted should be humanely killed in accordance with the Chapter on the Humane Killing of Fish for Disease Control Purposes (in preparation).

Annex XVI

CHAPTER X.X.X.

~~GUIDELINES ON~~ HANDLING AND DISPOSAL OF CARCASSES AND WASTES OF AQUATIC ANIMALS

Article X.X.X.1.

Introduction

~~In the event of any aquatic animal dying due to disease or accidentally due to different causes during aquaculture operations, or in the wild,~~ The scope of this Chapter ~~these guidelines~~ is the handling and *disposal* of carcasses and wastes of *aquatic animals* in the course of routine *aquaculture* operations, as well as in exceptional situations such as mass killing and mass mortality (including in the wild).

In the event of *aquatic animal* mortalities of a significant nature in *aquaculture* or in the wild, the *Competent Authority* should be notified so that necessary steps can be taken to dispose of the dead *aquatic animals*, in order to minimise the risk for possible spread of *disease*.

~~The method for disposal should be based on judgments depending on the cause of mortality of aquatic animals (disease, intoxication, environmental changes, etc.) and the possible risk of introducing a listed disease if no precautionary steps are taken.~~ *Disposal* methods should take into consideration a range of factors, including the cause of mortality. It may be appropriate to carry out a *risk assessment* on the *disposal* options. Relevant environmental and waste management legislation should be adhered to.

~~Carcasses to be disposed of and the disposal process to be chosen should be under the supervision of the *Competent Authority*.~~ Storage, transport and *disposal* of *aquatic animal carcasses* should be carried out in adherence with all relevant local and national legislations. In the case of killing of animals for disease control purposes or unusually large mortalities of unknown origin, this may be requires approval from, or supervision by, the *Competent Authority*.

The guidelines in this Appendix are general in nature. The choice of one or more of the recommended methods should be in compliance with relevant local and national legislations. ~~*The guidelines should be applied in conjunction with procedures described for the killing of aquatic animals in Appendix XXXXX.*~~

Article X.X.X.2.

Definitions

For the purpose of these guidelines, the following definitions are relevant to the *disposal* of *aquatic animal carcasses* and their waste~~s~~:

- ~~**Aquatic animal**. For the purposes of this chapter, '*aquatic animal*' refers to the following: *live fish* (including eggs and gametes), *molluscs, decapods* (lobsters, shrimps, crabs) from aquaculture or the wild. The definition does not cover water-living *amphibians, reptiles, birds* or *mammals*.~~

- **Aquatic animal carcass** means the entire body or parts ~~body/trunk~~ of an *aquatic animal* subsequent to killing or death.

- ~~**Aquatic animal population** means a group of holding units with *aquatic animals* sharing a common defined origin.~~

Annex XVI (contd)

- ~~**Aquatic animals for slaughter/harvest/killing/culling** means *aquatic animals* that are destined to be transported or taken to *fish slaughtering premises* or other *processing plants* preparing products for human consumption or for disposal.~~

- ~~**Aquatic animal offal/waste** means the whole or parts of an *aquatic animal* and *aquatic animal* products not approved for human consumption including sludge and sieve material collected during slaughtering.~~

- ~~**Biogas production** means decomposition of infected material by micro-organisms in an anaerobic environment.~~

- ~~**Container** means a transport appliance:~~

  - ~~of a permanent type and sufficiently strong to enable repeated use;~~
  - ~~specially constructed to facilitate *transportation of live aquatic animals* by one or several means of transport;~~
  - ~~provided with fittings that make it easy to manipulate, particularly for trans-shipment from one kind of transport vehicle to another;~~
  - ~~constructed in a water tight way, easy to load and unload and capable of being cleansed and disinfected between transport;~~
  - ~~ensuring safe and optimal transport of live aquatic animals from a welfare point of view.~~

- **Composting** means decomposition of infected material by micro-organisms under aerobic conditions.

- ~~**Death** means irreversible loss of brain activity in fish and crustaceans.~~

- ~~**Decontamination** means all stages of cleaning and disinfection.~~

- ~~**Disposal** means the inactivation of the pathogen with reduction of the *aquatic animal carcass* and parts of it to constituent components, e.g. by means of i.e. burial, chemical or thermal treatment.~~ **Disposal** means reduction of *aquatic animal carcasses* to its constituent components and inactivation of the pathogens of concern (e.g. by means of burial, chemical or thermal treatment.)

- **Disposal plant** means a plant approved by the *Competent Authority* for the *disposal* of *aquatic animal carcasses* and waste thereof.

- **Ensiling** means the process of grinding the *aquatic animal carcasses* and reducing the pH in the mass by adding an organic acid. The pH should ~~must~~ be kept below 4.0 for the duration of the process.

- **High risk waste** means *aquatic animals* or *aquatic animal carcasses*, waste or offal that constitute, or are suspected of constituting, a serious health risk to animals or humans. Waste that is not *high risk waste* is considered of low risk.

- ~~**High risk waste material** means animal wastes that constitute or are suspected of constituting a serious health risk to animals or humans including:~~

  - ~~dead aquatic animals; including companion animals that the *Competent Authority* make special provisions for;~~

? ~~aquatic animals that are being killed due to disease;~~

? ~~wastes of aquatic animals containing residues of substances that may represent a serious health risk to animals or humans or products of animal origin that is deemed unsuitable for human consumption due to such residual concentrations;~~

? ~~aquatic animals that show clinical signs or at slaughter show pathological signs of disease that is transmissible to fish as well as parts of and wastes from such fish.~~

- ~~**Low risk waste** means; *aquatic animal* wastes other than with the exception of what is defined as *high risk wastes* and that do not constitute serious risk for the spread of disease that may be transmitted to humans or animals, such as fresh wastes from aquatic animals from plants producing fish or fish products for consumption.~~

- ~~**Mass destruction** means an emergency destruction and disposal of the entire population of aquatic animals for disposal.~~

- ~~**Rendering** means a closed processing system for destruction of infective material in *aquatic animals* by means of mechanical and thermal treatment.~~

- ~~**Technology** means the process used for disposal of aquatic animals.~~

- ~~**Transport** means the *bio secure* removal of *aquatic animals*, *aquatic animal carcasses* or parts of *aquatic animals* from the infected *aquaculture establishment* to the site of disposal.~~

- ~~**Waste water** means effluent fluids from the slaughtering and processing process including water from the cleaning process of the slaughtering or processing plant premises.~~

Article X.X.X.3.

General provisions

All *aquatic animal carcasses* and processing waste~~s~~ should ~~shall~~ be treated in such a way that the raw waste material may easily be collected and transported to a separate storing place and subjected to *disposal* in order to ensure that the risk of spreading of *infection* is contained. The storage place should ~~must~~ be separated from the farm site/production area and have leak proof containers and a sufficient carrying capacity to store the waste until *disposal.*

Provisional storage of waste~~s~~ may take place after:

a) chilling/freezing down to 4º C or colder, or

b) preservation with organic acids to below pH of 4~~,~~.0 or lower, or

c) other methods approved by the *Competent Authorities*.

Annex XVI (contd)

Article X.X.X.4.

~~Regulations and Jurisdiction~~ Governance

~~The legislation regulating aquatic animal health and the organisation of the~~ The *Competent Authority* ~~Veterinary Administration~~ should oversee ~~give the *Veterinary Services* the authority and the legal powers to carry out the activities necessary for~~ the efficient and effective *disposal* of dead *aquatic animals* and their waste~~s~~. Cooperation among all ~~between the Veterinary Service and any other~~ relevant agencies and stakeholders ~~bodies~~ involved in *aquatic animal* health is necessary to ensure safe *disposal*. In this context the following aspects should be integrated ~~regulated~~:

1. ~~right of entry to an establishment for the veterinary services and associated personnel;~~ physical, logistical and data access by relevant personnel, in cooperation with involved stakeholders;

2. movement controls and the authority to make exemptions under certain biosecurity conditions, for example for transport of dead *aquatic animals* to another location for *disposal*;

~~3.~~ ~~the obligation of involved farmers/owner and aquatic animal handlers to cooperate with *Veterinary Services*;~~

~~4.~~3. ~~any need~~ mechanisms to transfer ownership of dead *aquatic animals* to the *C~~c~~ompetent A~~a~~uthority*;

~~5.~~4. the determination~~ing~~ of the method and location of *disposal*, and the necessary equipment and facilities, by the *Competent Authority* ~~*Veterinary Services*~~, in consultation with other authorities including national and local government organisations competent for the protection of the environment.

~~Should the chosen option for the *disposal* of dead aquatic animals or wastes of *aquatic animals carcasses* be applied near the border of a neighbouring country, the *competent authorityies* of that country should be consulted.~~

Article X.X.X.5.

Collection, storage and labelling of aquatic animal carcasses / other waste~~s~~

1. On farm storage

   Aquatic animal carcasses infected by an agent causing a~~n OIE listed~~ *disease* referred to in the *Aquatic Code* or suspected of being so, should ~~must~~ not be transported (moved from the farm) to fish slaughterhouse~~s~~ or to establishments for *disposal* ~~of *aquatic animal* waste~~ without permission from the *Competent Authority*.

   Aquatic animal carcasses and waste should ~~must~~ be stored ~~at an appropriate temperature or pH, and~~ in a manner that prevents leakage of infectious agents to the environment. Where possible, waste should be stored frozen or undergo *ensiling*. ~~It is recomended to make silage of the carcasses/waste immediately at the aquaculture establishment where the waste arise. The ensilage production shall include grinding and adding of formic acid so that pH does not exceeding 4.0.~~

   Unnecessary storage of *aquatic animal* waste should ~~must~~ not take place before being handled in an appropriate way according to these regulations. ~~Upon all storage, it must be secured that neither persons not concerned nor aquatic animals have access to aquatic animal waste.~~ All stored wastes should be secured to prevent contact with *aquatic animals*, other animals or birds. Access should be limited to authorised personnel only.

~~Measures must be in place to prevent birds or noxious animals including aquatic animals getting in touch with aquatic animal waste under the storage period.~~

The *Competent Authority* may authorise ~~exempt from the instructions and permit~~ transport of fresh or frozen products to establishments for further handling.

2. Intermediate storage

If intermediate storage sites are planned for *aquatic animal* waste prior to transport to a *disposal plant*, such intermediate storage should ~~must~~ be in ~~pursuance~~ compliance with regulations given by the *Competent Authority*.

Equipment used for transportation should ~~must~~ be cleaned and disinfected before being returned.

Containers used for storage and transport of *aquatic animal* ~~products/~~wastes not intended for human consumption should ~~must~~ be transported in bulk directly to a *disposal plant* for handling, and should ~~must~~ be labelled with the necessary information regarding content, origin and destination.

Article X.X.X.6.

Handling, storage and processing of risk waste ~~material~~

1. High risk waste

Waste material of *aquatic animals* considered to be *high risk waste* should be treated in a *disposal plant* or be destroyed in an incineration plant approved by the *Competent Authority* for this type of waste or according to specific regulations ~~regarding combat~~ on the control of contagious *diseases*. The *Competent Authority* may give exemptions from the instructions for *disposal* including permission to *disposal* by ~~embedment~~ burial or incineration outside an approved incineration plant, ~~upon judgment as regards spread of~~ after consideration of the epidemiology of the *disease*, capacity of the *disposal plant*, availability of transporting *vehicle*, distance of transportation and the amount of waste.

2. Low risk waste

Low risk waste from *aquatic animals* may be used as raw material in feedstuffs for other ~~fur and production~~ animals (such as pigs, poultry, ruminants), technical or pharmaceutical products (such as chitin) or it may be composted.

Alternatively, low risk waste may be treated at *disposal plants* or in other plants/sites according to the instructions given by the competent authority.

If low risk waste ~~are~~ is being handled or transported together with *high risk waste* or being mixed with *high risk waste*, such waste ~~are to~~ should be considered as *high risk waste* and ~~must~~ be treated as such.

3. Processing of high risk waste ~~material~~

a) Registration and labelling of batches

Disposal plants should ~~must~~ have a system for registration and labelling of each batch for tracing purposes ~~in order to trace each batch of products to time of production or sampling for examinations~~. ~~Exemptions may be given for products from incineration and biogas/ *composting* plants.~~

Annex XVI (contd)

b) Notification

If testing of *high risk waste ~~material~~* shows that the product is not satisfactorily produced and thus may be a risk for spreading of an infectious agent, *disposal plants* should ~~have to~~ report immediately to the *Competent Authority* which then may requir~~e~~ additional measures to solve the problem. Such ~~Unsatisfactorily processed~~ products should ~~must~~ not be transported from *disposal plants* without permission from the *Competent Authority*.

c) Reporting

Disposal plants should ~~must~~ report annually to the *Competent Authority* on their ~~its~~ operations. The report should ~~must~~ contain a short summary on quantity and type of raw material received, supplier, quantity and type of finished product, receivers, critical check points, ~~aberrations to~~ and deviations from provisions ~~in pursuance with the~~ stipulated in relevant regulations ~~and measures to correct this~~.

d) Disposal programme

After killing (culling) of *aquatic animals*, the process of *disposal* should take place as soon as possible to ~~prevent~~ minimise the risk of spread of any infectious agent. Procedures should also be in place to avoid spread of *diseases* ~~pathogens~~ by leakages, scavengers, etc. if delay in the *disposal* plan occurs.

e) Site of disposal

Selection of suitable sites for *disposal* should be identified on local or regional basis as part of a contingency plan established by the *Competent Authority*. Ideally, *disposal* on site should not be permitted. If *disposal* on site is necessary, a combination of different methods for treatment of the waste prior to landfill may be approved by the *Competent Authority* (i.e. *ensiling*, thermal treatment).

If the site for *disposal* is close to the border of a neighbouring country, the *Competent Authority* of that country should be notified.

f) Disposal methods

The methods of *disposal* include burial, *composting*, *ensiling*, incineration, pasteurisation, rendering, on-site processing and freezing. The method of choice for *disposal* should ~~must~~ depend on the pathogen in question, the number/volume of *aquatic animals* to be disposed and the site chosen for *disposal*. The choice should be based on an assessment of potential risk to public and animal health as well as potential effects on the environment arising from the *disposal.*

Article X.X.X.7.

Conditions for approval, inspection and supervision of disposal plants ~~and sampling~~ for high risk waste

1. Approval of disposal plants

Disposal plants handling waste~~s~~ of *aquatic animals* should ~~must~~ be approved by the *Competent Authority*.

The localisation and design for building and any substantial change of a *disposal plant* should ~~must~~ be approved by the *Competent Authority*.

Disposal plants using low risk ~~material~~ waste for production of technical or pharmaceutical products may be exempted from the demand for approval but should be registered by the *Competent Authority*.

2. Conditions for approval

In order for a *disposal plant* to be approved for handling of *aquatic animal* waste~~s~~, it should ~~must~~:

a) be adequately separated from the public highway and other premises such as fishfarms, fish slaughterhouses, fish processing plants and rivers, etc.;

b) fulfill requirements for buildings and equipment given by the *Competent Authority*;

c) have access to necessary laboratory services at approved laboratories;

d) fulfill requirements for handling of the *aquatic animal* waste~~s~~ given by the *Competent Authority*;

e) fulfill requirements for handling the products as given by the *Competent Authority*.

Approval should be withdrawn if a *disposal plant* no longer fulfils the criteria given by the *Competent Authority*.

3. General provisions for disposal plants

a) The plant should ~~must~~ be localised at an adequate distance from other establishments that handle *aquatic animals* ~~aquaculture enterprises such as fish slaughterhouses, processing plants and fish farms~~ to minimise the risk of spread ~~so that the risk of spread~~ of infectious agents to such establishments ~~is minimal~~.

b) Routines should ~~must~~ be established in order to prevent *aquatic animal* waste from contaminating ~~getting in touch with~~ equipment that can not be disinfected.

c) The plant should ~~must~~ be separated into a clean and an unclean sector/section.

d) The unclean section should ~~must~~ have floors from which it is easy to collect and lead away liquids. It should ~~must~~ be easy to clean and disinfect.

e) A system for the collection of waste water from the unclean section including the possibility for *disinfection* of the effluent water should ~~must~~ be in place.

f) Handling and treatment of *aquatic animal* waste should take place as soon as possible after being received and it should ~~must~~ be ensured that all organic materials are ~~being~~ treated.

g) Effluent waste water should be disinfected before leaving the premises in order to reduce the risk of spreading *disease*.

h) Measures to prevent birds, insects, rodents or other noxious animals from getting in touch with the *aquatic animal* waste prior to treatment should ~~must~~ be in place.

i) Personnel at the (unclean sector)(dirty section) should ~~must~~ use suitable working clothes and footwear that is easy to distinguish from working clothes used in clean sections. Such personnel should ~~must~~ not be admitted to clean sections without change of working clothes and footwear and after thorough hand washing. Separate pull on clothing and footwear for inspection personnel should ~~must~~ be at hand. Equipment should ~~must~~ not be brought from dirty to clean sections.

Annex XVI (contd)

j) The end product should ~~must~~ comply with requirements set by the *Competent Authority*.

4. Special provisions for *disposal plants*

a) Demands for treatment, refining and storing of animal waste in disposal plants

Aquatic animal waste, if not already ensiled, should ~~must~~ be ensiled as soon as possible after arrival.

The ensiled mass should ~~shall~~ be heated to a core temperature of minimum 85° C for at least 25 minutes and at earliest 24 hours after the admixture of formic acid.

b) Sterilisation plants

Minimum requirements for thermal treatment of the lots is a core temperature of at least 133° C for at least ~~4~~20 minutes at a pressure of 3 ~~bar or 136° C for 20 minutes at a pressure of 3.2 bar. This treatment is due to glueformation and hydrolysation of proteins not suitable for fish wastes unless mixed with other waste materials.~~

c) Incineration plants

Incineration plants treating animal *high risk wastes* of *aquatic animals* should ~~must~~ fulfil the general criteria given above. *Aquatic animal* waste should ~~must~~ be incinerated as soon as possible after being received. ~~Prior~~

d) Composting plants

A *composting* plant should ~~must~~ fulfil the general requirements given above. A *composting* plant should not receive *high risk waste* unless pretreated to a microbiological safe standard; and *aquatic animal* waste should ~~must~~ be composted as soon as possible after being received.

Composting should ~~must~~ take place in a reactor so that the process of decimation of possible infectious agents can be controlled and supervised. *Aquatic animal* waste products may also be composted by rank *composting*. The *composting* process should ~~must~~ not be ended until decimation of possible infectious agents have been achieved.

e) Biogas plants

A biogas plant should ~~must~~ fulfil the general requirements given above. The plant should not receive *high risk waste* unless pretreated to a microbiological safe standard; and *aquatic animal* waste should ~~must~~ be processed as soon as possible after being received.

f) Internal control in disposal plants

A system for internal control, identifying critical points and means of control for such points, should ~~must~~ be in place at the ~~destruction~~ *disposal plants*. A general documentation system for internal control including sampling for control of critical points should ~~must~~ be established.

Spot checks of batches should be carried out in order to check the microbiological standards. Products from incineration and *composting* plants may be exempted from such checks. The *Competent Authority* may grant exemptions on specified conditions.

Records with the results from the different samples and checks should ~~must~~ be kept for a given period decided upon by the *Competent Authority*. Analyses and sampling should ~~must~~ be carried out in accordance with international recognised standards.

g) Burial and burning

The following considerations are important in selecting a burial site:

- Access - both for equipment to dig and close or cover the burial pit and for the delivery of carcasses or other materials to be buried.

- Environment - including distance to watercourses, the sea, bore holes and wells; depth of the ground water level; susceptibility of the land to flooding; proximity to buildings, especially houses; proximity to neighbours or public lands including roads; slope of the land and drainage to and from the pit; permeability of soil; sufficient space for temporary storage of overburden; and direction of prevailing wind (to manage odour).

- Construction - rocky areas~~, with slow digging increase costs and~~ should be avoided. Soils with good stability, capable of withstanding the weight of equipment used to dig ~~construct~~ and fill the pits, should be selected. If required, diversion banks can be constructed to prevent surface runoff entering the pit or to prevent any liquids escaping from the burial site. Fencing may be necessary to exclude people and animals until the site is safe for use.

h) Pyre-burning

The following considerations are important in selecting a pyre-burning site:

- Location - the possible effects of the fire's heat, smoke and odour on nearby structures, underground and aerial utilities, roads and residential areas.

- Access to the site - both for equipment to construct the pyre and maintain the fire, and for the delivery of fuel and *aquatic animal carcasses* or other materials to be burnt.

- Environment - an adequate firebreak around the pyre is essential. Local bush fire brigades should be consulted for advice, for any required permits and for fire appliances to be on site during the burn.

- Fuel - pyres need considerable fuel to achieve complete incineration. The amount and types of fuel available will vary considerably. All required fuel should be on site before the burning is started.

Article X.X.X.12.

Methods for handling of waste ~~material~~ (aquatic animal carcasses, parts of aquatic animal carcasses)

Disposal may be carried out by several methods such as *composting*, ~~mounding,~~ fermentation, incineration, pyre burning, rendering and/or deep burial/landfill in order to prevent spread of pathogens causing *disease* in *aquatic animals*.

Waste ~~material~~ of *aquatic animal* origin, packing material, etc. should be collected, handled and disposed of to ensure that contamination and spread of *disease* is avoided. Such material should be stored in closed, leak proof containers prior to *disposal*. Special transportation procedures should ~~must~~ be in place when transporting infectious material (*aquatic animal carcasses*/other waste ~~material~~) from infected aquaculture premises to the place of pathogen inactivation/*disposal* ~~handling~~.

Annex XVI (contd)

Recommended methods for pathogen inactivation and *disposal* of ~~in~~ *aquatic animals* are as follows:

1. Burial

Burial is a general practice for *disposal* of animals. Controlled burial may take place either in a landfill site or ~~in a place (pit site)~~ other locations accepted by the *Competent Authority* based on *risk assessments* as regards *aquatic animal* health, public health and possible environmental pollution. ~~While landfill will be large, pit burials will be rather small and relatively close to the surface.~~

In selecting an acceptable burial site, the following considerations are important:

- The site should be easy to access by equipment for digging and closing of the burial pit as well as for the delivery of *aquatic animal carcasses* and/or other waste ~~material~~ to be buried. It should be located at a distance from watercourses, the sea, water supply (wells, boreholes), ~~fish farms~~ *aquaculture establishments* and proximity to areas easily accessed by the public. Fencing and restricted admittance may be necessary.

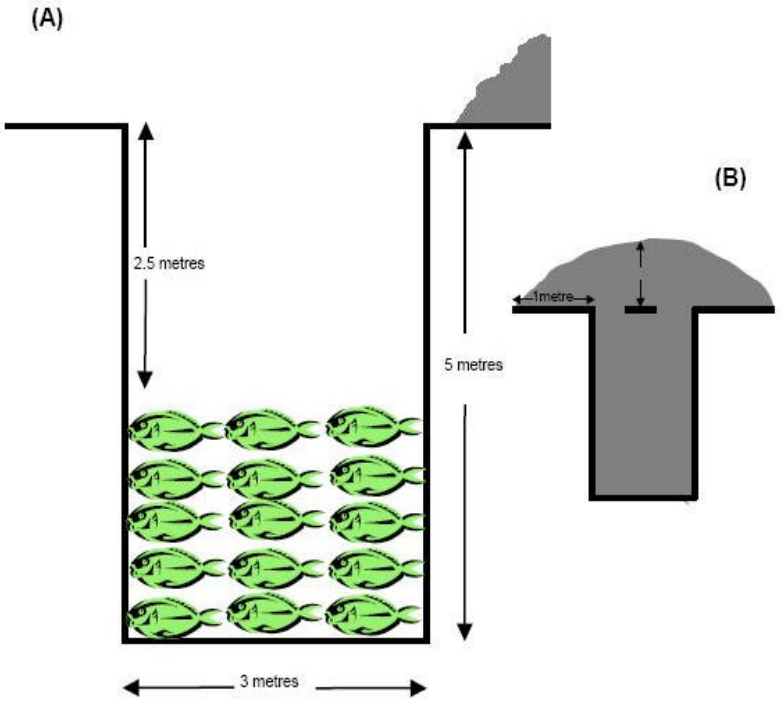
- The pit dimension depends on the volume of the ~~fish~~ *aquatic animal carcasses* and/or material to be buried. Furthermore, they should be constructed in such away that they are easy to fill with *aquatic animal carcasses* and other material to be buried. Figure 1 shows how a pit may be constructed ~~(by courtesy of *AQUAVETPLAN*~~).

- The pit filling content should be covered with unslake~~n~~d lime (CaO~~H~~) at a rate of 85 kg per 1000 kg ~~fish~~ of waste ~~material~~ to hasten decomposition and to prevent scavenging of ~~that~~ contaminated material. ~~to be surfaced by scavengers, etc. If necessary, s~~ Such pits should be inspected ~~in order~~ to confirm ~~ensure~~ that no leakages of infected material have occurred.

Whenever possible, the ~~material~~ waste should be subjected to a ~~pathogen reducing~~ treatment that ensures inactivation of the *disease agent*, such as *ensiling* or pasteurisation, prior to burial or landfill.

Figure 1 (Source: Aquavetplan 2002, Disposal)

Model of pit for disposal of carcasses by burial: (A) open pit; (B) freshly closed pit.



2. Maceration

Maceration by using a mechanical device ~~outfit~~ with rotating blades or projections causes immediate fragmentation and death in newly hatched *aquatic animals* and embryonated eggs (as well as fertilised/unfertilised eggs of fish) and is a suitable method for processing of such material.

~~Maceration requires specialised equipment which should be kept in excellent working order. The disadvantage of maceration is the need for specialised equipment. The rate of introducing the material should be such that the equipment is not jammed.~~

After maceration, the ~~material~~ waste should be subjected to a ~~pathogen-reducing~~ treatment that ensures inactivation of the *disease agent*, such as *ensiling* or pasteurisation.

~~For bio-security reason, macerated material from infected *aquatic animals* has to be treated by one of the processing methods given in this chapter, i.e. *ensiling*, etc.~~

3. Chemical and biological treatment of waste~~s~~

Chemical and biological treatment of *aquatic animal carcasses* / other waste~~s of *aquatic animals*~~ may be carried out aerobically or an-aerobically. The processes normally lead to end products that are microbiologically stable and that may be used as fertilisers (or for production of technical products).

Annex XVI (contd)

4. Ensiling

Ensiling of *aquatic animal carcasses* and other waste ~~material~~ from *aquatic animals* in an organic acid such as formic acid is an effective method to kill most infectious agents in *aquatic animals* within 48 hours. The pH in the *ensiling* process should be maintained at, ~~3.5 —~~ or below, 4.~~0~~ or above ~~pH~~ 12 throughout the process. ~~Thus, it is necessary to monitor pH throughout the entire process. Infectious pancreas necrosis virus (IPNv) is, however, resistant to such *ensiling*. In order to kill IPNv, additional processing or *disposal* should be carried out.~~ After ensilation, the waste should be subjected to a ~~pathogen reducing~~ treatment that ensures inactivation of the *disease agent*, such as pasteurisation.

~~Ensiling of *aquatic animal carcasses*/wastes for disease control purposes should always be followed by heat treatment or further processing.~~

5. Biogas/fermentation

Biogas production is a process where organic matter in biological waste products is fermented under anaerobic conditions. Fish waste is usually processed in co-digestion with a liquid substrate such as slurry. The main gases produced are methane (50-75%) and carbon dioxide. The energy in the methane may be used for heating purposes.

The two main types of *biogas production* are mesophilic anaerobe digestion and thermophilic anaerobe digestion. The mesophilic process takes place at 33-35°C where the liquid fraction remains for 20–25 days. The thermophilic process takes place at 52-55°C and the liquid fraction remains at that temperature for 15-20 days.

Both processes are normally continuous, and a portion of the end material is removed every 2-12 hours. There is a risk that new material which has been in the reactor for only 2-12 hours is removed with the finished products.

To get a biological stable end product, this is often pasteurised in specially constructed tanks or heaters by heating to 70°C for one hour.

6. Composting

Depending on the type of *composting* (e.g. windrows, closed vessel) and the raw material used, as well as the climatic conditions, the temperature parameters of the process and the heat distribution in the material may be different. An example is given in the German Bio waste Ordinance (1998) which specifies that *composting* plants should operate with a material having a moisture content of 45-50% at a pH of approximately 7.

When held in windrows, the entire material needs an exposure time of at least two weeks at 55°C, while in closed vessels exposure to 65°C for one week is required. In theory, many types of fish pathogens can be inactivated in a validated *composting* process. Even though systematic investigations with fish pathogens have not yet been performed, it may be possible to extrapolate from the behaviour of other similar pathogens of warm-blooded animals, as well as of relevant indicator organisms, that a validated process will be safe from the hygienic point of view. However, data presented has highlighted the robustness of IPN virus and its ability to survive this process. Consequently it is necessary to consider the capacity of individual fish pathogens to survive various treatment processes.

High risk waste should be heated at 85°C for at least 25 minutes prior to the *composting* process. ~~It's a normal procedure to heat high risk material prior to the biogas process. For fish material keeping at 85 °C for at least 25 minutes has been used.~~

To get a biological stable end product, the compost ~~is often~~ may be pasteurised in specially constructed tanks or heaters by heating to 70°C for one hour.

Inactivation data for fish pathogens in validated thermophilic anaerobic batch processes are not available, but it may be co ncluded from Table I, page 18 that under comparable circumstances similar fish pathogens will also be inactivated. In Table I the longest survival times are given without taking the exposed matrix (virus suspension or virus adsorbed to a membrane) into account.

7. Thermal treatments

Thermal treatment of *aquatic animal carcasses* or other organic material may be carried out by different methods, such as burning, incineration, heating (pasteurisation) and sterilisation.

8. Incineration

Incineration is a controlled burning process carried out in fixed incinerators, air curtain incinerators or municipal incinerators tested and authorised by the *Competent Authority*. Mobile ~~A~~air curtain incinerators ~~are a mobile incineration system that~~ may be brought on site. *Aquatic animal carcasses* / other waste~~s~~ may thus be burned to ashes on spot and transportation of infected material is not required.

Leak-proof transportation of ~~input~~ waste ~~material~~ for *disposal* to incinerators ~~on~~ at fixed locations ~~is~~ may be necessary, as well as requirements for subsequent *disinfection* of *vehicles* transporting *aquatic animal carcasses* / other waste ~~material~~.

Incinerators for biological material are very effective for a complete *disposal* of *aquatic animal carcasses* / other waste ~~material~~ of *aquatic animals* / *disease* agents~~pathogens~~ and with little or no pollution to the environment. However, such ~~I~~incinerators~~, however,~~ may only be capable of handling limited volumes of biological material.

9. Pyre burning

Pyre burning may not be suitable for ~~is not so convenient to handle~~ large numbers ~~amounts~~ of *aquatic animal carcasses* ~~/~~ or large volumes of waste~~s~~ of *aquatic animals*. ~~However, when constructing a pyre, the material to be destroyed, should be placed on top of inflammable material.~~

In selecting an acceptable pyre burning site, the following considerations are important:

- Site location should be away from residential areas, etc. to avoid unpleasant conditions caused by smoke and odour from the burning. Pyre burning sites should be placed in such a way that they are easy to access. ~~A fire-bed of 2,5 x 2,75 m is needed per tonne of fish.~~

- Fuel / other combustable material for pyre-burning are needed in considerable amounts to complete degradation of the *aquatic animal carcasses* / other ~~material~~ waste to be disposed.

- Fire management should ~~must~~ be administered in an appropriate manner using sufficient fuel supply in the initial phase and throughout the entire burning process. If the pyre-burning is carried out correctly, ~~fish~~ *aquatic animal carcasses* will be destroyed within 48 hours. The ashes should then be brought to a place of *disposal* approved by the *Competent Authority*.

Annex XVI (contd)

10. Heating

a) Pasteurisation

Heat treatment at temperatures below 100°C can be considered as pasteurisation. Pasteurisation may ~~and will~~ only have limited inactivating effects on micro-organisms. Heat resistant spores of mesophilic or thermophilic sporeformers will generally survive this procedure or will only be inactivated after extremely long exposure times or multiple heating steps with cooling steps in between.

The advantage of a moderate heat treatment such as pasteurisation is that product quality is maintained, especially with regard to easily hydrolysed proteins that are found in raw materials originating from fish.

The construction of the heating devices can vary, in that it may either be constructed as a pipe heater or as a pasteurisation tank. In the latter, stirring improves the heat transfer and heat distribution. Any time/temperature relationship that has been validated with the relevant organisms may be used for pasteurisation.

For materials likely to contain high numbers of pathogens, pasteurisation at 90°C for one hour should be used. For materials with a low pathogen load, 70°C for one hour may be applied. Thermal inactivation of pathogens also depends on the size of exposed particles if the material to be pasteurised contains solid material, such as animal tissues. Thus, a maximum particle size of 50 mm is recommended for heating at 90°C/one hour, and a particle size below 30 mm for heating at 70°C/one hour. Batch treatment should be used to safeguard the microbiological safety of the process and end-product.

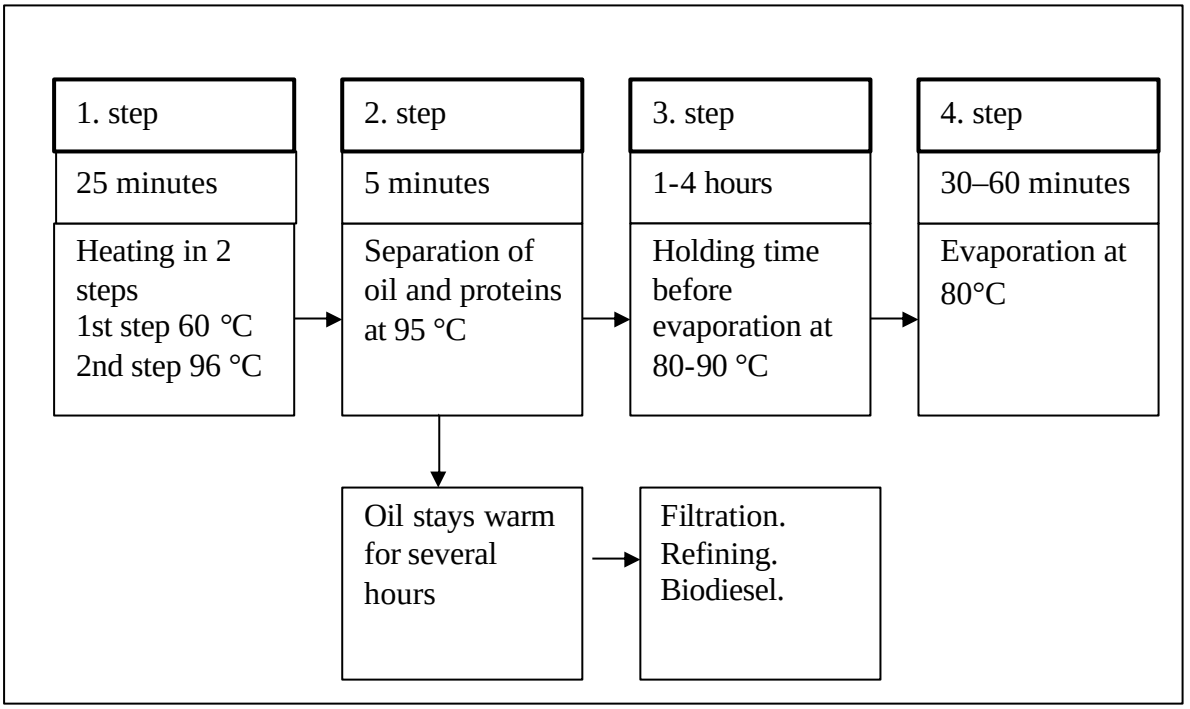
b) Sterilisation

Sterilisation of ~~fish material~~ *aquatic animal carcasses* and/or waste based on the process described for terrestrial animals (133ºC, at 3 bars for 20 minutes) may lead to problems due to technological difficulties, ~~and~~ or to a product that might ~~can~~not be used as feed or fertiliser due to glue formation and/or hydrolysis of proteins ~~(EU – Use of by products in aquaculture)~~.

11. Rendering

a) ~~This is~~ Rendering is generally achieved through a closed system for the mechanical and thermal treatment of *aquatic animal* tissues leading to stable, sterilised products, e.g. animal fat and dried animal protein.

b) The process is used for the production of fish meal and fish oil, and can also be used as a method for *disposal* of dead *aquatic animals*. This ~~kind of heat~~ treatment will eradicate all of the known *aquatic animal* pathogens, and the end products can, depending on the quality of the starting material, be used for the production of technical products or even as feed for pet and fur animals.



c) Description of the process

The raw material for this process can be either fresh or ensiled materials. The quality of the end product depends on the quality of the raw material.

Step 1: the raw materials are heated slowly to a temperature of 95°C.

Step 2: the oil and the proteins are separated by pressing and centrifuging.

Steps 3 and 4: the drying process should not be so hot that it denatures the fish proteins, but hot enough to remove all fish pathogens.

The oil fraction stays warm for several hours, and is typically ~~will be~~ decanted and purified before further processing.

* *
*

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Annex XVI (contd)

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Annex XVII

Original: English
June 2008

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES - CRUSTACEAN TEAM - FOR THE OIE *AQUATIC ANIMAL HEALTH CODE*

Taipei (Chinese Taipei), 27 - 29 June 2008

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The OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases - Crustacean Team for the OIE *Aquatic Animal Health Code* (hereinafter called the *ad hoc* Group) met in Taipei, Chinese Taipei on 27-29 June 2008.

The members of the OIE *ad hoc* Group are listed in Annex I and the adopted agenda is provided in Annex II. Below are agenda items, a summary of the *ad hoc* Group deliberations one each item, and the *ad hoc* Group recommendations to the Aquatic Animal Health Standards Commission.

Agenda Items:

Item 1. *Consider for listing by the OIE, 3 crustacean diseases still under study: necrotising hepatopancreatitis (NHP), hepatopancreatic parvovirus disease (HPVD) and Mourilyan virus disease (MoVD), using the OIE criteria for listing and taking into account previous comments made by Members.*

1.1. Necrotizing hepatopancreatitis (NHP) of penaeid shrimp

NHP was re-evaluated against the criteria for listing. The *ad hoc* Group was of the opinion that NHP meets the criteria and should be recommended for full listing for the following reasons:

After white spot disease, Taura syndrome and vibriosis, NHP is perhaps the most significant disease in the Americas in terms of production losses and its cost of management. Where NHP occurs it causes significant production losses in shrimp farms, which may approach 100% if not correctly diagnosed and treated. The occurrence of NHP disease seems to be dependent upon a combination of high temperature and high salinity, with the disease most often tending to occur in regions where the disease is enzootic during the dry season when water temperatures and salinity are near or greater than 30ºC and 30 ppt, respectively. In some epizootics of NHP, entire shrimp farming regions are severely impacted with significant crop losses. While NHP can be treated with medicated feeds containing certain antibiotics to which the causative bacterium is sensitive, cultured stocks with developing infections by NHP are often not diagnosed before going off feed and becoming difficult or impossible to treat.

The major shrimp producing countries of Southeast Asia have remained free of NHP despite numerous careless introductions of potentially infected stocks of *Penaeus vannamei*.

Annex XVII (contd)

While NHP has apparently not been introduced and become established in SE Asia, the reason may be due to the nature of NHP disease. In the Americas, NHP typically occurs when water temperatures and salinity are elevated. While high water temperatures are typical for the shrimp growing regions of SE Asia, high salinities (from a prolonged dry season) are not.

NHP was introduced to an arid, hot location in northeast Africa with a careless introduction of *P. vannamei* and it became temporarily established in the shrimp stocks reared at the importing location. Eradication of the disease required depopulation and fallowing.

Other regions of south central Asia (e.g. India, East Africa and the Middle East have extended dry seasons with high water temperatures and they are beginning to import *Penaeus vannamei*. Hence, the consequent risk of introduction and establishment of NHP-B and the emergence of NHP with introduced stocks was considered high by the *ad hoc* Group.

Recommendations:

The *ad hoc* Group concluded that NHP met criteria 1, 4, 6, 7 and 8 of the listing criteria in Article 1.2.2.1 of Chapter 1.2.2 in the *Aquatic Code* (Table 1, Appendix III), and that the disease should be recommended for full listing at this time.

1.2. Hepatopancreatic parvovirus disease (HPVD) of penaeid shrimp

The *ad hoc* Group considered the comments submitted for consideration by Thailand on why Hepatopancreatic parvovirus (HPV) should not be listed, and the *ad hoc* Group concluded that HPV should not remain under study and should not be considered for listing at this time for the following reasons:

Although HPV as a Group has global distribution, there are apparently significant differences in nucleotide sequence among the various geographic genotypes.

Although disease has been attributed to a genotype of HPV in Thailand, nothing is currently known about the pathogenicity of other genotypes from other geographic regions where HPV infections have been documented.

Although a diagnostic method for all members of the HPV Group has been developed, tests to distinguish pathogenic genotypes from those that may not be significant pathogens are not yet available.

Despite isolated reports of HPV being either the cause of or associated with significant disease outbreaks, recent reports that document significant productions losses (as described in Article 1.2.2.1 A.1.) are not available for HPV-caused disease(s) in penaeid shrimp.

Recommendations:

The *ad hoc* Group concluded that HPVD did not adequately met criteria 1, 7 and 8 of the listing criteria in Article 1.2.2.1 of Chapter 1.2.2 in the *Aquatic Code* (Table 1, Appendix III), and that HPVD should be de-listed from the listed diseases, that it not be listed as "under study," or be considered for full listing at this time.

1.3. Mourilyan virus disease (MoVD)

MoVD was re-evaluated against the criteria specified in Article 1.2.2. of the *Aquatic Code*. The *ad hoc* Group recommends de-listing of the disease for the following reasons:

Although Mourilyan virus (MoV) infection has been associated with mortalities in farmed *Penaeus japonicus* in Australia, there is, as yet, no evidence of a direct causal relationship between MoV infection and disease.

Although there is evidence of MoV infection in *Penaeus monodon* in Australia and several Asian countries, there have been no reports of disease in this species attributable to MoV infection.

Although there has been a significant trade in *Penaeus japonicus* from Australia and several Asian countries to Japan, there have been no reported disease outbreaks attributed to MoV infection.

Recommendations:

The *ad hoc* Group concluded that MoVD did not adequately met criteria 1 of the listing criteria in Article 1.2.2.1 of Chapter 1.2.2 in the *Aquatic Code* (Table 1, Appendix III), and that MoVD should be de-listed from the listed diseases, not be listed as "under study," or be considered for full listing at this time.

Item 2. *If any of those three diseases are considered by the ad hoc Group to meet the criteria for listing, revise the draft Aquatic Code chapter(s) (including consideration of Members' comments) and recommend to the AAHSC which Disease Information Card(s) should be updated, if appropriate.*

The results of the assessment by the *ad hoc* Group of the evidence for listing the three penaeid shrimp diseases, necrotizing hepatopancreatitis (NHP), hepatopancreatic parvovirus disease (HPVD), and Mourilyan virus disease (MoVD), against the listing criteria are shown in Table 1, Annex III.

A disease card for NHP already exists and is available from the "disease information" menu at the web site of the AAHSC. The *ad hoc* Group amended the draft chapter for NHP that had been developed at the previous *ad hoc* Group meeting in October 2006 in Bergen, Norway (see Annex IV).

Item 3. *Review the currently listed diseases, Spherical baculovirosis and Tetrahedral baculovirosis, as to whether they still meet the criteria for OIE listing.*

In addition to considering the recommendation for de-listing of these diseases submitted to the OIE by Thailand, the *ad hoc* Group considered the past and recent history of occurrence of both diseases throughout the world, and concluded that neither disease is currently causing significant production losses beyond regional locations where there is little or no international trade (Criteria A.1.; see Table 1, Annex III).

The very significant reduction in the incidence and significance of disease due the these baculoviruses has been due to the implementation of Best Management Practices (BMP) by the majority of the shrimp farming industry that grow the susceptible species. The same BMPs were previously used by Japan to completely control baculoviral midgut gland necrosis (BMN), and this led to the de-listing of BMN in 2002.

Recommendations:

The *ad hoc* Group recommends de-listing of spherical baculovirosis and tetrahedral baculovirosis.

Item 4. *Consider Milky Disease for listing by the OIE.*

The *ad hoc* Group reviewed a summary of the current knowledge (see Annex V) of the epizootiology of this recently emerging disease, the available diagnostic methods, and methods developed for its management.

The *ad hoc* Group assessed this information against the criteria in Article 1.2.2.2. of the *Aquatic Code* (Table 2, Annex III) and concluded that the disease meets the necessary criteria for listing as an emerging disease.

Annex XVII (contd)

The *ad hoc* Group further agreed that the common names "Milky Disease" is too non-specific and recommends that the disease be listed "Milky hemolymph disease of spiny (*Panulirus* spp.) lobsters."

Recommendations:

The *ad hoc* Group recommended 'Milky hemolymph disease of spiny (*Panulirus* spp.) lobsters' be listed as an OIE emerging disease.

Item 5. *If time allows:*

5a. Consider any other significant ("old" or emerging) crustacean diseases not previously assessed against the OIE criteria for listing.

5b. For any "new" disease found to meet the listing criteria, the ad hoc Group will assign responsibility for the development of a Disease Information Card and – where sufficient information on that disease is available – prepare a draft chapter for the Aquatic Code and identify possible authors for the development of a chapter for the Aquatic Manual.

The *ad hoc* Group did not identify any "old" or other emerging diseases which at the present time justify assessment for listing.

The *ad hoc* developed a draft chapter for the *Aquatic Code* (see Annex VI) and a disease information card (see Annex VII) for "Milky hemolymph disease of spiny (*Panulirus* spp.) lobsters". As the disease is currently confined to Vietnam and because the best available expertise and experience resides with Prof. Nguyen Huu Dung at the Center for Aquatic Animal Health and Breeding Studies, Nha Trang University, Vietnam, the *ad hoc* Group recommends that he be invited to develop the chapter for the *Aquatic Manual*.

Item 6. *Other business*

6.1. Criteria for disease listing:

Recommendations:

The *ad hoc* Group had concerns regarding the precision of some criteria for disease listing, particularly with respect to Criterion A.1 Consequences in Article 1.2.2.2. of the *Aquatic Code*, and recommended a review of the criteria to address the following issues:

The evaluation of 'significant production losses at a national or multinational (zonal or regional) level' is very subjective and open to different interpretations. The meaning of "significant" production losses needs better definition.

The requirement (explanatory notes) that 'morbidity or mortality are related primarily to the agent and not management or environmental factors' does not adequately reflect the biology of infection of many crustacean viruses for which pathogen, host and environmental factors all contribute to disease. For example, in the case of white spot syndrome virus, low level infections commonly occur in healthy shrimp and disease occurs as a result of environmental triggers that may be either natural or due to poor management. For this very important listed pathogen, the agent, as well as management and environmental factors, each contribute significantly to the occurrence of disease.

6.2. Experts and potential reference laboratory for NHP:

Dr. Trisha Varner, Texas Veterinary Medical Diagnostic Lab, 1 Sippel Rd., Drawer 3040College Station, TX 77841 USA.

e-mail: PVARNER@tvmdl.tamu.edu

Office: 1 979 845-3414. Fax: 979-845-1794

.../Annexes

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES - CRUSTACEAN TEAM - FOR THE OIE *AQUATIC ANIMAL HEALTH CODE*

Taipei (Chinese Taipei), 27 - 29 June 2008

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Annex XVII (contd)

Annex II

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES - CRUSTACEAN TEAM - FOR THE OIE *AQUATIC ANIMAL HEALTH CODE*

Taipei (Chinese Taipei), 27 - 29 June 2008

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Adopted agenda

1. Consider for listing by the OIE, 3 crustacean diseases still under study: necrotising hepatopancreatitis (NHP), hepatopancreatic parvovirus disease (HPVD) and Mourilyan virus disease (MoVD), using the OIE criteria for listing and taking into account previous comments made by Members.

2. If any of those three diseases are considered by the *ad hoc* Group to meet the criteria for listing, revise the draft *Aquatic Code* chapter(s) (including consideration of Members' comments) and recommend to the AAHSC which Disease Information Card(s) should be updated, if appropriate.

3. Review the currently listed diseases, Spherical baculovirosis and Tetrahedral baculovirosis, as to whether they still meet the criteria for OIE listing.

4. Consider for listing by the OIE, Milky Disease, using the OIE criteria for listing.

5. If time allows:

   a) Consider any other significant ("old" or emerging) crustacean diseases not previously assessed against the OIE criteria for listing.

   b) For any "new" disease found to meet the listing criteria, the *ad hoc* Group will assign responsibility for the development of a Disease Information Card and – where sufficient information on that disease is available – prepare a draft chapter for the *Aquatic Code* and identify possible authors for the development of a chapter for the *Aquatic Manual*.

6. Other business

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Annex XVII (contd)

Annex III

Table 1. Summary of the *ad hoc* Group's assessment of five currently listed crustacean diseases using the Criteria in Article 1.2.2.1. of Chapter 1.2.2. in the *Aquatic Code*.

Crustacean diseases considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*								(retain, add, delete)
	1	2	3	4	5	6	7	8	
Tetrahedral baculovirosis (*Baculovirus penaei* / BP)	+	–	–	+	NA	-	+	+	Remove
Spherical baculovirosis (*P. monodon*-type baculovirus/MBV)	+	–	–	+	NA	-	+	+	Remove
Necrotizing hepatopancreatitis (NHB-B / bacteria)	+	–	–	+	NA	+	+	+	Full listing
Hepatopancreatic parvovirus disease (HPV)	+/-	-	-	+	NA	+	+/-	+/-	Remove
Mourilyan virus disease (MoV)	+/-	-	-	+	NA	+	+	+	Remove

Table 2. Summary of the *ad hoc* Group's assessment of Milky hemolymph disease of spiny (*Panulirus* spp.) lobsters using the Criteria in Article 1.2.2.2. of Chapter 1.2.2. in the *Aquatic Code*.

Crustacean diseases considered by the *ad hoc* Group	Assessment Against the OIE Listing Criteria in the *Aquatic Code*				
	1	2	3	4	Recommendation
Milky hemolymph disease of spiny (*Panulirus* spp.) lobsters	+	N/A	-	+	Add to list

CHAPTER 2.3.X.

NECROTISING HEPATOPANCREATITIS

Article 2.3.X.1.

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

Methods for conducting surveillance and diagnosis of NHP are provided in the *Aquatic Manual* (under development).

Article 2.3.x.2.

Scope

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

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

Article 2.3.X.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any NHP related conditions, regardless of the NHP status of the *exporting country*, *zone* or *compartment*.

    a) For the species referred to in Article 2.3.X.2. intended for any purpose:

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

        ii) chemically extracted chitin;

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

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

    b) [The following products destined for human consumption from species referred to in Article 2.3.X.2. which have been prepared and packaged for direct retail trade:

        i) de-headed and “de-veined” (intestine removed) shrimp tails.

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

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.X.2., other than those listed in point 1 of Article 2.3.X.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.X.7. to 2.3.X.11. relevant to the NHP status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation / transit from an *exporting country*, *zone* or *compartment* not declared free of NHP of a *commodity* of a species not covered in Article 2.3.10.2. but which could reasonably be expected to be a potential mechanical vector for NHP-B, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.X.4.

Necrotising hepatopancreatitis free country

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from NHP if all the areas covered by the shared water are declared NHP free countries or *zones* (see Article 2.3.x.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.X.2. is present may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.X.2. are present but there has been no observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from NHP when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual)*, may make a *self-declaration of freedom* from NHP when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of NHP-B.

OR

4. A country that has previously made a *self-declaration of freedom* from NHP but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from NHP again when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of NHP-B and;

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 2.3.X.5.

Article 2.3.X.5.

Necrotising hepatopancreatitis free zone or free compartment

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a NHP free *zone* or *compartment* if all the relevant *Competent Authorit(ies)* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.X.2. is present may be declared free from NHP when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.x.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from NHP when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual)*, may be declared free from NHP when:

Annex XVII (contd)

Annex IV (contd)

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of NHP-B.

OR

4. A *zone* previously declared free from NHP but in which the *disease* is detected may be declared free from NHP again when the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of NHP-B; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.X.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from NHP following the provisions of points 1 or 2 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may maintain its status as NHP free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from NHP following the provisions of point 3 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as NHP free provided that conditions that are conducive to clinical expression of NHP, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.X.7.

Importation of live aquatic animals from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing live *aquatic animals* of the species referred to in Article 2.3.x.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.x.4. or 2.3.x.5. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from NHP.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.8.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:

    a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

    b) the treatment of all effluent and waste materials in a manner that ensures inactivation of NHP-B.

2. If the intention of the introduction is the establishment of a new stock, Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: http://www.ices.dk/indexfla.asp) may be summarised to the following main points:

    a) identify stock of interest (cultured or wild) in its current location;

    b) evaluate stock health/*disease* history;

    c) take and test samples for NHP-B, pests and general health/*disease* status;

    d) import and quarantine in a secure facility a founder (F-0) population;

    e) produce F-1 generation from the F-0 stock in *quarantine*;

    f) culture F-1 stock and at critical times in its development (life cycle) sample and test for NHP-B and perform general examinations for pests and general health/*disease* status;

    g) if NHP-B is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet *basic biosecurity conditions* of the *importing country*, *zone*, or *compartment*, the F-1 stock may be defined as NHP free or specific pathogen free (SPF) for NHP-B;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Annex XVII (contd)

Annex IV (contd)

Article 2.3.X.9.

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

When importing, for human consumption, live *aquatic animals* of the species referred to in Article 2.3.x.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until *processing* and/or consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the *processing* be treated in a manner that ensures inactivation of NHP-B.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.10.

Importation of aquatic animal products from a country, zone or compartment declared free from necrotising hepatopancreatitis

When importing *aquatic animal products* of the species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* declared free from NHP, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.X.4. or 2.3.X.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from NHP.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from necrotising hepatopancreatitis

When importing *aquatic animal products* of the species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from NHP, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Annex V

OIE Bulletin Article (No 2008 -2).

Collaboration on Milky Disease of Net-Pen Reared Spiny Lobsters in Vietnam

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Huu Dung Nguyen, Department of Fish Pathology, Nha Trang University, Nha Trang, Vietnam

Tu Cuong Nguyen, The National Fisheries Quality Assurance and Veterinary Directorate (NAFIQAVED), Ministry of Agriculture and Rural Development, Hanoi, Vietnam

At the request of the OIE Central Bureau in Paris and Dr. Nhu Tiep Nguyen, Deputy Director General of NAFIQAVED (National Fisheries Quality Assurance and Veterinary Directorate, Ministry of Agriculture and Rural Development of Vietnam, Hanoi), the Reference Laboratory at the University of Arizona (UAZ) began a collaborative project with Dr. Huu Dung Nguyen, Dean of the Department of Aquaculture Pathology, Nha Ttrang Univ, Hanoi, Vietnam, to determine the etiology of "milky disease", a very serious emerging disease in net-pen cultured spiny lobsters in Vietnam. Affected lobster species included at least four species of the genus *Panulirus* that are native to Vietnam. To investigate the etiology of milky disease, NAFIQAVED organized three working groups in October 2007, and requested assistance from the OIE Central Bureau in Paris. Author Lightner of the OIE Reference Laboratory at UAZ agreed to collaborate with the Vietnamese in the disease investigations. Dr. Huu Dung Nguyen was assigned leadership of working group 1, which was to perform an epidemiological survey for the disease, and to provide samples to the UAZ for diagnostic studies and possible diagnostic method development.

Because the gross signs presented by dying lobsters (see Figures 1 & 2) were very similar to those presented by black tiger shrimp (*Penaeus monodon*) and European shore crabs (*Carcinus maenas*) with systemic infections by an unclassified rickettsial-like bacteria (RLB) (Nunan et al. 2003a,b; Eddy et al. 2007), it was suspected by UAZ that the affected lobsters were infected with a similar, if not closely related, RLB. UAZ received samples in November 2007 from Dr. Huu Dung Nguyen for histopathology analysis and for possible use for PCR test development. Histopathology confirmed a severe systemic RLB infection in all of the histological samples, which represented three different *Panulirus* spp. A PCR test was subsequently developed by UAZ for the RLB in lobsters using the same approach as was used for detection of RLB in shrimp and crabs with milky disease (Nunan et al. 2003a; Eddy et al. 2007). Parallel studies run in Vietnam provided additional morphological evidence from Gram stained smears of the agent in hemolymph and from electron microscopic study of infected lobster tissues which showed that the agent of the disease is a very small gram-negative curved rod shaped bacteria that replicates in the cytoplasm of infected cells. Comparison of the 16 S rDNA sequence of the lobster RLB to sequences deposited in GenBank and in the UAZ database show it to be most closely related (93% similarity) to the RLB from *P. monodon* cultured in Mozambique, East Africa and to a group of soil bacteria found associated with certain plants. The lobster RLB also showed 83% similarity to another RLB that infects *P. monodon* farmed in Madagascar. The RLB from spiny lobsters, as well as those from shrimp and crabs, remain to be classified into what will likely be a new genus with several new species.

Field trials are planned for the PCR test developed by UAZ in Vietnam in early 2008 to determine if the test can be used to detect the disease before gross signs become apparent and to determine possible reservoirs or vectors of the disease agent in the areas where lobsters are being farmed.

The etiology of a very serious emerging disease in cultured spiny lobsters was determined and a PCR test for detection of its RLB agent were developed. It is hoped that PCR screening of lobsters, their feeds, and potential reservoir hosts in the culture environments will lead to methods to manage this disease so that the use of antibacterial compounds can be minimized or eliminated. A joint paper on the disease and its diagnosis is being planned for later in 2008.

Annex XVII (contd)

Annex V (contd)

Literature Cited:

methods developed for a systemic rickettsia-like bacterium (RLB) in *Penaeus monodon* (Decapoda: Crustacea). *Diseases of Aquatic Organisms*, **53**, 15-23.

NUNAN L.M., NOBLE B., LE GROUMELLEC M. & LIGHTNER D.V. 2003b. Experimental infection of *Penaeus vannamei* by a rickettsia-like bacterium (RLB) originating from *P. monodon*. *Diseases of Aquatic Organisms*, **54**, 43-48.

EDDY F., POWELL A., GREGORY S., NUNAN L.M., LIGHTNER D.V., DYSON P.J., ROWLEY A.F. & SHIELDS R.J. 2007. A novel bacterial disease of the European shore crab, *Carcinus maenas* - molecular pathology and epidemiology. *Microbiology*, **153**, 2839-2849.

Figure Legends:

Figure 1A & 1B. Milky syndrome infected lobster, *Panulirus* sp. being cultured in floating net-pens (shown in background of Fig. 1A) in Vietnam . Note swollen abdomen of the lobster in Figure 1A, the dark-coloured stripes and milky haemolymph leakage at the junction between cephalothorax and abdomen (arrow) in Fig. 2B.

Annex XVII (contd)

Annex VI

CHAPTER 2.3.X.

MILKY HEMOLYMPH DISEASE OF SPINY LOBSTERS

Article 2.3.X.1.

For the purposes of the *Aquatic Code*, milky hemolymph disease of spiny lobsters (*Panulirus* spp.) (MHD) means *infection* with an unclassified rickettsial-like bacteria.

Methods for conducting surveillance and diagnosis of MHD are provided in the *Aquatic Manual* (under development).

Article 2.3.X.2.

Scope

The recommendations in this Chapter apply to: tropical spiny lobsters in the genus *Panulirus* spp.), especially *Panulirus ornatus*, *P. homarus* and *P. stimpsoni.* Common names for these and other potential *susceptible species* are listed in the *Aquatic Manual.* These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

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

Article 2.3.X.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any MHD related conditions, regardless of the MHD status of the *exporting country*, *zone* or *compartment*.

    a) For the species referred to in Article 2.3.X.2. intended for any purpose:

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

        ii) chemically extracted chitin;

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

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

    b) [The following products destined for human consumption from species referred to in Article 2.3.X.2. which have been prepared and packaged for direct retail trade:

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

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.X.2., other than those listed in point 1 of Article 2.3.X.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.X.7. to 2.3.X.11. relevant to the MHD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of MHD of a *commodity* of a species not covered in Article 2.3.X.2. but which could reasonably be expected to be a potential mechanical vector for MHD, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.X.4.

Milky hemolymph disease free country

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from MHD if all the areas covered by the shared water are declared MHD free countries or *zones* (see Article 2.3.X.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.X.2. is present may make a *self-declaration of freedom* from MHD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.X.2. are present but there has been no observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from MHD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as described in Chapter X.X.X. of the *Aquatic Manual*) may make a *self-declaration of freedom* from MHD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of the bacterial agent of MHD.

OR

4. A country that has previously made a *self-declaration of freedom* from MHD but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from MHD again when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimize the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of the agent of MHD; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 2.3.X.5.

Article 2.3.X.5.

Milky hemolymph disease free zone or free compartment

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

If a *zone* or *compartment* extends over more than one country, it can only be declared an MHD free *zone* or *compartment* if all the relevant *Competent Authority(ies)* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.X.2. is present may be declared free from MHD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.X.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from MHD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

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Annex VI (contd)

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to its clinical expression as *described* in Chapter X.X.X. of the *Aquatic Manual*) may be declared free from MHD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years withoutdetection of the agent of MHD.

OR

4. A *zone* previously declared free from MHD but in which the *disease* is subsequently detected may be declared free from MHD again when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimize the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 3.3.1. of the *Aquatic Code* and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of the agent of MHD; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.X.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from MHD following the provisions of points 1 or 2 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may maintain its status as MHD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from MHD following the provisions of point 3 of Articles 2.3.X.4. or 2.3.X.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as MHD free provided that conditions that are conducive to clinical expression of MHD, as described in Chapter X.X.X.. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

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

Article 2.3.X.7.

Importation of live aquatic animals from a country, zone or compartment declared free from milky hemolymph disease

When importing live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* declared free from MHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.X.4. or 2.3.X.5. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from MHD.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from milky hemolymph disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from MHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:

    a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and

    b) the treatment of all effluent and waste materials in a manner that ensures inactivation of the agent of MHD.

2. If the intention of the introduction is the establishment of a new stock, the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code (full version see: http://www.ices.dk/indexfla.asp) may be summarised to the following main points:

    a) identify stock of interest (cultured or wild) in its current location;

    b) evaluate stock health/disease history;

    c) take and test samples for the agent of MHD, pests and general health/disease status;

    d) import and quarantine in a secure facility a founder (F-0) population;

    e) produce F-1 generation from the F-0 stock in *quarantine*;

    f) culture F-1 stock and at critical times in its development (life cycle) sample and test for MHD and perform general examinations for pests and general health/disease status;

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g) if the agent of MHD is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as MHD free or specific pathogen free (SPF) for the agent of MHD;

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from milky hemolymph disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from MHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until *processing* and/or consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the *processing* be treated in a manner that ensures inactivation of the agent of MHD.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.10.

Importation of aquatic animal products from a country, zone or compartment declared free from milky hemolymph disease

When importing *aquatic animal products* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* declared free from MHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.X.4. or 2.3.X.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from MHD.

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Article 2.3.X.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from milky hemolymph disease

When importing *aquatic animal products* of species referred to in Article 2.3.X.2. from a country, *zone* or *compartment* not declared free from MHD, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.X.3.

Milky Hemolymph Disease of Spiny (Panulirus spp.) Lobsters

PATHOGEN INFORMATION

1. CAUSATIVE AGENT

1.1. Pathogen type

Bacteria.

1.2. Disease name and synonyms

Milky hemolymph disease of spiny (*Panulirus* spp.) lobsters (MHD-SL).

1.3. Pathogen common name and synonyms

Rickettsail-like bacteria (RLB) of milky disease.

1.4. Taxonomic affiliation

1.4.1. Pathogen scientific name (Genus, species, sub-species or type).

Not classified.

1.4.2. Phylum, class, family, etc.

Not classified.

1.5. Description of the pathogen

From negatively stained bacteria "milky" hemolymph from infected spiny lobsters viewed by TEM, RLB are curved to slightly bend rod shaped organisms measuring 0.6 µm x 1.4 to 2.0 µm.

The bacterium has not been successfully cultured *in vitro*.

1.6. Authority (first scientific description, reference)

Lightner D.V., Pantoja C.P., Redman R.M., Poulos B.T. and Nguyen H.D., Do T.H. and Nguyen T.C. 2008. Collaboration on milky disease of net-pen-reared spiny lobsters in Vietnam. OIE Bulletin, (2), 46-47.

1.7. Pathogen environment (fresh, brackish, marine waters)

MHD-SL occurs in marine waters.

2. MODES OF TRANSMISSION

2.1. Routes of transmission (horizontal, vertical, direct, indirect)

Horizontal transmission by direct contact with lobsters in the same net-pens or indirectly by contaminated water from adjacent net-pens is suspected.

The disease has been experimentally transmitted among lobsters by cohabitation and by infection of unfiltered hemolymph from diseased lobsters into healthy lobsters. Filtered hemolymph from a 0.45 µm filter is not infectious.

2.2. Life cycle

Not applicable.

2.3. Associated factors (temperature, salinity)

None known.

2.4. Additional comments

Net-pen-reared spiny lobsters in Vietnam are fed a variety of fresh foods that includes fishery bycatch, various molluscs, and decapod crustaceans acquired locally from fishers. It is suspected that the RLB of MHD-SL infects one or more of the species in the lobster's fresh food diet.

3. HOST RANGE

3.1. Host type

Tropical spiny lobsters.

3.2. Host scientific names

Natural infections: *Panulirus* spp., especially *Panulirus ornatus*, *P. homarus* and *P. stimpsoni.*

Experimental infections: No information.

3.3. Other known or suspected hosts

Fresh foods (see 2.4 above) are suspected as the source of the RLB agent of MHD-SL.

3.4. Affected life stage

3 month-old or older juveniles and adults.

3.5. Additional comments

Very similar diseases, with similar gross and histopathological lesions, primarily in connective tissues, have been reported in farmed black tiger shrimp (*Penaeus monodon*) and in captive-wild European shore crab (*Carcinus maenas*). Sequence information generated from 16 S rDNA amplified from the RLB from infected *C. maenas*, *P. monodon* and *Panilurus* spp. show that the RLB in each of these diseases are similar, but not closely related (Nunan et al. 2003a & 2003b; Eddy et al. 2007).

4. GEOGRAPHICAL DISTRIBUTION

4.1. Region

Milky hemolymph disease of spiny (*Panulirus* spp.) lobsters (MHD-SL) has only been reported from Vietnam.

4.2. Countries

Vietnam.

DISEASE INFORMATION

5. CLINICAL SIGNS AND CASE DESCRIPTION

5.1. Host tissues and infected organs

Hemolymph and all connective tissues.

5.2. Gross observations and macroscopic lesions

Onset is relatively rapid. Affected lobsters become increasingly inactive and anorectic. Within another 3-5 days affected lobsters present milky hemolymph under swollen abdominal pleura of the exoskeleton (visible on ventral side), and die soon after clinical signs become apparent.

Hemolymph drawn with a syringe will range from slightly cloudy or turbid to milky white and will not clot.

Dissection of affected lobsters shows the presence of milky colored hemolymph in the hemocoel and tissue spaces and white hypertrophied connective tissues (especially serosa and capsules) of all major organs and tissues.

5.3. Microscopic lesions and tissue abnormality

Gram stained smears of hemolymph show the presence of very large numbers of small curved Gram negative rods. Stained and unstained hemolymph and tissue squashes show large numbers of small curved bacteria.

Routine H&E stained histological preparations show connective tissues, fixed phagocytes and hemocytes to possess large cytoplasmic masses (not distinct membrane-bound inclusion bodies) of very small basophilic bacterial cells. Some cells become enormously hypertrophied and their tissue type may not be discernable except by location. Hemolymph present in the hemocoel spaces may appear to contain large number of basophilic, very small bacterial cells that may occur in large aggregates, presumably from recently lysed cells.

5.4. OIE status

Listing proposed according to Article 1.2.2.2. (Emerging Disease) of the Aquatic Code.

6. SOCIAL AND ECONOMIC SIGNIFICANCE

Milky disease appeared in 2007 spiny lobster farms in Binh Dinh to Binh Thuan providences (800 km of coast line) of Vietnam. Losses in 2007 were estimated at US$10 million, or about 10% of the expected income from production for 2007.

7. ZOONOTIC IMPORTANCE

None.

8. DIAGNOSTIC METHODS

Three levels of examination procedures may be used: screening methods for surveillance, presumptive diagnostic methods when abnormal mortalities occur, and confirmatory

methods if available when a pathogen is encountered during screening or mortality outbreaks.

8.1. Screening methods

8.1.1. Level I

Onset of gross signs as described in section 5 (above).

8.1.2. Level II

By histopathology using routine H&E stained paraffin sections (Bell and Lightner, 1988), lobsters with advanced infections will present basophilic cytoplasmic masses of bacteria in hemocytes, fixed phagocytes and connective tissue cells.

8.1.3. Level III

PCR using the methods listed in Table 1.

8.2. Presumptive methods

8.2.1. Level I

See Section 5.

8.2.2. Level II

See Section 8.1.2.

8.2.3. Level III

See Section 8.1.3.

8.3. Confirmatory methods

8.3.1. Level I

See section 5 for the available diagnostic option.

8.3.2. Level II

See section 8.1.2. for the available diagnostic option.

8.3.3. Level III

See section 8.1.3 for the available diagnostic option.

Table 1. PCR methods for detection of MHD-SL from Vietnam.

Two PCR tests for detection of the RLB agent of MHD-SL have been developed. The primers for each are provided in the Table.

Geographic origin: Vietnam. Primer set designation: 137 F/R. Size of PCR product: 137 bp. Primer sequences:
137F: 5'-AAC-GAT-CTC-TTC-GGA-GAG-AGT-G-3' 137R: 5'-GCC-CAT-TCA-ATG--GCG-ATA-3'
Geographic origin: Vietnam. Primer set designation: 254F/R. Size of PCR product: 254 bp. Primer sequences: 254F: 5'-CGA-GGA-CCA-GAG-ATG-GAC-CTT-3' 254R: 5'-GCT-CAT-TGT-CAC-CGC-CAT-TGT-3'

9. CONTROL METHODS

Injection of oxytetracycline at 10 mg/kg into the abdominal muscle or hemocoel of lobsters presenting early signs of MHD-SL, or into at-risk lobsters at affected farms, has been found to be extremely effective in treatment and prevention of MHD-SL.

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OIE Reference Experts and Laboratories in 2008	
none	none

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Annex XVIII

Original: English
April 2008

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

Paris (France), 14–16 April 2008

The OIE *ad hoc* Group on Aquatic Animal Health Surveillance (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters in Paris from 14 to 16 April 2008.

The members of the *ad hoc* Group and other participants are listed at Annex I. The Agenda adopted is given at Annex II.

On behalf of the Director General of the OIE, Dr Sarah Kahn, Head of the International Trade Department, welcomed all members and thanked them for their work on this important topic. She discussed the time line for the publication of the OIE Handbook on Aquatic Animal Health Surveillance and it was agreed that although an ambitious timetable, the *ad hoc* Group will endeavour to prepare the draft manuscript by early August for peer review by experts before submission to the OIE Central Bureau for preparation for publishing for early 2009. The arrangements for the peer review were discussed and it was agreed that the OIE would approach two or three experts in aquatic animal health in multiple OIE regions and request that they undertake the peer review, which could hopefully take place in September-October, with a view to the *ad hoc* Group finalising the text by December.

Dr Barry Hill then took over as Chair of the meeting and acknowledged the importance of the work of the *ad hoc* Group, in particular the drafting of the manuscript for the Handbook, and the large amount of work involved in this task.

1. Appendix of the OIE *Aquatic Animal Health Code* on Guidelines for Aquatic Animal Health Surveillance

The *ad hoc* Group reviewed comments received from Canada on the draft Guidelines for aquatic animal health surveillance that had been referred to them by the Aquatic Animal Health Standards Commission (hereinafter referred to as the Aquatic Animals Commission) from their March meeting, due to their highly technical nature.

The *ad hoc* Group discussed these comments, agreed with most of them and amended the text accordingly. The *ad hoc* Group's responses to all the comments and proposed amendments will be submitted to the OIE Aquatic Animals Commission for consideration at their next meeting in October 2008.

The amended draft Guidelines are presented at Annex III with proposed text changes shown as highlighted text. The strikeout/double underlined texts are amendments proposed for adoption at the 76th General Session in May 2008.

2. OIE Handbook on Aquatic Animal Health Surveillance

The *ad hoc* Group continued to develop the content of the chapters based on the outline developed at the previous meeting. Although substantial progress was made in drafting the manuscript they recognised that a significant amount of new text is necessary to address the comprehensive scope of the practical Handbook.

The *ad hoc* Group will meet again in July 2008 with the intention of finalising the first complete draft of the manuscript. It is anticipated that further revisions will be necessary through electronic communication prior to completion of a draft ready for peer review. Although not currently confirmed, a final *ad hoc* Group meeting has been scheduled in November in the event that the draft manuscript requires significant revision following peer review.

The draft manuscript will also be sent to the Aquatic Animals Commission to review at their next meeting in October 2008.

3. Surveillance of diseases in wild aquatic animals

The Aquatic Animals Commission had asked the *ad hoc* Group to provide advice on the time periods for self declaration of freedom based on historical freedom or targeted surveillance for diseases in wild aquatic animal populations and whether they should be considered differently to farmed populations. The *ad hoc* Group discussed at some length the complex issue of surveillance for specific diseases in wild aquatic animal populations.

Considering that any recommendation on time periods is subject to scientific debate, evidence based modifications to the required surveillance periods for diseases of wild aquatic animals will require further discussion and it is anticipated that the Handbook will provide further guidance. However, it was concluded that since diseases in wild aquatic animal populations are more difficult to detect than in farmed populations, the self declaration of freedom should in general be based on historical freedom for at least 25 years or targeted surveillance for at least 5 years. This issue will be further considered during the development of the Handbook and the *ad hoc* Group will make recommendations to the Aquatic Animals Commission when this is completed.

.../Annexes

Annex I

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

Paris (France), 14–16 April 2008

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Annex II

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

Paris (France), 14–16 April 2008

Adopted agenda

Welcome from the Director General

Adoption of the agenda

1. Member comments on the Guidelines for aquatic animal health surveillance

Review Member comments referred to the *ad hoc* Group by the Aquatic Animals Commission (March 2008 meeting) on the *Aquatic Code* chapter on Guidelines for aquatic animal health surveillance, and revise text as appropriate.

2. Surveillance for diseases of wild aquatic animals

Provide advice to Aquatic Animals Commission on the time periods for declaration of freedom based on historical freedom or targeted surveillance for diseases in wild aquatic animal populations

3. OIE Handbook on Aquatic Animal Health Surveillance

Prepare the manuscript for the OIE Handbook on Aquatic Animal Health Surveillance.

4. Any other business

ANNEX X.X.X.

GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE

Article x.x.x.1.

Introduction and objectives

1. Surveillance activities may be performed to achieve any of the following objectives:

   - demonstrating the absence of *disease*,
   - identifying events requiring notification as listed in Article 1.2.1.3. of the *Aquatic Code*.
   - determining the occurrence or distribution of endemic *disease*, including changes to their incidence or prevalence (or its contributing factors), in order to:
     - provide information for domestic *disease* control programmes,
     - provide relevant *disease* occurrence information to be used by trading partners for qualitative and quantitative risk assessment.

   The type of surveillance applied depends on the desired outputs needed to support decision-making. Surveillance data determine the quality of *disease* status reports and should satisfy information requirements for accurate risk analysis both for *international trade* as well as for national decision-making. Surveillance of endemic diseases provides valuable information for day-to-day health management and can act as the foundation for detecting outbreaks of exotic disease and demonstrating specific disease freedom.

   Surveillance systems described in this chapter should also be used to generate information for decisions on prescribed disease prevention and control programmes. However, the actual strategies for prevention and control are beyond the scope of this chapter on surveillance guidelines.

   Having a suitable management strategy to respond to surveillance data is of utmost importance for the successful implementation of surveillance systems.

2. Essential prerequisites to enable a Member to provide information for the evaluation of its animal health status are:

   a) that the particular Member complies with the provisions of Chapter 1.4.3. of the *Aquatic Code* on the quality and evaluation of the *Competent Authorities*;

   b) that, where possible, surveillance data be complemented by other sources of information (e.g. scientific publications, research data, documented field observations and other non-survey data);

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Annex III (contd)

c) that transparency in the planning and execution of surveillance activities and the analysis and availability of data and information, be maintained at all times, in accordance with Chapter 1.2.1. of the *Aquatic Code*.

3. The following guidelines may be applied to all *diseases*, their agents, and susceptible species as listed in the *Aquatic Manual*, and are designed to assist with the development of surveillance methodologies. Where possible, the development of surveillance systems using these guidelines should be based on the relevant information in the individual *disease* chapters in the *Aquatic Manual*. These guidelines are also applicable to ~~other~~ non *OIE-listed diseases* that ~~are not included in the *Aquatic Code* but which~~ may be of importance to a country or region, such as new or emerging diseases. There is sometimes a perception that surveillance can only be conducted using sophisticated methodologies. However, an effective surveillance system can also be developed by making use of gross observations and already available resources.

4. It would be impractical to try to develop a surveillance system for all the known *aquatic animal* diseases for which a country has susceptible species. Therefore prioritising the diseases to be included in a surveillance system should be conducted considering:

- the needs to provide assurance of disease status for trade purposes
- the resources of the country
- the financial impact or threat posed by the different diseases
- the importance of an industry-wide disease control programme within a country or region

5. More detailed information in each disease chapter (where it exists) of the *Aquatic Manual* may be used to further refine the general approaches described in this chapter. Where detailed *disease* specific information is not available, surveillance can also be conducted following the guidelines in this chapter. Access to epidemiological expertise would be invaluable for the design, implementation of the system and interpretation of results derived from a surveillance system.

Article x.x.x.2.

Principles of surveillance

1. Surveillance may be based on many different data sources and can be classified in a number of ways, including:

a) the means by which data are collected (targeted versus non-targeted);

b) the *disease* focus (pathogen-specific versus general surveillance); and

c) the way in which *units* for observation are selected (~~structured~~ surveys versus non-random data sources).

2. Surveillance activities include:

a) ~~structured~~ population-based surveys, such as:

i) systematic sampling at slaughter;

ii) random surveys;

b) ~~structured~~ non-random surveillance activities, such as:

i) *disease* reporting or notifications;

ii) control programmes/health schemes;

iii) targeted testing/screening;

iv) ante-mortem and post-mortem inspections;

v) laboratory investigation records;

vi) biological specimen banks;

vii) sentinel *units*;

viii) field observations;

ix) farm production records.

3. In addition, surveillance data should be supported by related information, such as:

a) data on the epidemiology of the *disease*, including environmental, and host and wild reservoir population distributions;

b) data on farmed and wild animal movements and trading patterns for *aquatic animals* and *aquatic animal products*, including potential for exposure to *populations* of wild *aquatic animal ~~populations~~*, water sources or other contacts;

c) national animal health regulations, including information on compliance with them and their effectiveness;

d) history of imports of potentially infected material; and

e) biosecurity measures in place.

4. The sources of evidence should be fully described. ~~In the case of a structured~~ A survey~~, this~~ should include a description of the sampling strategy used for the selection of *units* for testing. For ~~structured~~ non-random data sources, a full description of the system is required including the source(s) of the data, when the data were collected, and a consideration of any *biases* that may be inherent in the system.

Article x.x.x.3.

Critical elements of surveillance

In assessing the quality of a surveillance system, the following critical elements need to be addressed in conjunction with an evaluation of the *Competent Authority* (Chapter 1.4.3.).

1. Populations

Ideally, surveillance should be carried out in such a way as to take into account all animal species susceptible to the *disease* in a country, *zone* or *compartment*. The surveillance activity may cover all individuals in the *population* or part of them. Estimates of total *population* at risk for each species are required. When surveillance is conducted only on a *subpopulation*, care should be taken regarding the inferences made from the results.

For *OIE-listed diseases*, d~~D~~efinitions of appropriate *populations* should be based on the specific recommendations of the *disease* chapters of the *Aquatic Manual.*

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Annex III (contd)

2. Epidemiological unit

The relevant *epidemiological unit* for the surveillance system should be defined and documented to ensure that it is representative of the *population* or targeted *subpopulations* that would generate the most useful inferences about *disease* patterns. Therefore, it should be chosen taking into account factors such as carriers, reservoirs, vectors, immune status, genetic resistance and age, sex, and other host criteria.

3. Clustering

Disease in a country, *zone* or *compartment* usually clusters rather than being uniformly or randomly distributed through a *population*. Clustering of *disease* may occur in space (e.g. tank, pond, farm, or *compartment*), time (e.g. season), or animal subgroups (e.g. age, physiological condition). Clustering should be taken into account in the design of surveillance activities and interpretation of surveillance data.

4. Case and outbreak definitions

Clear and unambiguous case and outbreak definitions should be developed and documented for each *disease* under surveillance, using, where they exist, the standards in this Annex and the *Aquatic Manual*.

5. Analytical methodologies

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant pathogens, varying production and surveillance systems, and types, quality, and amounts of data/ ~~and~~ information available.

The methodology used should be based on the best available information that is in accord with current scientific thinking. The methodology should be in accordance with this Annex and fully documented, and supported by reference to the scientific literature and other sources, including expert opinion. Sophisticated mathematical or statistical analyses should only be carried out when justified by the proper amount and quality of field data.

Consistency in the application of different methodologies should be encouraged and transparency is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding. The uncertainties, assumptions made, and the effect of these on the final conclusions should be documented.

6. Testing

Surveillance involves the detection of *disease* by the use of appropriate *case definitions* based on the results of one or more tests for evidence of *disease* status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the *population* level (including field observations) may be described in terms of its *sensitivity* and *specificity* and predictive values. Imperfect *sensitivity* and/or *specificity* will have an impact on the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data as described in this Annex.

Although not determined for many *aquatic animal diseases*, *sensitivity* and *specificity* should be estimated as best as possible for a specific testing situation. Alternatively, where values for *sensitivity* and/or *specificity* for a particular test and testing situation are estimated in the disease chapter in the *Aquatic Manual*, these values may be used as a guide.

Samples from a number of *aquatic animals* or *units* may be pooled and subjected to a testing protocol. The results should be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pool size and testing procedure.

7. Quality assurance

Surveillance systems should incorporate the principles of quality assurance and be subjected to periodic auditing to ensure that all components of the system function and provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the design.

8. Validation

Results from animal health surveillance systems are subject to one or more potential *biases*. When assessing the results, care should be taken to identify potential *biases* that can inadvertently lead to an over-estimate or an under-estimate of the parameters of interest.

9. Data collection and management

The success of a surveillance system is dependent on a reliable process for data collection and management. The process may be based on paper records or computerised. Even where data are collected for non-survey purposes (e.g. during *disease* control interventions, inspections for movement control or during *disease* eradication schemes), the consistency and quality of data collection and event reporting in a format that facilitates analysis, is critical. Factors influencing the quality of collected data include:

a) the distribution of, and communication between, those involved in generating and transferring data from the field to a centralised location;

b) motivation of the people involved in the surveillance system;

c) the ability of the data processing system to detect missing, inconsistent or inaccurate data, and to address these problems;

d) maintenance of disaggregated data rather than the compilation of summary data;

e) minimisation of transcription errors during data processing and communication.

Annex XVIII (contd)

Annex III (contd)

Article x.x.x.4.

~~Structured p~~Population-based surveys

In addition to the principles for surveillance discussed in article 6, the following guidelines should be used when planning, implementing and analysing surveys.

1. Types of surveys

Surveys may be conducted on the entire *target population* (i.e. a census) or on a sample. Periodic or repeated surveys conducted in order to document *disease* freedom should be done using probability based sampling methods (simple random selection, cluster sampling, stratified sampling, systematic sampling) so that data from the *study population* can be extrapolated to the *target population* in a statistically valid manner. Non-probability based sampling methods (convenience, expert choice, quota) can also be used. Recognising the inherent impracticalities in sampling from some *aquatic animal populations*, non-probability based sampling could be used when *biases* are recognised and used to optimise detection.

The sources of information should be fully described and should include a detailed description of the sampling strategy used for the selection of *units* for testing. Also, consideration should be made of any *biases* that may be inherent in the survey design.

2. Survey design

The *population* of epidemiological *units* should first be clearly defined; hereafter sampling *units* appropriate for each stage, depending on the design of the survey, should be defined.

The design of the survey will depend on the size and structure of the *population* being studied, the epidemiology of the *disease* and the resources available.

3. Sampling

The objective of sampling from a *population* is to select a subset of *units* from the *population* that is representative of the *population* with respect to the object of the study such as the presence or absence of *disease*. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the *population*, within the practical constraints imposed by different environments and production systems. In order to detect the presence of a *disease* in a *population* of unknown *disease* status, ~~targeted~~ sampling methods that optimise the detection of *disease* can be used. In such cases, care should be taken regarding the inferences made from the results.

4. Sampling methods

When selecting *epidemiological units* from within a *population* the objectives of the surveillance system should be considered. In general, *probability sampling* (e.g. simple random selection) is preferable. When this is not possible, sampling should provide the best practical chance of generating optimal inferences about *disease* patterns in the *target population*.

In any case, the sampling method used at all stages should be fully documented and justified.

5. Sample size

In general, surveys are conducted either to demonstrate the presence or absence of a factor (e.g. *disease*) or to estimate a parameter (e.g. the prevalence of *disease*). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence (also referred to as the threshold prevalence), the level of confidence desired of the survey results and the performance (e.g. *sensitivity* and *specificity* estimates) of the tests used.

Article x.x.x.5.

~~Structured n~~Non-random data sources used in surveillance

Surveillance systems routinely use ~~structured~~ non-random data, either alone or in combination with surveys.

1. Common non-random surveillance data sources

A wide variety of non-random surveillance data sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some surveillance systems are primarily established as *early detection systems*, but may also provide valuable information to demonstrate freedom from *disease*. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. *disease* reporting systems, sentinel sites, testing schemes).

a) Disease reporting or notification systems

Data derived from *disease* reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection. The first step of a *disease* reporting or notification system is often based on the observation of abnormalities (e.g. clinical signs, reduced growth, elevated mortality rates, behavioural changes, etc.), which can provide important information about the occurrence of endemic, exotic or new *diseases*. Effective laboratory support is however, an important component of most reporting systems. Reporting systems relying on laboratory confirmation of suspect clinical cases should use tests that have a high *specificity*. Reports should be released by the laboratory in a timely manner, with the amount of time from *disease* detection to report generation minimised.

b) Control programmes / health schemes

Animal *disease* control programmes or health schemes, while focusing on the control or eradication of specific *diseases*, should be planned and structured in such a manner as to generate data that are scientifically verifiable and contribute to ~~structured~~ surveillance.

c) Targeted ~~testing / screening~~ sampling

This may involve sampling ~~testing~~ targeted to selected sections of the *population* (*subpopulation*s), in which *disease* is more likely to be introduced or found. Examples include selecting ~~testing~~ culled and dead animals for testing, animals exhibiting clinical signs, animals located in a defined geographical area and specific age or commodity group.

Annex XVIII (contd)

Annex III (contd)

d) Post-harvest inspections

Inspections of *aquatic animal* slaughter premises or processing plants may provide valuable surveillance data provided diseased *aquatic animals* survive to slaughter. Post-harvest inspections are likely to provide good coverage only for particular age groups and geographical areas. Post-harvest surveillance data are subject to obvious *biases* in relation to *target* and *study populations* (e.g. only animals of a particular class and age may be slaughtered for human consumption in significant numbers). Such *biases* need to be recognised when analysing surveillance data.

Both for traceback in the event of detection of *disease* and for analysis of spatial and *population*-level coverage, there should be, if possible, an effective identification system that relates each animal in the slaughter premises/processing plant to its locality of origin.

e) Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. If available, the method listed in the *Aquatic Manual* in relation to the purpose of testing should be used. As with post-harvest inspections, there needs to be a mechanism to relate specimens to the farm of origin. It must be recognised that laboratory submissions may not accurately reflect the *disease* situation on the farm.

f) Biological specimen banks

Specimen banks consist of stored specimens, gathered either through representative sampling or opportunistic collection or both. Specimen banks may contribute to retrospective studies, including providing support for claims of historical freedom from *disease*, and may allow certain studies to be conducted more quickly and at lower cost than alternative approaches.

g) Sentinel *units*

Sentinel *units*/sites involve the identification and regular testing of one or more of animals of known health/exposure status in a specified geographical location to detect the occurrence of *disease*. They are particularly useful for surveillance of *diseases* with a strong spatial component, such as vector-borne *diseases*. Sentinel *units* provide the opportunity to *target surveillance* depending on the likelihood of *disease* (related to vector habitats and host *population* distribution), cost and other practical constraints. Sentinel *units* may provide evidence of freedom from *disease*, or provide data on prevalence and incidence as well as the distribution of *disease*. Cohabitation of sentinel *units* (preferably of the most susceptible species and life stage) with a susceptible *population* should be considered for testing *disease* in *populations* of valuable animals, the lethal sampling of which may be unacceptable (e.g. ornamental fish) or in animal *subpopulations* where sampling techniques are incapable of detecting the presence of disease or infection (e.g. where vaccination means that serological tests are inapplicable).

h) Field observations

Clinical observations of epidemiological *units* in the field are an important source of surveillance data. The *sensitivity* and/or *specificity* of field observations may be relatively low, but these can be more easily determined and controlled if a clear, unambiguous and easy to apply standardised *case definition* is applied. Education of potential field observers in application of the *case definition* and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

i) Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of *disease* at the *population* level. If production records are accurate and consistently maintained, the *sensitivity* of this approach may be quite high (depending on the *disease*), but the *specificity* is often quite low.

2. Critical elements for ~~structured~~ non-random data used in surveillance

There ~~is~~ are a number of critical factors that should be taken into account when using ~~structured~~ non-random surveillance data such as coverage of the *population*, duplication of data, and *sensitivity* and *specificity* of tests that may give rise to difficulties in the interpretation of data. Surveillance data from non-random data sources may increase the level of confidence or be able to detect a lower level of prevalence with the same level of confidence compared to ~~structured~~ surveys.

3. Analytical methodologies

Different scientifically valid methodologies may be used for the analysis of non-random surveillance data. This most often requires information on parameters of importance to the surveillance system, such as *sensitivity* and *specificity* and prior probabilities of infection, i.e., apparent prevalences (e.g. for ~~negative~~ predictive value calculations). Where no such data are available, estimates based on expert opinions, gathered and combined using a formal, documented and scientifically valid methodology may be used.

4. Combination of multiple sources of data

The methodology used to combine the evidence from multiple or recurrent (e.g. time series) data sources should be scientifically valid, and fully documented including references to published material.

Surveillance information gathered from the same country, *zone* or *compartment* at different times (e.g. repeated annual surveys) may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take into account the decreased value of older information. The *sensitivity*, *specificity* and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

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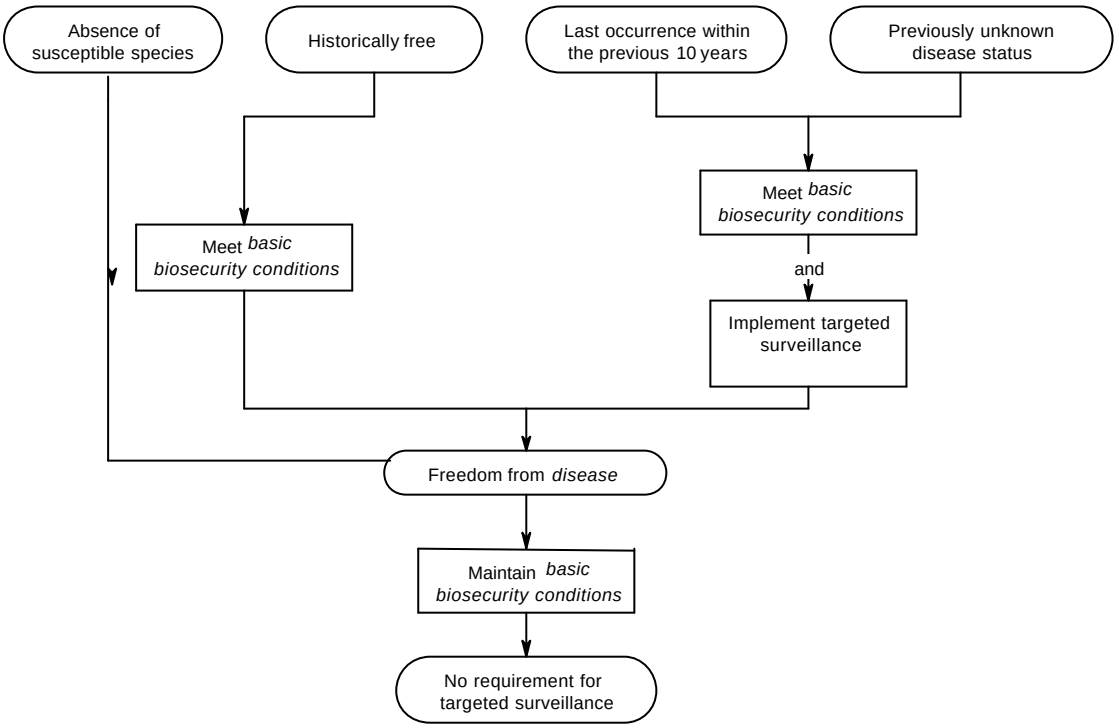
Annex III (contd)

Article x.x.x.6.

Pathways to demonstrate freedom from disease

The different paths to declaration of freedom from *disease* are summarised in the diagram below.



1. Absence of susceptible species

   Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be recognised as being free from *disease* without applying *targeted surveillance* if there are no *susceptible species* (as listed in the relevant chapter of this *Aquatic Manual*, or in the scientific literature) present in that country, *zone* or *compartment*.

2. Historically free

   Unless otherwise specified in the relevant *disease* chapter, a country, *zone* or *compartment* may be declared free from *disease* without formally applying a pathogen-specific surveillance programme when:

   a) there has never been a substantiated occurrence of *disease* reported officially or in the scientific literature (peer reviewed), or

   b) *disease* has not occurred for at least 10 years, provided that the *disease* agents are likely to produce identifiable clinical signs in observable susceptible animals,

   and for at least the past 10 years:

   c) the *basic biosecurity conditions* are in place and effectively enforced;

d) no vaccination against the *disease* has been carried out unless otherwise allowed for in the *Aquatic Code*;

e) *disease* is not known to be established in wild *aquatic animals* within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for historical freedom if there is any evidence of *disease* in wild *aquatic animals*. However, specific surveillance in wild *aquatic animals* is not necessary.)

A country, *zone* or *compartment* that was *self-declared* free on the basis of the absence of susceptible species, but subsequently introduces any of the susceptible species as listed in the *Aquatic Manual*, may be considered historically free from the *disease* provided that:

f) the country, *zone* or *compartment* of origin was declared free of the *disease* at the time of introduction;

g) *basic biosecurity conditions* were introduced prior to the introduction;

h) no vaccination against the *disease* has been carried out unless otherwise allowed for in the *disease* specific chapter of this *Aquatic Code*.

3. Last occurrence within the previous 10 years / previously unknown status

Countries, *zones* or *compartments* that have achieved eradication (or in which the *disease* has ceased to occur) within the previous 10 years or where the *disease* status is unknown, should follow the pathogen-specific surveillance requirements in the *Aquatic Manual* if they exist. In the absence of *disease* specific information to aid the development of a surveillance system, declaration of *disease* freedom should follow at least 2 surveys per year (for at least 2 consecutive years) to be conducted 3 or more months apart, on the appropriate species, at the appropriate life stage and at times of the year when temperature and season offer the best opportunity to detect the pathogen. Surveys should be designed to provide an overall 95% confidence or greater and with a design prevalence at the animal and higher levels of aggregation (i.e. pond, farm, village, etc.) ~~levels being~~ of 2% or lower (this value may be different for different *diseases* and may be provided in the specific *disease* chapter in the *Aquatic Manual*). Such surveys should not be based on voluntary submission and should be developed following the guidelines provided in the *Aquatic Manual*. Survey results will provide sufficient evidence of *disease* freedom provided that for at least the past 10 years these additional criteria are met:

a) the *basic biosecurity conditions* are in place and effectively enforced;

b) no vaccination against the *disease* has been carried out unless otherwise provided in the *Aquatic Code*;

c) *disease* is not known to be established in wild *aquatic animals* within the country or *zone* intended to be declared free. (A country or *zone* cannot apply for freedom if there is any evidence of *disease* in wild *aquatic animals*. Specific surveillance in wild *aquatic animals* of susceptible species is necessary to confirm absence.)

Article x.x.x.7.

Maintenance of disease free status

A country or *zone* that has been declared free from *disease* following the provisions of the *Aquatic Code* may discontinue pathogen-specific surveillance while maintaining the *disease* free status provided that:

Annex XVIII (contd)

Annex III (contd)

1. if present, the pathogen is likely to produce identifiable clinical signs in observable *susceptible species*;

2. the *basic biosecurity conditions* are in place and effectively enforced;

3. no vaccination against the *disease* has been carried out unless otherwise provided in the *Aquatic Code*;

4. where applicable, surveillance has previously demonstrated that *disease* is not present in *populations* of wild *aquatic animal ~~population~~s* of *susceptible species*.

A special case can be made for a disease free *compartment* ~~located~~ in a country or *zone* ~~that is~~ not declared disease free, ~~proven to be free from *disease* if~~ surveillance should be ~~is~~ maintained at a level commensurate with the degree of risk and exposure to potential sources of *disease* is prevented.

Article x.x.x.8.

Design of surveillance programmes to demonstrate freedom from disease

A surveillance programme to demonstrate freedom from *disease* should meet the following requirements in addition to the general requirements for surveillance outlined in this Annex.

Freedom from *disease* implies the absence of the pathogenic agent in the country, *zone* or *compartment*. Scientific methods cannot provide absolute certainty of the absence of *disease*. Demonstrating freedom from *disease* involves providing sufficient evidence to demonstrate (to a level of confidence acceptable to Members) that *disease* with a specified pathogen is not present in a *population*. In practice, it is not possible to prove (i.e. be 100% confident) that a *population* is free from *disease*. Instead, the aim is to provide adequate evidence (to an acceptable level of confidence), that *disease*, if present, is present in less than a specified proportion of the *population* (i.e., threshold prevalence).

However, apparent *disease* at any level in the *target population* automatically invalidates any freedom from *disease* claim unless the positive test results are accepted as false positives based on *specificity* values described in the relevant *disease* chapter.

The provisions of this Article are based on the principles described above and the following premises:

– in the absence of *disease* and vaccination, the farmed and wild animal *populations* would become susceptible over a period of time;

– the *disease* agents to which these provisions apply are likely to produce identifiable clinical signs in observable susceptible animals;

– to increase the probability of detecting the specific disease agent, the susceptibility of the *aquatic animal* and the timing of sampling must be under appropriate conditions;

– the *Competent Authority* will be able to investigate, diagnose and report *disease*, if present;

– the appropriate diagnostic method as described in the *Aquatic Manual* be used

– any claim for the absence of *disease* over a long period of time in a susceptible *population* can be substantiated by effective *disease* investigation and reporting by a Member.

Annex XVIII (contd)

Annex III (contd)

1. Objectives

The objective of this kind of surveillance system is to contribute on an on-going basis evidence to demonstrate freedom from disease in a particular country, *zone* or *compartment* with a known confidence and reference to a predetermined design prevalence and diagnostic test characteristics. The level of confidence and the design prevalence will depend on the testing situation, disease and host *population* characteristics and on the resources available.

A single such survey can contribute evidence adding to an on-going collection of health data (see also Section 5. Specific requirements for complex non-survey data sources). However, single surveys in isolation rarely, if ever, provide sufficient evidence that an *aquatic animal* disease is absent and must be augmented with on-going targeted evidence collection (e.g. ongoing disease sampling or passive detection capabilities) to substantiate claims of freedom from disease.

2. Population

The *population* of *epidemiological units* must be clearly defined. The *target population* consists of all individuals of all *susceptible species* to the disease in a country, *zone* or *compartment* to which the surveillance results apply. Sometimes components of the *target population* are at higher risk of being the point of introduction for an exotic disease. In these cases, it is advisable to focus surveillance efforts on this part of the *population*, such as farms on a geographical border.

The design of the survey will depend on the size and structure of the *population* being studied. If the *population* is relatively small and can be considered to be homogenous with regards to risk of infection, a single-stage survey can be used. If different *subpopulations* of the same *aquaculture* establishment do not share water, they may be considered as epidemiologically separate *populations*.

In larger *populations* where a sampling frame is not available, or when there is a likelihood of clustering of disease, multi-stage sampling is required. In two-stage sampling, at the first stage of sampling, groups of animals (e.g. ponds, farms or villages) are selected. At the second stage, animals are selected for testing from each of the selected groups.

In the case of a complex (e.g. multi-level) *population* structure, multi-level sampling may be used and the data analysed accordingly.

3. Sources of evidence

Surveillance data may originate from a number of different sources, including:

a) ~~structured,~~ *population*-based surveys using one or more tests to detect the aetiological agent or evidence of infection;

b) other ~~structured~~ non-random sources of data, such as:

   i) sentinel sites;

   ii) disease notifications and laboratory investigation records;

   iii) academic and other scientific studies;

c) a knowledge of the biology of the agent, including environmental, host *population* distribution, known geographical distribution, vector distribution and climatic information;

Annex XVIII (contd)

Annex III (contd)

d) history of imports of potentially infected material;

e) biosecurity measures in place;

f) any other sources of information that provide contributory evidence regarding disease in the country, *zone* or *compartment*.

The sources of evidence must be fully described. ~~In the case of a~~ A ~~structured~~ survey~~, this~~ must include a description of the sampling strategy used for the selection of *units* for testing. For complex *surveillance* systems, a full description of the system is required including consideration of any *biases* that may be inherent in the system. Evidence to support claims of freedom from disease can use ~~structured~~ non-random sources of information provided that, overall, any *biases* introduced subsequently favour the detection

4. Statistical methodology

Analysis of test results from a survey shall be in accordance with the provisions of this chapter and consider the following factors:

a) The survey design

b) The *sensitivity* and *specificity* of the test, or test system

c) The design prevalence (or prevalences where a multi-stage design is used)

d) The results of the survey.

Analysis of data for evidence of freedom from infection involves estimating the probability of type I error (a, alpha) that the evidence observed (the results of surveillance) could have been produced under the null hypothesis that infection is present in the *population* at, or greater than a specified prevalence(s) (the design prevalences). The confidence in (or, equivalently, the *sensitivity* of) the surveillance system that produced the evidence is equal to 1–a. If the confidence level exceeds a pre-set threshold, the evidence is deemed adequate to demonstrate freedom from infection.

The required level of confidence in the surveillance system (probability that the system would detect infection if infection were present at the specified level) must be greater than or equal to 95%.

The power (probability that the system would report that no infection is present if infection is truly not present) may be set to any value. By convention, this is often set to 80%, but may be adjusted according to the country's or *zone*'s requirements.

Different statistical methodologies for the calculation of the probability a (the alpha error), including both quantitative and qualitative approaches, are acceptable as long as they are based on accepted scientific principles~~.~~, and that they are clearly documented, including references to published work describing the methodology.

~~The methodology used to calculate the confidence in the surveillance system must be scientifically based and clearly documented, including references to published work describing the methodology.~~

Statistical analysis of surveillance data often requires assumptions about *population* parameters or test characteristics. These are usually based on validation studies, expert opinion, previous studies on the same or different *populations*, expected biology of the agent, and so on. The uncertainty around these assumptions must be quantified and considered in the analysis (e.g. in the form of prior probability distribution~~s~~ functions ~~in a Bayesian setting~~).

For surveillance systems used to demonstrate freedom from specific diseases, calculation of the confidence of a surveillance system is based on the null hypothesis that infection is present in the *population.* The level of infection is specified by the design prevalence. In the simplest case, this is the prevalence of infection in a homogenous *population.* More commonly, in the presence of a complex (e.g. multi-level) *population* structure more than one design prevalence value is required, for instance, the animal-level prevalence (proportion of infected animals in an infected farm) and the group-level prevalence (proportion of infected farms in the country, *zone* or *compartment*). Further levels of clustering may be considered, requiring further design prevalence values.

The values for design prevalence used in calculations must be those specified in the relevant disease chapter (if present) of this *Aquatic Manual*. If not specified for the particular disease, justification for the selection of design prevalence values must be provided, and should be based on the following guidelines:

– At the individual animal level, the design prevalence is based on the biology of the infection in the *population*. It is equal to the minimum expected prevalence of infection in the *study population*, if the infection had become established in that *population*. It is dependent on the dynamics of infection in the *population* and the definition of the *study population* (which may be defined to maximise the expected prevalence in the presence of infection).

– A suitable design prevalence value at the animal level (e.g. prevalence of infected animals in a cage) may be:

  • between 1% and 5% for infections that are present in a small part of the *population* e.g. are transmitted slowly or are at the early stages of an outbreak, etc.;

  • over 5% for highly transmissible infections.

  If reliable information, including expert opinion, on the expected prevalence in an infected *population* is not available, a value of 2% should be used for the design prevalence.

– At higher levels (e.g. cage, pond, farm, village, etc.) the design prevalence usually reflects the prevalence of infection that is practically and reasonably able to be detected by a *surveillance* system. Detection of infection at the lowest limit (a single infected *unit* in the *population*) is rarely feasible in large *populations*. The expected behaviour of the infection may also play a role. Infections that have the ability to spread rapidly between farms may have a higher farm-level design prevalence than slow-moving infections.

  A suitable design prevalence value for the first level of clustering, (e.g. proportion of infected farms in a *zone*) ~~may be up to~~ is normally not greater than 2%. If a higher design prevalence is selected, it must be justified.

When surveillance data are used to estimate incidence and prevalence measures for the purpose of describing disease occurrence in terms of animal *unit*, time and place, these measures can be calculated for an entire *population* and specific time period, or for subsets defined by host characteristics (e.g. age-specific incidence). Incidence estimation requires on-going surveillance to detect new cases while prevalence is the estimated proportion of infected individuals in a *population* at a given time point. The estimation process must consider test *sensitivity* and *specificity*.

Annex XVIII (contd)

Annex III (contd)

5. Clustering of infection

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly distributed through a *population*. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a *zone*). Except when dealing with demonstrably homogenous *populations*, surveillance must take this clustering into account in the design and the statistical analysis of the data, at least at what is judged to be the most significant level of clustering for the particular animal *population* and infection.

6. Test characteristics

All surveillance involves performing one or more tests for evidence of the presence of current or past infection, ranging from detailed laboratory examinations to farmer observations. The performance level of a test at the *population* level is described in terms of its *sensitivity* and *specificity*. ~~These probabilities of the correct test result refer to the entire sampling process, including sample selection, collection, handling and processing (which if not conducted in the optimal way for the disease in question, as described in the disease chapters of the *Aquatic Manual*, will reduce the *sensitivity* of the method), and the actual laboratory test performance.~~ Imperfect *sensitivity* and/or *specificity* impact on the interpretation of surveillance results and must be taken into account in the analysis of surveillance data. For example, in the case of a test with imperfect *specificity*, if the *population* is free of disease or has a very low prevalence of infection, all or a large proportion of positive tests will be false. Subsequently, samples that test positive can be confirmed or refuted using a highly specific test. Where more than one test is used in a *surveillance* system (sometimes called using tests in series or parallel), the *sensitivity* and *specificity* of the test combination must be calculated.

All calculations must take the performance level (*sensitivity* and *specificity*) of any tests used into account. The values of *sensitivity* and *specificity* used for calculations must be specified, and the method used to determine or estimate these values must be documented. Test *sensitivity* and *specificity* can be different when applied to different *populations* and testing scenarios. For example, test sensitivity may be lower when testing carrier animals with low level infections compared to moribund animals with clinical disease. Alternatively, *specificity* depends on the presence of cross-reacting agents, the distribution of which may be different under different conditions or regions. Ideally, test performance should be assessed under the conditions of use otherwise increased uncertainty exists regarding their performance. In the absence of local assessment of tests, values for *sensitivity* and/or *specificity* for a particular test that are specified in this *Aquatic Manual* may be used but the increased uncertainty associated with these estimates should be incorporated into the analysis of results.

Pooled testing involves the pooling of specimens from multiple individuals and performing a single test on the pool. Pooled testing is an acceptable approach in many situations. Where pooled testing is used, the results of testing must be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pooled testing procedure and for the applicable pool sizes being used. Analysis of the results of pooled testing must, where possible, be performed using accepted, statistically based methodologies, which must be fully documented, including published references.

When applied to a *surveillance* system, the probabilities of correct assessment of the health status of the *epidemiological unit* is affected by the entire sampling process, including sample selection, collection, handling and processing, as well as the actual laboratory test performance.

7. Multiple sources of information

Where multiple different data sources providing evidence of freedom from infection exist, each of these data sources may be analysed accordingly. The resulting estimates of the confidence in each data source may be combined to provide an overall level of confidence for the combined data sources.

The methodology used to combine the estimates from multiple data sources:

a) must be scientifically valid, and fully documented, including references to published material; and

b) should, where possible, take into account any lack of statistical independence between different data sources.

Surveillance information gathered from the same country, *zone* or *compartment* at different times (e.g. repeated annual surveys) may provide cumulative evidence of animal health status. Such evidence gathered over time may be combined to provide an overall level of confidence. However, a single larger survey, or the combination of data collected during the same time period from multiple random or non-random sources, may be able to achieve the same level of confidence in a shorter period of time.

Analysis of surveillance information gathered intermittently or continuously over time should, where possible, incorporate the time of collection of the information to take into account the decreased value of older information. The *sensitivity*, *specificity* and completeness of data from each source should also be taken into account for the final overall confidence level estimation.

8. Sampling

The objective of sampling from a *population* is to select a subset of *units* from the *population* that is representative of the *population* with respect to the characteristic of interest (in this case, the presence or absence of infection). The survey design may involve sampling at several levels. For sampling at the level of the *epidemiological units* or higher *units*, a formal *probability sampling* (e.g. simple random sampling) method must be used. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the *population*, within the practical constraints imposed by different environments and production systems.

When sampling below the level of the *epidemiological unit* (e.g. individual animal), the sampling method used should provide the best practical chance of generating a sample that is representative of the *population* of the chosen *epidemiological unit*. Collecting a truly representative sample of individual animals (whether from a pond, cage or fishery) is often very difficult. To maximise the chance of finding infection, the aim should be to *bias* the sampling towards infected animals, e.g. selecting moribund animals, life stages with a greater chance of active infection, etc.

Biased ~~or targeted~~ sampling in this context involves sampling from a defined *study population* that has a different probability of infection than the *target population* of which it is a *subpopulation*. Once the *study population* has been identified, the objective is still to select a representative sample from this *subpopulation*.

The sampling method used at all levels must be fully documented and justified.

Annex XVIII (contd)

Annex III (contd)

9. Sample size

The number of *units* to be sampled from a *population* should be calculated using a statistically valid technique that takes at least the following factors into account:

– The *sensitivity* and *specificity* of the diagnostic test, or test system;

– The design prevalence (or prevalences where a multi-stage design is used);

– The level of confidence that is desired of the survey results.

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

– The size of the *population* (but it is acceptable to assume that the *population* is infinitely large);

– The desired power of the survey;

– Uncertainty about *sensitivity* and *specificity*.

The specific sampling requirements will need to be tailor-made for each individual disease, taking into account its characteristics and the *specificity* and *sensitivity* of the accepted testing methods for detecting the disease agent in host *populations*. In the situation where uncertainty is expressed in a range of *sensitivity* and *specificity* values the more conservative approach would be to take the largest sample size from the range calculated.

FreeCalc[1] is a suitable software for the calculation of sample sizes at varying parameter values. The table below provides examples of sample sizes generated by the software for a type I and type II error of 5% (i.e. 95% confidence and 95% statistical power). However, this does not mean that a type 1 and type 2 error of 0.05 should always be used. For example, using a test with *sensitivity* and specificity of 99%, 528 *units* should be sampled. If 9 or less of those *units* test positive, the *population* can still be considered free of the disease at a design prevalence of 2% provided that all effort is made to ensure that all presumed false positives are indeed false. This means that there is a 95% confidence that the prevalence is 2% or lower.

In the case in which the values of Se and Sp are not known (e.g. no information is available in the specific disease chapter in the *Aquatic Manual*), they should not automatically be assumed to be 100%. All positive results should be included and discussed in any report regarding that particular survey and all efforts should be made to ensure that all presumed false positives are indeed false.

10. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

1 FreeCalc – Cameron, AR. Software for the calculation of sample size and analysis of surveys to demonstrate freedom from disease. Available for free download from http://www.ausvet.com.au.

Annex XVIII (contd)

Annex III (contd)

Design prevalence	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false +ve if the population is free
2	100	100	149	0
2	100	99	524	9
2	100	95	1671	98
2	99	100	150	0
2	99	99	528	9
2	99	95	1707	100
2	95	100	157	0
2	95	99	542	9
2	95	95	1854	108
2	90	100	165	0
2	90	99	607	10
2	90	95	2059	119
2	80	100	186	0
2	80	99	750	12
2	80	95	2599	148
5	100	100	59	0
5	100	99	128	3
5	100	95	330	23
5	99	100	59	0
5	99	99	129	3
5	99	95	331	23
5	95	100	62	0
5	95	99	134	3
5	95	95	351	24
5	90	100	66	0
5	90	99	166	4
5	90	95	398	27
5	80	100	74	0
5	80	99	183	4
5	80	95	486	32
10	100	100	29	0
10	100	99	56	2
10	100	95	105	9
10	99	100	29	0
10	99	99	57	2
10	99	95	106	9
10	95	100	30	0
10	95	99	59	2
10	95	95	109	9
10	90	100	32	0
10	90	99	62	2
10	90	95	123	10
10	80	100	36	0
10	80	99	69	2
10	80	95	152	12

Annex XVIII (contd)

Annex III (contd)

Article x.x.x.9.

Specific requirements for complex non-survey data sources for freedom from disease

Data sources that provide evidence of freedom from infection, but are not based on ~~structured~~ *population*-based surveys may also be used to demonstrate freedom, either alone or in combination with other data sources. Different methodologies may be used for the analysis of such data sources, but the methodology must comply with the provisions of Section B.3. The approach used should, where possible, also take into account any lack of statistical independence between observations.

Analytical methodologies based on the use of step-wise probability estimates to describe the surveillance system may determine the probability of each step either by:

1. the analysis of available data, using a scientifically valid methodology; or where no data are available,
2. the use of estimates based on expert opinion, gathered and combined using a formal, documented and scientifically valid methodology.

Where there is significant uncertainty and/or variability in estimates used in the analysis, stochastic modelling or other equivalent techniques should be used to assess the impact of this uncertainty and/or variability on the final estimate of confidence.

Article x.x.x.10.

Surveillance for distribution and occurrence of disease

Surveillance to determine distribution and occurrence of *disease* or of other relevant health related events is widely used to assess the prevalence and incidence of selected *disease* as an aid to decision making, for example implementation of control and eradication programmes. It also has relevance for the international movement of animals and products when movement occurs among infected countries.

In contrast to surveillance to demonstrate freedom from *disease*, surveillance for the distribution and occurrence of *disease* is usually designed to collect data about a number of variables of animal health relevance, for example:

– prevalence or incidence of *disease* in wild or cultured animals;

– morbidity and mortality rates;

– frequency of *disease* risk factors and their quantification;

– frequency distribution of variables in *epidemiological units*;

– frequency distribution of the number of days elapsing between suspicion of *disease* and laboratory confirmation of the diagnosis and/or to the adoption of control measures;

– farm production records, etc.

This section describes surveillance to estimate parameters of disease occurrence.

1. Objectives

   The objective of this kind of surveillance system is to contribute on an on-going basis evidence to assess the occurrence and distribution of disease or infection in a particular country, *zone* or *compartment*. This will provide information for domestic disease control programmes and relevant disease occurrence information to be used by trading partners for qualitative and quantitative risk assessment.

A single such survey can contribute evidence adding to an on-going collection of health data (see also Section 5. Specific requirements for complex non-survey data sources).

2. Population

The *population* of *epidemiological units* must be clearly defined. The *target population* consists of all individuals of all species susceptible to the disease in a country, *zone* or *compartment* to which the surveillance results apply. Some local areas within a region may be known to be free of the disease of concern, allowing resources to be concentrated on known positive areas for greater precision of prevalence estimates and only verification of expected 0 prevalence areas.

The design of the survey will depend on the size and structure of the *population* being studied. If the *population* is relatively small and can be considered to be homogenous with regards to risk of infection, a single-stage survey can be used.

In larger *populations* where a sampling frame is not available, or when there is a likelihood of clustering of disease, multi-stage sampling is required. ~~In two-stage sampling, at the first stage of sampling, groups of animals (e.g. ponds, farms or villages) are selected. At the second stage, animals are selected for testing from each of the selected groups.~~ For example, a multi-stage sampling process may involve sampling of farms or villages followed by sampling of fish from selected ponds within the sampled farms/villages.

In the case of a complex (e.g. multi-level) *population* structure, multi-level sampling may be used and the data analysed accordingly.

3. Sources of evidence

Surveillance data may originate from a number of different sources, including:

a) ~~structured~~, *population*-based surveys using one or more tests to detect the agent;

b) other ~~structured~~ non-random sources of data, such as:

   i) sentinel sites;

   ii) disease notifications and laboratory investigation records;

   iii) academic and other scientific studies;

c) a knowledge of the biology of the agent, including environmental, host *population* distribution, known geographical distribution, vector distribution and climatic information;

d) history of imports of potentially infected material;

e) biosecurity measures in place;

f) any other sources of information that provide contributory evidence regarding disease or infection in the country, *zone* or *compartment*.

The sources of evidence must be fully described. ~~In the case of a~~ A ~~structured~~ survey~~, this~~ must include a description of the sampling strategy used for the selection of *units* for testing. For complex surveillance systems, a full description of the system is required including consideration of any *biases* that may be inherent in the system. Evidence to support changes in prevalence/incidence of endemic disease must be based on valid, reliable methods to generate precise estimates with known error.

Annex XVIII (contd)

Annex III (contd)

4. Statistical methodology

Analysis of survey data should be in accordance with the provisions of this chapter and should consider the following factors:

a) The survey design;

b) The *sensitivity* and *specificity* of the test, or test system;

c) The results of the survey.

For surveillance systems used to describe disease patterns, the purpose is to estimate prevalence or incidence with confidence intervals or probability intervals. The magnitude of these intervals expresses the precision of the estimates and is related to sample size. Narrow intervals are desirable but will require larger sample sizes and more dedication of resources. The precision of the estimates and the power to detect differences in prevalence between *populations* or between time points depends not only on sample size, but also on the actual value of the prevalence in the *population* or the actual difference. For this reason, when designing the surveillance system, a prior estimate/assumption of expected prevalence or expected difference in prevalence must be made.

For the purpose of describing disease occurrence, measures of animal *unit*, time and place can be calculated for an entire *population* and specific time period, or for subsets defined by host characteristics (e.g. age-specific incidence). Incidence estimation requires on-going surveillance to detect new cases in a specified time period while prevalence is the estimated proportion of infected individuals in a *population* at a given time point. The estimation process must consider test *sensitivity* and *specificity*.

Statistical analysis of surveillance data often requires assumptions about *population* parameters or test characteristics. These are usually based on expert opinion, previous studies on the same or different *populations*, expected biology of the agent, information contained in the specific disease chapter of the *Aquatic Manual*, and so on. The uncertainty around these assumptions must be quantified and considered in the analysis (e.g. in the form of prior probability distributions in a Bayesian setting).

When surveillance objectives are to estimate prevalence/incidence or changes in disease patterns, statistical analysis must account for sampling error. Analytic methods should be thoroughly considered and consultation with biostatistician/quantitative epidemiologist consulted beginning in the planning stages and continued throughout the programme.

5. Clustering of infection

Infection in a country, *zone* or *compartment* usually clusters rather than being uniformly distributed through a *population*. Clustering may occur at a number of different levels (e.g. a cluster of moribund fish in a pond, a cluster of ponds in a farm, or a cluster of farms in a *zone*). Except when dealing with demonstrably homogenous *populations*, surveillance must take this clustering into account in the design and the statistical analysis of the data, at least at what is judged to be the most significant level of clustering for the particular animal *population* and infection. For endemic diseases, it is important to identify characteristics of the *population* which contribute to clustering and thus provide efficiency in disease investigation and control.

6. Test characteristics

All surveillance involves performing one or more tests for evidence of the presence of current or past infection, ranging from detailed laboratory examinations to farmer observations. The performance level of a test at the *population* level is described in terms of its *sensitivity* and *specificity*. Imperfect *sensitivity* and/or *specificity* impact on the interpretation of surveillance results and must be taken into account in the analysis of surveillance data. For example, in *populations* with low prevalence of infection, a large proportion of positive tests may be false unless the tests used have perfect *specificity*. To ensure detection in such instances, a highly sensitive test is frequently used for initial screening and then confirmed with highly specific tests.

All calculations must take the performance level (*sensitivity* and *specificity*) of any tests used into account. The values of *sensitivity* and *specificity* used for calculations must be specified, and the method used to determine or estimate these values must be documented. Test *sensitivity* and *specificity* can be different when applied to different *populations* and testing scenarios. For example, test *sensitivity* may be lower when testing carrier animals with low level infections compared to moribund animals with clinical disease. Alternatively, *specificity* depends on the presence of cross-reacting agents, the distribution of which may be different under different conditions or regions. Ideally, test performance should be assessed under the conditions of use otherwise increased uncertainty exists regarding their performance. In the absence of local assessment of tests, values for *sensitivity* and/or *specificity* for a particular test that are specified in this *Aquatic Manual* may be used but the increased uncertainty associated with these estimates should be incorporated into the analysis of results.

Pooled testing involves the pooling of specimens from multiple individuals and performing a single test on the pool. Pooled testing is an acceptable approach in many situations. Where pooled testing is used, the results of testing must be interpreted using *sensitivity* and *specificity* values that have been determined or estimated for that particular pooled testing procedure and for the applicable pool sizes being used. Analysis of the results of pooled testing must, where possible, be performed using accepted, statistically based methodologies, which must be fully documented, including published references.

Test results from surveillance for endemic disease will provide estimates of apparent prevalence (AP). Using diagnostic *sensitivity* (DSe) and diagnostic *specificity* (DSp) as described in chapter 1.1.2 of this *Aquatic Manual*, true prevalence (TP) should be calculated with the following formula:

$$TP = (AP + DSp - 1)/(DSe + DSp - 1)$$

In addition, it should be remembered that different laboratories may obtain conflicting results for various test, host, or procedure-related reasons. Therefore, *sensitivity* and *specificity* parameters should be validated for the particular laboratory and process.

7. Multiple sources of information

Where multiple different data sources providing information on infection or disease are generated, each of these data sources may be analysed and presented separately.

Surveillance information gathered from the same country, *zone* or *compartment* at different times and similar methodology (e.g. repeated annual surveys) may provide cumulative evidence of animal health status and changes. Such evidence gathered over time may be combined (e.g. using Bayesian methodology) to provide more precise estimates and details of disease distribution within a *population*. Apparent changes in disease occurrence of endemic diseases may be real or due to other factors influencing detection proficiency.

Annex XVIII (contd)

Annex III (contd)

8. Sampling

The objective of sampling from a *population* is to select a subset of *units* from the *population* that is representative of the *population* with respect to the characteristic of interest (in this case, the presence or absence of infection). The survey design may involve sampling at several levels. For sampling at the level of the *epidemiological units* or higher *units*, a formal *probability sampling* (e.g. simple random sampling) method must be used. Sampling should be carried out in such a way as to provide the best likelihood that the sample will be representative of the *population*, within the practical constraints imposed by different environments and production systems.

When sampling below the level of the *epidemiological unit* (e.g. individual animal), the method used should be probability-based sampling. Collecting a true probability-based sample is often very difficult and care should therefore be taken in the analysis and interpretation of results obtained using any other method, the danger being that inferences could not be made about the sampled *population*.

The sampling method used at all levels must be fully documented and justified.

9. Sample size

The number of *units* to be sampled from a *population* should be calculated using a statistically valid technique that takes at least the following factors into account:

– The *sensitivity* and *specificity* of the diagnostic test (single or in combination);

– Expected prevalence or incidence in the *population* (or prevalences/incidences where a multi-stage design is used);

– The level of confidence that is desired of the survey results.

– The precision desired (i.e. the width of the confidence or probability intervals).

Additionally, other factors may be considered in sample size calculations, including (but not limited to):

– The size of the *population* (but it is acceptable to assume that the *population* is infinitely large);

– Uncertainty about *sensitivity* and *specificity*.

The specific sampling requirements will need to be tailor-made for each individual disease, taking into account its characteristics and the *specificity* and *sensitivity* of the accepted testing methods for detecting the disease agent in host *populations*. In the situation where uncertainty is expressed in a range of *sensitivity* and *specificity* values the more conservative approach would be to take the largest sample size from the range calculated.

A number of software packages, e.g. Survey Tool Box (www.aciar.gov.au; www.ausvet.com.au), WinPEPI (www.sagebrushpress.com/pepibook.html) can be used for the calculation of sample sizes.

In the case in which the values of Se and Sp are not known (e.g. no information is available in the specific disease chapter in the *Aquatic Manual*), they should not automatically be assumed to be 100%. Assumed values should be produced in consultation with subject-matter experts.

10. Quality assurance

Surveys should include a documented quality assurance system, to ensure that field and other procedures conform to the specified survey design. Acceptable systems may be quite simple, as long as they provide verifiable documentation of procedures and basic checks to detect significant deviations of procedures from those documented in the survey design.

Article x.x.x.11.

Examples of surveillance programmes

The following examples describe surveillance systems and approaches to the analysis of evidence for demonstrating freedom from *disease*. The purpose of these examples is:

- to illustrate the range of approaches that may be acceptable;
- to provide practical guidance and models that may be used for the design of specific surveillance systems; and
- to provide references to available resources that are useful in the development and analysis of surveillance systems.

While these examples demonstrate ways in which freedom from *disease* may be successfully demonstrated, they are not intended to be prescriptive. Countries are free to use different approaches, as long as they meet the requirements of this chapter.

The examples deal with the use of ~~structured~~ surveys and are designed to illustrate different survey designs, sampling schemes, the calculation of sample size, and analysis of results. It is important to note that alternative approaches to demonstrating freedom using complex non-survey-based data sources are also currently being developed and may soon be published[2].

1. Example 1. – one-stage ~~structured~~ survey (farm certification)

   a) Context

      A freshwater aquaculture industry raising fish in tanks has established a farm certification scheme. This involves demonstrating farm-level freedom from a particular (hypothetical) disease (Disease X). The disease does not spread very quickly, and is most common during the winter months, with adult fish at the end of the production cycle being most severely affected. Farms consist of a number of grow-out tanks, ranging from 2 to 20, and each tank holds between 1000 and 5000 fish.

   b) Objective

      The objective is to implement surveillance that is capable of providing evidence that an individual farm is free from Disease X. (The issue of national or *zone* freedom, as opposed to farm freedom, is considered in the next example.)

   c) Approach

      The accreditation scheme establishes a set of standard operating procedures and requirements for declaration of freedom, based on the guidelines given in this chapter. These require farms to undertake a ~~structured~~ survey capable of producing 95% confidence that the disease would be detected if it were present. Once farms have been surveyed without detecting disease, they are recognised as free, as long as they maintain a set of minimum biosecurity standards. These standards are designed to prevent the introduction of Disease X into the farm (through the implementation of controls specific to the method of spread of that disease) and to ensure that the disease would be detected rapidly if it were to enter the farm (based on evidence of adequate health record keeping and the prompt investigation of unusual disease events). The effective implementation of these biosecurity measures is evaluated with annual on-farm audits conducted by independent auditors.

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2 International EpiLab, Denmark, Research Theme 1: Freedom from disease. http://www.vetinst.dk/high_uk.asp?page_id=196

Annex XVIII (contd)

Annex III (contd)

d) Survey standards

Based on the guidelines given in this chapter, a set of standards are established for the conduct of surveys to demonstrate freedom from infection with causative agent of Disease X. These standards include:

i) The level of confidence required of the survey is 95% (i.e. Type I error = 5%).

ii) The power of the survey is arbitrarily set at 95% (i.e. Type II error = 5%, which means that there is a 5% chance of concluding that a non-diseased farm is infected).

iii) The *target population* is all the fish on the farm. Due to the patterns of disease in this production system, in which only fish in the final stages of grow-out, and only in winter are affected, the *study population* is defined as grow-out fish during the winter months.

iv) The issue of clustering is considered. As fish are grouped into tanks, this is the logical level at which to consider clustering. However, when a farm is infected, the disease often occurs in multiple tanks, so there is little evidence of strong clustering. Also, the small number of tanks on a single farm means that it is difficult to define a design prevalence at the tank level (i.e. the proportion of infected tanks that the survey should be able to detect on the farm). For these reasons, it is decided to treat the entire grow-out *population* of each farm as a single homogenous *population*.

v) Stratification is also considered. In order to ensure full representation, it is decided to stratify the sample size by tank, proportional to the *population* of each tank.

vi) The design prevalence at the animal level is determined based on the epidemiology of the disease. The disease does not spread quickly, however, in the defined *target population*, it has been reported to affect at least 10% of fish, if the *population* is infected. In order to take the most conservative approach, an arbitrarily low design prevalence of 2% is used. A prevalence of 10% may have been used (and would result in a much smaller sample size), but the authorities were not convinced by the thought that the *population* could still be infected at a level of say 5%, and disease still not be detected.

vii) The test used involves destructive sampling of the fish, and is based on an antigen-detection enzyme-linked immunosorbent assay (ELISA). Disease X is present in some parts of the country (hence the need for a farm-level accreditation programme). This has provided the opportunity for the *sensitivity* and the *specificity* of the ELISA to be evaluated in similar *populations* to those on farms. A recent study (using a combination of histology and culture as a gold standard) estimated the *sensitivity* of the ELISA to be 98% (95% confidence interval 96.7–99.2%), and the *specificity* to be 99.4% (99.2–99.6%). Due to the relatively narrow confidence intervals, it was decided to use the point estimates of the *sensitivity* and *specificity* rather than complicate calculations by taking the uncertainty in those estimates into account.

e) Sample size

The sample size required to meet the objectives of the survey is calculated to take the *population* size, the test performance, the confidence required and the design prevalence into account. As the *population* of each farm is relatively large, differences in the total *population* of each farm have little effect on the calculated sample size. The other parameters for sample size calculation are fixed across all farms. Therefore, a standard sample size (based on the use of this particular ELISA, in this *population*) is calculated. The sample size calculations are performed using the *FreeCalc* software[3]. Based on the parameters listed above, the sample size required is calculated to be 410 fish per farm. In addition, the program calculates that, given the imperfect *specificity*, it is still possible for the test to produce up to five false-positive reactors from an uninfected *population* using this sample size. The authorities are not comfortable with dealing with false-positive reactors, so it is decided to change the test system to include a confirmatory test for any positive reactors. Culture is selected as the most appropriate test, as it has a *specificity* that is considered to be 100%. However, its *sensitivity* is only 90% due to the difficulty of growing the organism.

As two tests are now being used, the performance of the test system must be calculated, and the sample size recalculated based on the test system performance.

Using this combination of tests (in which a sample is considered positive only if it tests positive to both tests), the *specificity* of the combined two tests can be calculated by the formula:

$$Sp_{Combined} = Sp_1 + Sp_2 - (Sp_1 \times Sp_2)$$

which produces a combined *specificity* of $1 + 0.994 - (1 \times 0.994) = 100\%$

The *sensitivity* may be calculated by the formula:

$$Se_{Combined} = Se_1 \times Se$$

which produces a combined *sensitivity* of $0.9 \times 0.98 = 88.2\%$

These new values are used to calculate the survey sample size yielding a result of 169 fish. It is worth noting that attempts to improve the performance of a test (in this case increase *specificity*) generally result in a decrease in the performance of the other aspect of the test performance (*sensitivity* in this example). However, in this case, the loss of *sensitivity* is more than compensated for by the decreased sample size due to the improved *specificity*.

It is also worth noting that, when using a test system with 100% *specificity*, the effective power of the survey will always be 100%, regardless of the figure used in the design. This is because it is not possible to make a Type II error, and conclude that the farm is infected when it is not.

A check of the impact of *population* size on the calculated sample size is worthwhile. The calculated sample size is based on an infinitely large *population*. If the *population* size is smaller, the impact on sample size is shown in the following table:

[3] FreeCalc – Cameron, AR. Software for the calculation of sample size and analysis of surveys to demonstrate freedom from disease. Available for free download from http://www.ausvet.com.au.

Annex XVIII (contd)

Annex III (contd)

Population size	Sample size
1000	157
2000	163
5000	166
10,000	169

Based on these calculations, it is clear that, for the *population* sizes under consideration, there is little effect on the sample size. For the sake of simplicity, a standard sample size of 169 is used, regardless of the number of grow-out fish on the farm.

f) Sampling

The selection of individual fish to include in the sample should be done in such a manner as to give the best chance of the sample being representative of the *study population*. A fuller description of how this may be achieved under different circumstances is provided in *Survey Toolbox*[4]. An example of a single farm will be used to illustrate some of the issues.

One farm has a total of eight tanks, four of which are used for grow-out. At the time of the survey (during winter), the four grow-out tanks have 1850, 4250, 4270 and 4880 fish, respectively, giving a total *population* of 15,250 grow-out fish.

Simple random sampling from this entire *population* is likely to produce sample sizes from each tank roughly in proportion to the number of fish in each tank. However, proportional stratified sampling will guarantee that each tank is represented in proportion. This simply involves dividing the sample size between tanks in proportion to their *population*. The first tank has 1850 fish out of a total of 15,250, representing 12.13%. Therefore 12.13% of the sample (21 fish) should be taken from the first tank. Using a similar approach the sample size for the other three tanks is 47, 47 and 54 fish, respectively.

Once the sample for each tank is determined, the problem remains as to how to select 21 fish from a tank of 1850 so that they are representative of the *population*. Several options exist.

i) If the fish can be handled individually, random systematic sampling may be used. ~~This is likely to be the case if, for example:~~ For example, samples can be collected at harvest or during routine management activities involving handling the fish (such as grading or vaccination).

- ~~fish are harvested during winter and samples can be collected at harvest; or~~
- ~~routine management activities involving handling the fish (such as grading or vaccination) are conducted during the winter.~~

If fish are handled, systematic sampling simply involves selecting a fish at regular intervals. For instance, to select 21 from 1850, the sampling interval should be 1850/21 = 88. This means that every 88th fish from the tank should be sampled. To ensure randomness, it is good practice to use a random number between 1 and 88 (in this case) to select the first fish (e.g. using a random number table), and then select every 88th fish after that.

[4] Survey Toolbox for Aquatic Animal Diseases – A Practical Manual and Software Package. Cameron A.R. (2002). Australian Centre for International Agricultural Research (ACIAR), Monograph No. 94, 375 pp. ISBN 1 86320 350 8. Printed version available from ACIAR (http://www.aciar.gov.au) Electronic version available for free download from http://www.ausvet.com.au.

ii) If fish cannot be handled individually (by far the most common, and more difficult, circumstance) then the fish to be sampled must be captured from the tanks. Fish should be captured in the most efficient and practical way possible, however every effort should be made to try to ensure that the sample is representative. In this example, a dip net is the normal method used for capturing fish. Using a dip net, convenience sampling would involve capturing 21 fish by repeatedly dipping at one spot and capturing the easiest fish (perhaps the smaller ones). This approach is strongly discouraged. One method of increasing the representativeness is to sample at different locations in the tank – some at one end, some at either side, some at the other end, some in the middle, some close to the edge. Additionally, if there are differences among the fish, an attempt should be made to capture fish in such a way as to give different groups of fish a chance of being caught (i.e. do not just try to catch the small ones, but include big ones as well).

This method of collecting a sample is far from the ideal of random sampling, but due to the practical difficulties of implementing random sampling of individual fish, this approach is acceptable, as long as the efforts made to increase the representativeness of the sample are both genuine and fully documented.

g) Testing

Specimens are collected, processed and tested according to standardised procedures developed under the certification programme and designed to meet the requirements of this *Aquatic Manual*. The testing protocol dictates that any specimens that test positive to ELISA be submitted for culture, and that any positive culture results indicate a true positive specimen (i.e. that the farm is not free from disease). It is important that this protocol be adhered to exactly. If a positive culture is found, then it is not acceptable to retest it, unless further testing is specified in the original testing protocol, and the impact of such testing accounted for in the test system *sensitivity* and *specificity* estimates (and therefore the sample size).

h) Analysis

If the calculated sample size of 169 is used, and no positive reactors are found, then the survey will have a confidence of 95%. This can be confirmed by analysing the results using the *FreeCalc* software mentioned above (which reports a confidence level of 95.06%).

It may happen in some cases that the survey is not conducted exactly as planned, and the actual sample size is less than the target sample size. However, the size of the farm may also be smaller. In these cases, it is advisable to analyse the farm data on a farm-by-farm basis. For example, if only 165 specimens were collected from a farm with only 2520 fish, the resulting confidence would still be 95%. If only 160 fish were collected, the confidence is only 94.5%. If a rigid target of 95% confidence is used, then this survey would fail to meet that target and more evidence would be required.

2. Example 2 – two-stage ~~structured~~ survey (national freedom)

a) Context

A country aims to declare freedom from Disease Y of crustaceans. The industry in this country is based largely on small-holder ponds, grouped closely together in and around villages. The disease is reasonably highly contagious, and causes mass mortality mid to late in the production cycle, with affected animals becoming moribund and dying in a matter of days. Affected animals

how few characteristic signs, but an infected pond will almost invariably break down with mass mortality unless harvested beforehand. It is more common in late summer, but can occur at any time of year. It also occurs occasionally early in the production cycle. In this country, there are some limitations to the availability of laboratory facilities and the transport infrastructure. However, there is a relatively large government structure, and a comprehensive network of fisheries officers.

b) Objective

The objective is to establish national freedom from Disease Y. The surveillance system must meet the requirements of this chapter, but must also be able to be practically implemented in this small-holder production system.

c) Approach

The aquaculture authorities decide to use a survey to gather evidence of freedom, using a two-stage survey design (sampling villages at the first level, and ponds at the second). Laboratory testing of specimens from a large number of farms is not considered feasible, so a combined test system is developed to minimise the need for expensive laboratory tests.

The *unit* of observation and analysis is, in this case, the pond, rather than the individual animal. This means that the diagnosis is being made at the pond level (an infected pond or a non-infected pond) rather than at the animal level.

The survey is therefore a survey to demonstrate that no villages are infected (using a random sample of villages and making a village-level diagnosis). The test used to make a village-level diagnosis is, in fact, another survey, this time to demonstrate that no ponds in the village are affected. A test is then performed at the pond level (farmer observation followed, if necessary, by further laboratory testing).

d) Survey standards

i) The confidence to be achieved by the survey is 95%. The power is set at 95% (but is likely to be virtually 100% if the test system used achieves nearly 100% *specificity*, as demonstrated in the previous example).

ii) The *target population* is all ponds stocked with shrimp in the country during the study period. The *study population* is the same, except that those remote areas to which access is not possible are excluded. As outbreaks can occur at any time of year, and at any stage of the production cycle, it is decided not to further refine the definition of the *population* to target a particular time or age.

iii) Three tests are used. The first is farmer observation, to determine if mass mortality is occurring in a particular pond. If a pond is positive to the first test (i.e. mass mortality is detected), a second test is applied. The second test used is polymerase chain reaction (PCR). Cases positive to PCR are further tested using transmission experiments.

iv) Farmer observation can be treated as a test just like any other. In this case, the observation of mass mortality is being used as a test for the presence of Disease Y. As there are a variety of other diseases that are capable of causing mass mortality, the test is not very specific. On the other hand, it is quite unusual for Disease Y to be present, and not result in mass mortality, so the test is quite sensitive. A standard *case definition* is established for

'mass mortality' (for instance, greater than 20% of the pond's *population* of shrimp observed dead in the space of less than 1week). Based on this definition, farmers are able to 'diagnose' each pond as having mass mortality. Some farmers may be over-sensitive and decide that mass mortality is occurring when only a small proportion of shrimp are found dead (false positives, leading to a decrease in *specificity*) while a small number of others fail to recognise the mortalities, decreasing *sensitivity*.

In order to quantify the *sensitivity* and *specificity* of farmer observation of mass mortalities, as a test for Disease Y, a separate study is carried out. This involves both a retrospective study of the number of mass mortality events in a *population* that is thought to be free from disease, as well as a study of farmers presented with a series of mortality scenarios, to assess their ability to accurately identify a pond with mass mortality. By combining these results, it is estimated that the *sensitivity* of farmer-reported mass mortalities as a test for Disease Y is 87% while the *specificity* is 68%.

v) When a farmer detects a pond with mass mortality, specimens are collected from moribund shrimp following a prescribed protocol. Tissue samples from 20 shrimp are collected, and pooled for PCR testing. In the laboratory, the ability of pooled PCR to identify a single infected animal in a pool of 20 has been studied, and the *sensitivity* of the procedure is 98.6%. A similar study of negative specimens has shown that positive results have occasionally occurred, probably due to laboratory contamination, but maybe also because of the presence of non-viable genetic material from another source (shrimp-based feed stuffs are suspected). The *specificity* is therefore estimated at 99%.

vi) Published studies in other countries have shown that the *sensitivity* of transmission tests, the third type of test to be used, is 95%, partly due to variability in the load of the agent in inoculated material. The *specificity* is agreed to be 100%.

vii) Based on these figures, the combined test system *sensitivity* and *specificity* are calculated using the formulae presented in Example 1, first with the first two tests, and then with the combined effect of the first two tests and the third test. The result is a *sensitivity* of 81.5% and a *specificity* of 100%.

viii) The design prevalence must be calculated at two levels. First, the pond-level design prevalence (the proportion of ponds in a village that would be infected if disease were present) is determined. In neighbouring infected countries, experience has shown that ponds in close contact with each other are quickly infected. It is unusual to observe an infected village with fewer than 20% of ponds infected. Conservatively, a design prevalence of 5% is used. The second value for design prevalence applies at the village level, or the proportion of infected villages that could be identified by the survey. As it is conceivable that the infection may persist in a local area without rapid spread to other parts of the country, a value of 1% is used. This is considered to be the lowest design prevalence value for which a survey can be practically designed.

ix) The population of villages in the country is 65,302, according to official government records. Those with shrimp ponds number 12,890, based on records maintained by the aquaculture authorities. These are generated through a five-yearly agricultural census, and updated annually based on reports of fisheries officers. There are no records available of the number of ponds in each of these villages.

Annex XVIII (contd)

Annex III (contd)

e) Sample size

Sample size is calculated for the two levels of sampling, first the number of villages to be sampled and then the number of ponds to be sampled. The number of villages to be sampled depends on the *sensitivity* and the *specificity* of the test used to classify villages as infected or not infected. As the 'test' used in each village is really just another survey, the *sensitivity* is equal to the confidence and the *specificity* is equal to the power of the village-level survey. It is possible to adjust both confidence and power by changing the sample size in the village survey (number of ponds examined), which means that we can determine, within certain limits, what *sensitivity* and *specificity* we achieve.

This allows a flexible approach to sample size calculation. If a smaller first-stage sample size is desired (a small number of villages), a high *sensitivity* and *specificity* are needed, which means that the number of ponds in each village that need to be examined is larger. A smaller number of ponds will result in lower *sensitivity* and *specificity*, requiring a larger number of villages. The approach to determining the optimal (least cost) combination of first- and second-stage sample sizes is described in *Survey Toolbox*.

A further complication is presented by the fact that each village has a different number of ponds. In order to achieve the same (or similar) confidence and power (*sensitivity* and *specificity*) for each village, a different sample size may be required. The authorities choose to produce a table of sample sizes for the number of ponds to sample in each village, based on the total ponds in each village.

An example of one possible approach to determining the sample size follows:

The target *sensitivity* (confidence) achieved by each village-level survey is 95%. The target *specificity* is 100%. Using the *FreeCalc* software, with a design prevalence of 1% (the survey is able to detect disease if 1% or more villages are infected), the first-stage sample size is calculated as 314 villages. Within each village, the test used is the combined test system described above with a *sensitivity* of 81.5% and a *specificity* of 100%. Based on these figures the following table is developed, listing the number of ponds that need to be sampled in order to achieve 95% *sensitivity*.

f) Sampling

First-stage sampling (selection of villages) is done using random numbers and a sampling frame based on the fisheries authorities list of villages with shrimp ponds. The villages are listed on a spreadsheet with each village numbered from 1 to 12,890. A random number table (such as that included in *Survey Toolbox*) or software designed for the generation of random numbers (such as EpiCalc[5]) is used.

5 http://www.myatt.demon.co.uk/epicalc.htm

Population	Sample size
30	29
40	39
60	47
80	52
100	55
120	57
140	59
160	61
180	62
200	63
220	64
240	64
260	65
280	65
300	66
320	66
340	67
360	67
380	67
400	67
420	68
440	68
460	68
480	68
500	68
1000	70

The second stage of sampling involves random selection of ponds within each village. This requires a sampling frame, or list of each pond in the village. The fisheries authorities use trained local fisheries officers to coordinate the survey. For each selected village, the officer visits the village and convenes a meeting of all shrimp farmers. At the meeting, they are asked how many ponds they have and a list of farmers' names and the number of ponds is compiled. A simple random sample of the appropriate number of ponds (between 29 and 70, from the table above, depending on the number of ponds in the village) is selected from this list. This is done either using software (such as *Survey Toolbox's Random Animal program*), or manually with a random number table or decimal dice for random number selection. Details of this process are described in *Survey Toolbox*. This selection process identifies a particular pond in terms of the name of the owner, and the sequence number amongst the ponds owned (e.g. Mr Smith's 3rd pond). Identification of the actual pond is based on the owners own numbering system for the ponds.

g) Testing

Once ponds have been identified, the actual survey consists of 'testing those ponds'. In practice, this involves the farmers observing the ponds during one complete production cycle. The local fisheries officer makes weekly visits to each farmer to check if any of the selected ponds have suffered mass mortality. If any are observed (i.e. the first test is positive), 20 moribund shrimp are collected for laboratory examination (first PCR, and then, if positive, transmission experiments).

h) Analysis

Analysis is performed in two stages. First, the results from each village are analysed to ensure that they meet the required level of confidence. If the target sample size is achieved (and only negative results obtained), the confidence should be 95% or greater in each village. At the second stage, the results from each village are analysed to provide a country level of confidence. Again, if the target sample size (number of villages) is achieved, this should exceed 95%.

3. Example 3. – spatial sampling and the use of tests with imperfect specificity

a) Context

A country has an oyster culture industry, based primarily on rack culture of oysters in 23 estuaries distributed along the coastline. In similar regions in other countries, Disease Z causes mortalities in late summer/early autumn. During an outbreak a high proportion of oysters are affected, however, it is suspected that the agent may be present at relatively low prevalence in the absence of disease outbreaks.

b) Objective

The national authorities wish to demonstrate national freedom from Disease Z. If the disease should be detected, a secondary objective of the survey is to collect adequate evidence to support zoning at the estuary level.

c) Approach

The authorities conclude that clinical surveillance for disease outbreaks is inadequate because of the possibility of low level subclinical infections. It is therefore decided to base surveillance on a ~~structured~~ two-stage survey, in which sampled oysters are subjected to laboratory testing. The first stage of the survey is the selection of estuaries. However, due to the objective of providing evidence for zoning (should disease be found in any of the estuaries), it is decided to use a census approach and sample every estuary. In essence this means that there will be 23 separate surveys, one for each estuary. A range of options for sampling oysters are considered, including sampling at harvest or marketing, or using farms (oyster leases) as a level of sampling or stratification. However the peak time of activity of the agent does not correspond to the harvest period, and the use of farms would exclude the significant numbers of wild oysters present in the estuaries. It is therefore decided to attempt to simulate simple random sampling from the entire oyster *population* in the estuary, using a spatial sampling approach.

d) Survey standards

i) The *target population* is all of the oysters in each of the estuaries. The *study population* is the oysters present during the peak disease-risk period in late summer early autumn. Wild and cultured oysters are both susceptible to disease, and may have associated with them different (but unknown) risks of infection. They are therefore both included in the *study population*. As will be described below, sampling is based on mapping. Therefore the *study population* can more accurately be described as that *population* falling within those mapped areas identified as oyster habitats.

ii) A design prevalence value is only required at the oyster level (as a census is being used at the estuary level). While the disease is often recognised with very high prevalence during outbreaks, a low value is used to account for the possibility of persistence of the agent in the absence of clinical signs. A value of 2% is selected.

iii) The test used is histopathology with immuno-staining techniques. This test is known to produce occasional false-positive results due to nonspecific staining, but is very sensitive. Published studies indicate values of 99.1% for *sensitivity* and 98.2% for *specificity*. No other practical tests are available. This means that it is not possible to definitively differentiate false positives from true positives, and that in a survey of any size, a few false positives are expected (i.e. 1.8%).

iv) The confidence is set at 95% and the power at 80%. In the previous examples, due to the assumed 100% *specificity* achieved by use of multiple tests, the effective power was 100%. In this case, with imperfect *specificity*, there will be a risk of falsely concluding that a healthy estuary is infected, so the power is not 100%. The choice of a relatively low figure (80%) means that there is a 1 in 5 chance of falsely calling an estuary infected when it is not infected, but it also dramatically decreases the survey costs, through a lower sample size.

e) Sample size

Based on the assumption that the sampling procedure will mimic simple random sampling, the sample size (number of oysters to sample per estuary) can be calculated with *FreeCalc*. The *population* size (number of oysters per estuary) is assumed to be very large. The calculated sample size, using the *sensitivity*, *specificity* and design prevalence figures given above, is 450. *FreeCalc* also reports that, based on this sample size and the *specificity* of the test, it is possible to get 10 or fewer false-positive test results, and still conclude that the *population* is free from disease. This is because, if the *population* were infected at 2% or greater, the anticipated number of positive reactors from a sample of 450 would be greater than 10. In fact, we would expect 9 true positives (450 × 2% × 99.1%) and 8 false positives (450 × 98% × 1.8%) or a total of 17 positives if the *population* were infected at a prevalence of 2%.

This illustrates how probability theory and adequate sample size can help differentiate between true- and false-positive results when there is no alternative but to use a test with imperfect *specificity*.

f) Sampling

The aim is to collect a sample of 450 oysters that represent an entire estuary. Simple random sampling depends on creating a sampling frame listing every oyster (not possible) and systematic sampling depends on being able to (at least conceptually) line up all the oysters (again, not possible). The authorities decide to use spatial sampling to approximate simple random sampling. Spatial sampling involves selecting random points (defined by coordinates), and then selecting oysters near the selected points. In order to avoid selecting many points with no oysters nearby, the estuary is first mapped (the fisheries authorities already have digital maps defining oyster leases available). To these maps areas with significant concentrations of wild oysters are also added, based on local expertise. Pairs of random numbers are generated such

Annex XVIII (contd)

Annex III (contd)

that the defined point falls within the defined oyster areas. Other schemes are considered (including using a rope marked at regular intervals, laid out on a lease to define a transect, and collecting an oyster adjacent to each mark on the rope) but the random coordinate approach is adopted.

Survey teams then visit each point by boat (using a GPS Global Positioning System unit to pinpoint the location). A range of approaches is available for selecting which oyster to select from a densely populated area, but it should involve some effort at randomness. Survey staff opt for a simple approach: when the GPS receiver indicates that the site has been reached, a pebble is tossed in the air and the oyster closest to the point where it lands is selected. Where oysters are arranged vertically (e.g. wild oysters growing up a post), a systematic approach is used to determine the depth of the oyster to select. First, an oyster at the surface, next, an oyster halfway down, and thirdly, an oyster as deep as can be reached from the boat.

This approach runs the risk of *bias* towards lightly populated areas, so an estimate of the relative density of oysters at each sampling point is used to weight the results (see *Survey Toolbox* for more details).

g) Testing

Specimens are collected, processed, and analysed following a standardised procedure. The results are classified as definitively positive (showing strong staining in a highly characteristic pattern, possibly with associated signs of tissue damage), probably positive (on the balance of probabilities, but less characteristic staining), and negative.

h) Analysis

The interpretation of the results when using a test with imperfect *specificity* is based on the assumption that, in order to conclude that the *population* is free from infection, any positive result identified is really a false positive. With a sample size of 450, up to 10 false positives may be expected while still concluding that the *population* is free from disease. However, if there is reasonable evidence that there is even a single true positive, then the *population* cannot be considered free. This is the reason for the classification of positive results into definitive and probable positives. If there are any definitive positives at all, the *population* in that estuary must be considered infected. The probable positives are consistent with false positives, and therefore up to 10 may be accepted. Using *FreeCalc* the actual confidence achieved based on the number of (presumed) false positives detected can be calculated. For instance, if 8 'probably positive' results were detected from an estuary, the confidence level for the survey would be 98.76%. On the other hand, if 15 'probably positive' results were detected, the confidence is only 61.9%, indicating that the estuary is likely to be infected.

i) Discussion

Normally, it may be safely assumed that a surveillance system aimed at demonstrating freedom from disease is 100% specific. This is because any suspected occurrence of disease is investigated until a definitive decision can be made. If the conclusion is that the case is truly a case of disease, then there is no issue of declaring freedom – the disease is known to be present. This example presents a different situation where, due to lack of suitable tests, it is not possible for the surveillance system to be 100% specific. This may represent an unusual situation in practice, but illustrates that methods exist for dealing with this sort of problem. In practice, a conclusion that a country (or estuary) is free from infection, in the face of a small (but statistically acceptable) number of positive results, will usually be backed up by further evidence (such as the absence of clinical disease).

Annex XVIII

Original: English
July 2008

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

Paris (France), 15–17 July 2008

The OIE *ad hoc* Group on Aquatic Animal Health Surveillance (hereinafter referred to as the *ad hoc* Group) met at the OIE Headquarters in Paris from 15 to 17 July 2008.

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

The Director General of the OIE, Dr Bernard Vallat welcomed all members and thanked them for their contribution to the OIE and for their work in the development of an OIE *Handbook on Aquatic Animal Health Surveillance*. Dr Vallat noted that the Handbook would make a valuable contribution towards improving aquatic animal health worldwide and would provide the first authoritative publication in the field of aquatic animal health surveillance and an important resource for OIE Members. He also congratulated Dr Barry Hill, the Chairperson of the *ad hoc* Group on his 20 years of active involvement in the work of the OIE.

Sarah Kahn, Head of the International Trade Department, reviewed the proposed schedule for the publication of the Handbook. Members of the *ad hoc* Group indicated they were on target to have the draft manuscript ready for peer review by 1 September. It was agreed that the OIE would approach external experts in aquatic animal health in several OIE regions and request that they undertake the peer review during September-October. The *ad hoc* Group will meet again in November to review comments and finalise the manuscript. The OIE Central Bureau will then prepare the manuscript for publication in early 2009.

Dr Barry Hill then took over as Chair of the meeting and acknowledged the large amount of work already done by the *ad hoc* Group and indicated that more work needed to be done at this meeting in order to meet the target to complete the draft manuscript by 1 September.

Annex XVIII (contd)

1. OIE Handbook on Aquatic Animal Health Surveillance

The *ad hoc* Group continued to develop the draft manuscript during this meeting. It was agreed that the manuscript could be finalised via electronic exchange before sending to experts for peer review on 1 September. The draft manuscript will also be sent to the Aquatic Animal Health Standards Commission for comment at their next meeting in October 2008. A final *ad hoc* Group meeting has been scheduled in November 2008 to consider peer reviewers' comments and to finalise the manuscript prior to scientific editing and publication.

.../Annexes

Annex I

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

Paris, 15–17July 2008

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Annex XVIII (contd)

Annex II

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

Paris, 15–17July 2008

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Adopted agenda

Welcome from Director General

1. OIE Handbook on Aquatic Animal Health Surveillance

Continue preparation of the manuscript for the OIE Handbook on Aquatic Animal Health Surveillance.

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Annex XIX

Original: English
August 2008

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

Paris, 27-29 August 2008

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Dr Sarah Kahn welcomed participants to the meeting on behalf of Dr Bernard Vallat, Director General of the OIE, who was out of the office at the time of the meeting. Dr Kahn thanked the experts for participating in the *ad hoc* Group and in particular Dr Frank Berthe for agreeing to chair the meeting and for providing a direct link to the Aquatic Animal Health Standards Commission (AAHSC). Dr Kahn explained, for the benefit of participants, the OIE procedures for standard setting and the anticipated handling of the *ad hoc* Group's report, which would be submitted to the AAHSC and subsequently circulated to OIE Members for comment.

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

Agenda Item 1 Adoption of the Agenda

After thanking Dr Kahn for her welcome, Dr Berthe took over the chairmanship of the meeting. The agenda was adopted as proposed. Dr Berthe recommended that the *ad hoc* Group focus, at this meeting, on aquatic animal products to which OIE Members had requested clarification as to risk.

It was agreed that issues related to the safety of disinfected fish eggs and invertebrate larvae (Agenda items 4 and 5) would be addressed as priorities because several OIE Members have submitted comments on these products.

Dr Berthe recommended that the *ad hoc* Group make recommendations identifying safe aquatic animal products where there is a scientific basis for this. In the case of aquatic animal products for which such a clear rationale for safety is lacking, Dr Berthe suggested that the *ad hoc* Group could recommend areas of investigation or research that would help to clarify how safe aquatic animal products might be defined.

Annex XIX (contd)

The *ad hoc* Group spent some time discussing the certification of aquatic animal products moving in international trade. Certification may be provided on the health status of the source population and/or on the processing applied to the product traded. The quality and reliability of certification is an important consideration and relates to the aquatic animal health services and infrastructure. Some OIE Members conduct formal assessments of the certification systems of exporting countries. Dr Kahn noted that the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) can be used to assess aquatic animal health services, including capacity and reliability to provide export certification.

Agenda Item 2 Discussion on Background Documents

Dr Berthe reminded members of the definition of commodities contained in the *Aquatic Animal Health Code* (hereafter refereed to as the *Aquatic Code),* which includes live animals of all life stages, as well as non-viable products of aquatic animals. Dr Berthe clarified that, for the purpose of this meeting, the *ad hoc* Group should focus on viable aquatic animal commodities (eggs, larvae, and other juvenile life forms) and on non-viable products derived from aquatic animals, including aquatic animal products for human consumption, for aquatic animal feed and for other purposes (e.g. leather produced from fish skin).

At Dr Berthe's request, Dr Kahn explained the background to the work of the *ad hoc* Group on terrestrial animal commodities, which met recently, and discussed some considerations that could be relevant to the work of this *ad hoc* Group.

Agenda Item 3 Items for Discussion

3.3. Identify gaps/inconsistencies and propose improvements in the Aquatic Code

The *ad hoc* Group reviewed the existing contents of the *Aquatic Code* as these relate to safe commodities and noted that the formulation of disease chapters varies. Article X.X.X.2., dealing with the scope of the chapter, lists the species that are considered to be susceptible to the disease agent in question. All other species, and their products, are then considered to be safe, except that there are provisions: 1) to take account of any additional species listed in the *Manual of Diagnostic Tests for Aquatic Animals* and 2) to conduct a risk analysis in the case of species 'which could reasonably be expected to be a potential mechanical vector' for the pathogen in question.

In some chapters (e.g. Chapter 2.2.1. Infection with *Bonamia ostreae*), the *Aquatic Code* lists species considered not to be susceptible (e.g. *Crassostrea gigas*) in point 1 of Article X.X.X.3.on commodities.

While it is not practical to list all the species that are not susceptible to each pathogen, the *ad hoc* Group agreed that the listing of species as 'non susceptible' could be useful to facilitate an understanding of certification requirements for species that have similar names and are traded under similar conditions (e.g. for *Ostrea* spp. and *Crassostrea* spp., where certification for *B. ostreae* would/would not be required respectively). However, where it is beneficial to list non-susceptible species, this should be addressed in the article on scope, not in the article on commodities.

Recommendations:

- The *ad hoc* Group recommended that the OIE check all the disease chapters and move the list of non-susceptible species in Article X.X.X.3. to the article on scope in the *Aquatic Code* when this situation occurs.

- In Article X.X.X.3. of disease chapters, 'biological samples preserved for diagnostic applications in such a manner as to inactivate the disease agent' are considered a safe commodity. The *ad hoc* Group agrees that such products are safe but recommended that the AAHSC develop a new article for inclusion in Chapter 1.5.6. that specifies fixation treatments.

3.1. Review the current status of international trade in aquatic animal products

The *ad hoc* Group briefly considered FAO reporting on global trade in aquaculture products but did not have time during the meeting to analyse this information in any detail. Globally there is an increasing production and trade in aquatic animal products. The volume of trade in aquatic animal products is significantly larger compared to live aquatic animals. The *ad hoc* Group noted there is a wide diversity in species and types of aquatic animal products.

Recommendations:

- The *ad hoc* Group recommended that the OIE seek further advice from FAO regarding the aquaculture products of greatest importance in terms of value and/or volume of global trade, with a view to giving direction on the aquatic animal products and commodities that should be the subject of additional recommendations from the OIE in future. The *ad hoc* Group also undertook to develop examples of trade trends in aquaculture products based on more specific information from one of the major exporting countries (Vietnam) and one of the major importing regions (the EU).

3.2. Develop a list of safe aquatic animal products for possible inclusion in the Aquatic Code

The *ad hoc* Group drafted a list of broad categories of aquatic animal commodities regardless of their respective risk status (excluding biological products and pathological material). The *ad hoc* Group recognised the large diversity of aquatic animal products traded and acknowledge that this list may not be exhaustive.

This list includes aquatic animal commodities derived from fish, molluscs, crustaceans and amphibians (refer to Annex III).

In all disease chapters, point 1 of Article X.X.X.3. lists aquatic animal commodities that can be traded irrespective of country disease status. The *ad hoc* Group developed criteria for assessing the safety of aquatic animal commodities. Those criteria are based on the absence of the disease agent in the traded commodity or inactivation of the disease agent by processing (refer to Annex IV).

The *ad hoc* Group evaluated the criteria using an example commodity/disease combination (i.e. fish oil / VHSV). After application of the criteria the conclusion was that fish oil (produced as outlined in Annex V) should be considered a safe commodity for all diseases (refer to Annex V). This example was developed to evaluate the criteria and show how they could be applied to assess safety of a specific commodity with regards to a given disease agent.

Recommendation:

- The *ad hoc* Group requested that the AAHSC approve these criteria (Annex IV) to be used for the evaluation of aquatic animal commodities to be listed in point 1 of Article X.X.X.3 for all disease chapters

In determining which processed aquatic animal products should be included in point 1 of Article X.X.X.3, the *ad hoc* Group realised it was necessary to define the aquatic animal product with sufficient precision, including the tissues included in the product and the processing that has been applied. Another important consideration is the extent to which commercial processing is conducted according to standardised processes. For commercial processes that are highly variable (e.g. different processes in different countries or regions), it will be necessary to specify the class of commercial product that would be covered by the provisions in point 1 of Article X.X.X.3.

The listing of commodities in point 1 of Article X.X.X.3. based on mitigation measures for human consumption are related to provisions of Article X.X.X.12. The *ad hoc* Group agreed that the current structure of the *Aquatic Code* could be modified in a way that would significantly clarify the text. With this in mind, the *ad hoc* Group proposed a modification of Article X.X.X.12 to be applied across all disease chapters (refer to Annex VI). The *ad hoc* Group also identified the need to amend other Articles (X.X.X.3. and X.X.X.9) to reflect the proposed changes (refer to Annex VI).

Recommendation:

- The *ad hoc* Group requested that the AAHSC approve this proposal.

The *ad hoc* Group developed criteria for assessing the safety of aquatic animal products destined for human consumption. Those criteria are based on the expected volume of waste and absence of the pathogen in the waste tissue (refer to Annex VII).

The *ad hoc* Group evaluated the criteria using a commodity/disease combination (ie eviscerated, head off fish/ SVCV). After application of the criteria the conclusion was that eviscerated, head off fish, packaged and prepared for retail trade should be included in *Article* 2.1.4.12 of the SVC chapter (refer to Annex VIII).

Recommendations:

- The *ad hoc* Group requested that the AAHSC approve these criteria for the evaluation of aquatic animal products destined for human consumption.
- On this basis the *ad hoc* Group recommended that the square brackets be removed from point 1 b) of Article 2.3.X.3. in all Crustacean disease chapters and that specific products be the subject of further assessment against the proposed criteria.

Agenda Item 4 Disinfected Fish Eggs

The *ad hoc* Group recognised that disinfection of salmonid eggs is well documented but not for other fish species. Therefore the *ad hoc* Group agreed to focus on diseases of salmonids. The *ad hoc* Group recognized there are no Guidelines for the disinfection of eggs in the current OIE Standards. The *ad hoc* Group recommended that the AAHSC addresses this issue.

The *ad hoc* Group recognises that disinfection of eggs will not prevent true vertical transmission. The Fish Egg Trade Report [6] does not clarify this issue for the 4 salmonid listed diseases (EHNV, IHNV, VHSV, ISAV). It was agreed that Dr Klotins will prepare some background documents for the next meeting of the *ad hoc* Group on this issue (criteria to assess the evidence for true vertical transmission, critical appraisal of scientific literature).

Recommendations:

- The *ad hoc* Group requested that the AAHSC address the lack of guidelines on disinfection of eggs in the OIE Standards.
- On the basis of this information, the *ad hoc* Group decided that more studies would be needed before it could recommend that disinfected fish eggs be considered as a safe commodity.

[6] Bovo G., T. Håstein, B. Hill, S. LaPatra, C. Michel, N.J. Olesen, I. Shchelkunov, A. Storset, T. Wolffrom, P.J. Midtlyng, 2005. Hazard identification for vertical transfer of fish disease agents. Fish Egg Trade (QLK2-CT-2002-01546) Work package 4 report, pp36.

Agenda Item 5 Larvae, spat and juvenile stages (molluscs and crustacea)

Mollusc larvae, spat and juvenile stages

Based on the criteria developed to assess the safety of aquatic animal commodities irrespective of country disease status (refer to Annex IV), mollusc larvae, spat and juvenile stages could not be considered as a safe commodity. While criterion 1a (i.e. absence of disease agent in the traded commodity) is satisfied (based on expert opinion), criterion 1b (i.e. water used to rear or process the commodity is not contaminated with the disease agent) could not be satisfied as the disease agent(s) could be present in the water and the processing could not be relied upon to prevent contamination of the final product.

Crustacean nauplii, zoeae and mysis

Based on the criteria developed to assess the safety of aquatic animal commodities irrespective of country disease status (refer to Annex IV), crustacean nauplii, zoea and mysis could not be considered as a safe commodity as neither criterion 1a nor 1b is satisfied.

Recommendations:

- The *ad hoc* Group recommended that point 1 of Article X.X.X.3. of the disease chapters for molluscs and crustacea remain unchanged.

3.4 Identify research needs to address specific key questions regarding the safety of certain aquatic animal products

The *ad hoc* Group discussed the question of data availability on the effect of processing conditions on pathogen load in aquatic animal products and recognized that there is likely to be limited information. Further assessment of aquatic animal products will highlight specific areas where further data are required.

.../Annexes

Annex I

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

Paris, 27-29 August 2008

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Adopted agenda

1. Adoption of the agenda

2. Background documents

2.1. Report of the OIE *ad hoc* Group on trade in animal products;

2.2. Devising import health measures for animal commodities;

2.3. Current recommendations in the *Aquatic Code* relevant to safe aquatic products including paragraphs under study and recent changes in Article 2.X.X.3.

3. Terms of Reference and main issues for discussion:

3.1. Review the current status of international trade of aquatic animal products.

3.2. Develop a list of safe products for possible inclusion in the relevant *Aquatic Code* chapters;

3.3. Identify gaps/inconsistencies and propose improvements in *Aquatic Code* Article on safe commodities (Article 2.X.X.3.);

3.4. Identify research needs to address specific key questions regarding the safety of certain aquatic animal products;

4. Disinfected fish eggs
- Determine whether should they be listed in Article 3 point 1a) of disease chapters.

5. Larvae, spat and juvenile stages
- Determine whether they should they be listed in Article 3 point 1a) of mollusc disease chapters.

6. Any other business

Annex II

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

Paris, 27-29 August 2008

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List of participants

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Annex III

BROAD CATEGORIES OF AQUATIC ANIMAL COMMODITIES

1. Live (fish, molluscs, crustaceans, amphibians):

Eggs (fertilized)
Eggs (unfertilized)
Sperm
Larvae for crustaceans: this includes nauplii, mysis and zoea
Larvae for mollusc: this includes all stages before settlement
Larvae for fish: (all stages before yolk sac absorption)
Larvae for amphibians: this includes all stages before legs and lungs
Juveniles
Adults

2. Dead:

FISH:
Fresh, chilled eviscerated
Fresh, chilled, head off, eviscerated
Fresh, chilled, head on, gills out, eviscerated
Fresh, chilled, partially eviscerated
Fresh, chilled uneviscerated
Fresh, chilled, head off, unviscerated
Fresh, chilled, head on, gills out, uneviscerated
Fresh chilled, headless, finless, skinless, uneviscerated/eviscerated
Fresh chilled, heads and spine
Fresh chilled, fillets/steaks/cutlet – bone/boneless; skin/skinless; fins/finless
Fresh chilled selected organs (e.g. liver, stomach, skin, swim bladder, roe)
Fresh chilled, without scales (such a product is traded)
Fresh chilled, fins
Frozen eviscerated
Frozen, head off, eviscerated
Frozen, head on, gills out, eviscerated
Frozen, partially eviscerated
Frozen uneviscerated
Frozen, head off, unviscerated
Frozen, head on, gills out, uneviscerated
Frozen headless, finless, skinless, uneviscerated/eviscerated
Frozen, heads and spine
Frozen, fillets/steaks/cutlet – bone/boneless; skin/skinless; fins/finless
Frozen selected organs (e.g. liver, stomach, skin, swim bladder, roe)
Frozen, without scales (such a product is traded)
Frozen, fins

Brains in oil (for injection into breeding fish)
Dried, with/without salt, eviscerated/uneviscerated, etc.
Semi-moist
Smoked eviscerated, etc.
Pickled, with salt, eviscerated, etc.
Marinated
Heat treated (cooked/canned/retort packaged/ready-to-eat/ pasteurised)
Cured

Annex XIX (contd)

Annex III (contd)

Salted
In brine
Fermented
Acidified products, i.e. without salt
Leather made from skin (http://www.freepatentsonline.com/4755186.html)
Fish meal (based on specific processing criteria)
Presscake (derived from fish oil/meal production)
Fish oil (based on specific processing criteria)

MOLLUSC
Chilled, frozen, off the shell (shucked)
Chilled, frozen, half shelled
Chilled, frozen, eviscerated (scallops, abalone)
Dried, with/without salt, eviscerated/uneviscerated, etc.
Semi-moist
Smoked
Pickled, with salt
Marinated
Heat treated (cooked/canned/ retort packaged/ready-to-eat/ pasteurised)
Curing
Salted
In brine
Fermented
Acidified products, ie without salt
Shells

CRUSTACEANS
Chilled, frozen, uneviscerated, shell on
Chilled, frozen, partially eviscerated
Chilled, frozen, deveined
Chilled/frozen peeled (with last shell segment and tail fans) - head, legs and shell removed
Chilled/frozen peeled - head, legs, shell and tail fans removed (also called “round” or “prawn meat)
Chilled/frozen - whole or partially peeled
Chilled/frozen - highly processed
Cooked

Dried, with/without salt, eviscerated/uneviscerated, etc.
Semi-moist
Smoked
Pickled, with salt
Marinated
Heat treated (cooked/canned/retort packaging/ready-to-eat/ pasteurised)
Curing
Salted
In brine
Fermented
Acidified products, i.e. without salt
Shells
Oil
Meal
Chemically extracted chitin (currently in Article 2.3.X.3 of the *Aquatic Code* chapters)

Annex XIX (contd)

Annex III (contd)

AMPHIBIANS

Chilled, frozen, skinned frog legs

Chilled, frozen, skinned meat/carcasses

Skin

Leather made from skin

Heat treated (cooked/canned/retort packaging/ready-to-eat?/ pasteurized?)

Dried

Fermented

Annex XIX (contd)

Annex IV

CRITERIA TO ASSESS THE SAFETY OF AN AQUATIC ANIMAL COMMODITY IRRESPECTIVE OF COUNTRY DISEASE STATUS

1. Absence of disease agent in the traded commodity:

   1a) There is strong evidence that the disease agent does not occur in the tissues from which the commodity is derived;

   AND

   1b) The water used to rear or process the commodity is not contaminated with the disease agent and the processing prevents cross contamination of the final product.

OR

2. Even if the disease agent does occur in the tissues from which the commodity was derived, the processing to produce the final commodity involves processes known to inactivate the disease agent:

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

   AND/OR

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

   AND/OR

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

Annex XIX (contd)

Annex V

EVALUATION OF THE CRITERIA TO ASSESS THE SAFETY OF AN AQUATIC ANIMAL COMMODITY IRRESPECTIVE OF COUNTRY DISEASE STATUS

Example: Fish oil derived from whole fish / all fish listed pathogens using VHSV as the initial example:

1. Absence of pathogen in the traded commodity:

   1a) There is strong evidence that the pathogen does not occur in the tissues from which the commodity is derived;

Assessment: No, virus occurs in multiple tissues in infected fish

AND

   1b) The water used to rear or process the commodity is not contaminated with the pathogen. The processing prevents cross contamination of the final product.

Assessment: No, if the fish are infected then the water is likely to be contaminated.

OR

2. Even if the pathogen does occur in the tissues from which the commodity was derived, the processing to produce the final commodity involves processes known to inactivate the pathogen

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

   AND/OR

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

   AND/OR

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

   AND

   2d) There is separation of inputs from final product to prevent cross contamination.

Assessment: Yes, during production fish oil and fish meal undergoes multiple heat treatments and the final water content of the product is extremely low.

Conclusion: Fish oil and fish meal are considered safe because of the multiple heat treatments undertaken during production and that the final water content of the product is extremely low.

Fish meal/oil production

Background

- derived from whole fish or by-products of processing
- majority produced by “wet pressing” method
- 1000 kg raw fish produces between 34 and 108 kg fish oil, depending on the oil content of the fish
- temperatures of 50°C sufficient to break down the cell membrane of lipocytes and release the oil
- temperatures of 75°C sufficient to coagulate the cell proteins.

Annex XIX (contd)

Annex V (contd)

Process

1. Raw material is cooked:
   1.1. Raw material may be pre-heated to 50-60°C before cooking (FAO).
   1.2. Traditionally at temperatures of 95-100°C for 15-20 minutes (FAO), or 20-30 minutes (EC).
   1.3. For energy cost reasons, and nutritional content some processors use 80-85°C for 20 minutes (Pers. comm., Skretting Australia).
2. Cooked material is pressed to produce press liquor and presscake (apologies …not "fishcake"). Presscake can be dried (75-80°C, =30 minutes) and milled to presscake meal.
3. Press liquor heated to 90-95°C (FAO) with steam for centrifugation, which produces oil and stickwater.
4. Oil is "polished" with hot water (at 90°C) and centrifugation to produce fish oil at 99-99.9% purity.
5. Stickwater is evaporated at =100°C (<130°C) and the fish solubles resulting added to presscake.
6. Presscake + fish soluble mix dried at 75-80°C (EC) or 80°C (FAO) for =30 minutes to reduce water content to =12%. This is then milled to whole fishmeal.

Fishmeal is used in the production of fish feed which involves:

1. preconditioning at 60-100°C for 3 minutes
2. extrusion at 120°C for 1 minute
3. drying (starting at 120°C and decreasing to 60°C) over 30 minutes.

References

Food and Agriculture Organization of the United Nations. (1986). The production of fishmeal and oil, FAO Fisheries Technical Papers T142, 63 pp.

European Commission. (2003). The use of fish by-products in aquaculture, European Commission Report of the Scientific Committee on Animal Health and Welfare, 93 pp.

Annex VI

REVISED ARTICLES 2.1.X.3. AND 2.1.X.9. AND ARTICLE 2.1.X.12. USING CHAPTER 2.1.4. USING SVC AS THE EXAMPLE CHAPTER

Article 2.1.4.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any SVC related conditions, regardless of the SVC status of the *exporting country*, *zone* or *compartment*:

   a) From the species referred to in Article 2.1.4.2. intended for any purpose:

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

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

   ~~b) The following *commodities* destined for human consumption from the species referred to in Article 2.1.4.2. which have been prepared and packaged for direct retail trade:~~

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

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

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

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

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.1.4.2., other than those referred to in point 1 of Article 2.1.4.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.1.4.7. to 2.1.4.12. relevant to the SVC status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation~~/~~ or transit of a *commodity* from an *exporting country*, *zone* or *compartment* not declared free of SVC ~~of a live *commodity*~~ from a species not covered in Article 2.1.4.2. but which could reasonably be expected to be a ~~potential~~ mechanical vector/fomite for SVC, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.4.9.

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

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

Annex XIX (contd)

Annex VI (contd)

1. the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.4.3., or products described in point 1 ~~2~~ of Article 2.1.4.12., or other products authorised by the *Competent Authority*; and

2. all effluent and waste material from the processing are treated in a manner that ensures inactivation of SVCV.

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

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

Article 2.1.4.12.

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

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

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

   ii) fillets or cutlets (chilled or frozen);

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

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

2. When importing *aquatic animal products*, other than those referred to in point 1. above, of the species referred to in Article 2.1.4.2. from a country, *zone* or *compartment* not declared free from SVC, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

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

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

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

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

Annex XIX (contd)

Annex VII

CRITERIA FOR ASSESSING AQUATIC ANIMAL PRODUCTS DESTINED FOR HUMAN CONSUMPTION WHICH HAVE BEEN PREPARED AND PACKAGED FOR DIRECT RETAIL TRADE:

1. Small amount of waste tissues;

   AND

2. The disease agent is unlikely to be present in the waste tissues.

   OR

3. If the disease agent does occur in the waste tissues, the processing to produce the final commodity involves processes known to inactivate and/or reduce the load of disease agent:

   3a) Physical (e.g. temperature, drying, smoking);

   AND/OR

   3b) Chemical (e.g. pH, salting, smoking);

   AND/OR

   3c) Biological (e.g. fermentation).

Annex XIX (contd)

Annex VIII

APPLICATION OF THE CRITERIA FOR ASSESSING AQUATIC ANIMAL PRODUCTS DESTINED FOR HUMAN CONSUMPTION WHICH HAVE BEEN PREPARED AND PACKAGED FOR DIRECT RETAIL TRADE.

Example: Eviscerated, head off carp infected with Spring Viremia of Carp Virus (SVCV)

1. Small amount of waste tissues;

Assessment: Yes, some waste is likely to be generated from a gutted, head-off fish carcass. This is likely to be the vertebral column, bones and possibly skin.

AND

2. The disease agent is unlikely to be present in the waste tissues.

Assessment: Uncooked bones or vertebral column are likely to carry a minimal amount of virus and can therefore be considered a relatively low risk waste product

OR

3. If the disease agent does occur in the waste tissues, the processing to produce the final commodity involves processes known to inactivate and/or reduce the load of disease agent:

   3a) Physical (e.g. temperature, drying, smoking);

   AND/OR

   3b) Chemical (e.g. pH, salting, smoking);

   AND/OR

   3c) Biological (e.g. fermentation).

Assessment: Yes 3a) The removal of tissues that would be expected to carry high amounts of virus from the fish carcass prior to importation will substantially reduce the risk of pathogen introduction. The carcass then consists largely of parts that are all likely to be heat treated in the process of preparation for human consumption. The risk associated with such carcasses is extremely low.

Conclusion: Eviscerated, head off carp destined for human consumption which have been prepared and packaged for direct retail trade is considered a product to trade carrying a negligible risk.

Annex XIX (contd)

Annex VIII (contd)

Technical Information:

Data on viral loads in various tissues of infected fish are available for most of the viral fish diseases listed by OIE. Data are usually available for internal organs (liver, spleen, kidney) and sometimes also for brain and gills. However, studies on virus load in the muscle tissue are sparse. Data on viral load in muscle tissue of SVCV-infected carp were not available for this example exercise. The example therefore carries a certain amount of uncertainty. Generally, viral infections in fish have a viremic stage, in which all tissues, including muscle tissue, can be expected to carry a viral load to some extent.

Table 1: Quantification of SVCV from various tissues[1]

	Type of infection	
Tissue	Natural[a]	Experimental[b]
Liver	6.5	6.8
Spleen	3.8	5.5
Intestine	ND	5.5
Kidney	5.8	5.2
Brain	4.3	4.5
Gills	3.5	ND

Infectivity expressed as exponents of $\log_{10}$ $TCID_{50}$/g; ND, no data.
[a] from Fijan et al. (1971); [b] from Ahne (1973); [1] from: Ken Wolf (1988)

Assuming the viral load in muscle tissue and skin is very low, a SVCV infected carp, from which:

- head (and therefore gills and brain) and
- internal organs (liver, spleen, kidney, intestines)

have been removed, is likely to carry a low load of virus in the eviscerated, head-off carcass.

Some waste is likely to be generated from a gutted, head-off fish carcass. This is likely to be:

- vertebral column
- Bones
- (possibly skin).

The above parts may or may not be removed prior to preparation for human consumption. Uncooked bones or vertebral column are likely to carry a minimal amount of virus and can therefore be considered a relatively low risk waste product. The further preparation for human consumption would under most circumstances include some kind of heat treatment step, which would be expected to reduce or remove any viable virus in the carcass.

It is worth noting that studies of viral concentrations in various fish tissues rarely include muscle tissue. Since muscle tissue is the body part most likely to be traded for human consumption, there is a need for studies to fill this important knowledge gap. This will allow a better assessment of the true risk associated with such commodities.

References:

AHNE W. (1973). Zellkulturen aus verschiedenen Süsswasserteleosteergeweben und Untersuchungen über die Ätiologie der Schwimmblasenentzündung der Karpfen. PhD thesis, Ludwig-Maximilians Universität, Munich.

FIJAN N., PETRINEC Z., SULIMANOVIC D. & ZWILLENBERG L. (1971). Isolation of the viral causative agent from the acute form of infectious dropsy of carp, *Veterinarski Arhiv.*, **41**, 125–138.

WOLF K. (1988). Fish viruses and fish viral diseases. Cornell University Press, Ithaca, NY.

Annex XX

Annex to OIE PVS Tool

Modifications in Approach when Evaluating the Pe rformance of Competent Authorities Responsible for Aquatic Animal Health

The OIE recommends the following modifications in approach when evaluating the performance of *Competent Authorities* responsible for aquatic animal health, using the OIE PVS Tool.

1. The evaluation team should have relevant general competence in aquatic animal health management and disease reporting.

2. The following chapters in the *Aquatic Code* provide the legal basis for the evaluation:

   Chapter 1.1.1 – Definitions

   Section 1.3. – Obligations and ethics in international trade

   Chapter 1.4.1 – Risk analysis, general considerations

   Chapter 1.4.2 – Import risk analysis

   Chapter 1.4.3 – Evaluation of Competent Authorities

   Chapter 1.4.4 – Zoning and compartmentalisation

   Sections 4.1. and 4.2 – Model health certificates

3. Where the responsible authority for aquatic animal health is not the *Veterinary Authority*, the term VS in the PVS tool should be read as "aquatic animal health services". Where the VS have the responsibility for aquatic animal health controls this is not necessary.

4. A modified approach should be taken to the assessment of the following PVS competencies when considering aquatic animal health systems:

   I-1 Professional and technical staffing of Veterinary Services

   The assessor should assess staffing levels and competencies at the various professional levels (e.g. veterinarians, other professionals, technical personnel).

   The term *veterinary para-professional* is not relevant to aquatic animal health systems.

   I-2 Competencies of veterinarians and veterinary para-professionals

   The evaluation of veterinary competence should include a special focus on the parts of the veterinary curriculum (if any) referring to aquatic animal health. Competence of other (university educated) professionals in aquatic animal health should be assessed in the same manner, identifying the relevant educational institutions and their curriculum.

   The term *veterinary para-professional* is not relevant to aquatic animal health systems.

   I-3 Continuing education (CE)

   For aquatic animal health personnel within the authority and for private aquatic animal health services the assessor should consider CE related to aquatic animal health in the same manner as for veterinarians. Such CE may be provided by the authority, the veterinary association or an animal health professional association.

Annex XX (contd)

I-6 Coordination capability of the sectors and institutions of the Veterinary Services (public and private)

Where there are separate aquatic and veterinary chains of command with relevance to aquatic animal health, the coordination and communication between the chains should be evaluated. Effective interaction between veterinary and non-veterinary chains of command is important to avoid uncertainty about responsibilities and functional gaps, which could lead to failure to meet the country's obligations towards the OIE.

II-1 Veterinary laboratory diagnosis

This competence should be read as 'aquatic animal health laboratory diagnosis'. The levels of competencies should be evaluated similarly to the assessment of veterinary diagnostic laboratories.

III-5 Veterinary Statutory Body

The activities of aquatic animal health professionals (non veterinary) may be regulated through formal professional approval, codes of ethics and authorizations for certain activities, e.g. to dispense medication to aquatic animals. Where such mechanisms exist, they should be evaluated similarly to the assessment of the Veterinary Statutory Body.

Annex XXI

AQUATIC ANIMALS COMMISSION WORK PLAN FOR 2009/2010

Aquatic Animal Health Code
• Ongoing review of the list of diseases • Review emerging diseases
• Finalise revised disease Chapter for Crayfish plague
• Prepare text for disease chapters for gaining and regaining freedom for compartments
• Harmonise horizontal chapters with those in the *Terrestrial Code*
• Develop text on surveillance for VHS as a model for other individual diseases
• Finalise new Aquatic Animal Health Model Certificates
• Finalise new chapter on Handling and disposal of carcasses and wastes of aquatic animals
• Prepare and finalise chapters on welfare for farmed fish (excluding ornamental species)
• Antimicrobial resistance in the field of aquatic animals – contribute to OIE work
• Identify commodities that can be considered safe for trade and be included in the *Aquatic Code*
• Consider development of text on trade in vaccinated fish
Manual of Diagnostic Tests for Aquatic Animals
• Update individual disease chapters using the new template
• Revise chapter on methods for disinfection
• Prepare disease chapters for amphibian diseases
• Prepare disease chapter for AVM complex
• Prepare disease chapters for Necrotising hepatopancreatitis and Milky haemolymph disease of spiny lobsters (*Panulirus* spp.), and the sabellid worm if listing of these diseases is adopted
• Revise introductory chapters for fish, mollusc, crustacean sections
Meetings
• Make presentations on the activities of the Aquatic Animals Commission at the conferences of the OIE Regional Commissions
• Be proactive in presenting the activities of the Aquatic Animals Commission at scientific conferences
Other issues
• Keep the Commission's web pages up to date
• Consider new candidates for OIE Reference Laboratories for listed diseases
• Provide input into the PVS to ensure its applicability to the evaluation of aquatic animal health systems
• Contribute to FAO/OIE Regional Aquatic Biosecurity Framework Project for Africa
• Provide input into the review of the OIE Handbook on Import Risk Analysis