EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Deputy Director–General

Brussels,
D1/PRM/rd(2007) D/412904

SANCO

22. 01. 2008

Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of Code Commission with reference to certain Chapters in the OIE Aquatic Animal Health Code. In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Report.

Thank you for the continued excellent collaboration and trust you will find our comments constructive and useful.

Vida Čadonič-Špelič
Chief Veterinary Officer

Paola Testori Coggi
Deputy *Director General*

Enclosures: 1

Copy: All CVOs Member States, Iceland, Norway, and Switzerland

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, dd.mm.2007
SANCO/10524rev3/2007
SEC(2007)

COMMISSION STAFF WORKING DOCUMENT

Written comments of the Community on the OIE Aquatic Animal Health Code following the Annual General Session 2007 and prior to the next Aquatic Animal Commission meeting March 2008.

EXPLANATORY MEMORANDUM

The OIE Aquatic Animal Health Standards Commission (AAC) met at the OIE Headquarters in Paris in October 2007.

These proposals for modifications are for eventual adoption or consideration at the next General Session in May 2008.

The Community comments need to reach the OIE Headquarters by 4 February 2008 in order to be considered at the next meeting of the Commission in March 2008.

The Commission therefore proposes to the Council to authorise the Commission to present to the OIE, as since 1995, the following written comments in the Annex before 4 February prior to the meeting referred to above. This is in order to allow the OIE to take the Community comments into account during their meeting in March, prior to submission of the final version at the General Session in May 2008. The cover letter to be sent with our response is attached at Annex A (Doc D/prm D1/2007/D/412904)).

In order to facilitate the examination of the comments of the Community, they have been incorporated in boxes into the OIE reports. In this context, the Community thanks the OIE for providing the electronic version of the Report.

UNION EUROPEENNE

Bruxelles, le
D(2007) prm D1/2007/D/xxx)

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

Original: English
October 2007

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

Paris, 1-5 October 2007

The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the "Aquatic Animals Commission") met at OIE headquarters from 1 to 5 October 2007.

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

Dr Eva-Maria Bernoth, President of the Aquatic Animals Commission, opened the meeting by reminding members of the extensive work programme for the meeting. Dr Sarah Kahn welcomed the Aquatic Animals Commission members on behalf of Dr Bernard Vallat, Director General, who was unable to attend the opening of the meeting. Dr Kahn conveyed the continuing appreciation of the OIE for the efforts of Aquatic Animals Commission members and the good progress being made in the work programme.

Dr Vallat joined the last day the Aquatic Animals Commission for a discussion of strategic priorities. Dr Vallat indicated that key priorities for the Aquatic Animals Commission include the harmonisation of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the "*Terrestrial Code*") and the OIE *Aquatic Animal Health Code* (hereafter referred to as the "*Aquatic Code*"), taking into account the current work to divide the *Terrestrial Code* into two volumes. In response to Dr Bernoth's update on progress in developing guidelines for aquatic animal welfare, Dr Vallat confirmed that this topic is sensitive and OIE Members will have diverse opinions. He indicated that the concept should be maintained, even if the recommendations are developed over a period of time. Dr Vallat underlined the importance of the *OIE PVS Tool* and procedures, and urged the Aquatic Animals Commission to include this as an important work priority. Finally, Dr Vallat reminded the Aquatic Animals Commission of current developments in the inspection of aquatic products for human consumption. In many countries, the official *Veterinary Services* are responsible for the inspection of aquatic products. Hazards to human health that may be associated with aquatic products include veterinary drug residues and microbial contamination, e.g. *Salmonella* spp. The Director General urged the Aquatic Animals Commission to involve itself in the OIE's work on critically important antimicrobials for use in aquaculture animals, perhaps via the establishment of an *ad hoc* Group, with support from the Scientific and Technical Department. The auditing of inspection systems for aquatic animals and their products is another area for attention.

The Aquatic Animals Commission recognised the contribution of the following Members in providing comments: Australia, Canada, European Union (EU), Japan, New Zealand, the United States of America; and the OIE Reference Laboratory for Infection with *Mikrocytos mackini*. The President expressed her disappointment at the low number of Members submitting comments and will address this point at the 76th General Session.

The outcome of the Aquatic Animals Commission's work is presented as Annexes III to XX to this report.

Members are invited to submit their comments to the OIE on Annexes III to XVII of this report **prior to 4 February 2008**. The comments should be sent **preferably by electronic mail** to the following address: **trade.dept@oie.int**. The Aquatic Animals Commission will address the comments received at its next meeting.

The table below summarises the texts – as presented in the Annexes – that are presented for Members' comment, with a view to proposing them for adoption to the OIE International Committee for adoption at the 76th General Session, depending on comments received (first part), and texts for Members' information (second part).

Community comment

The Community appreciates the efforts done by the OIE AAC with respect to submitting the report in a reasonable time after the AAC meeting.

However the Community expects that the OIE submits the outcome of the March 2008 meeting as soon as possible after the meeting, in order to allow EU member states to establish their position before the General Session in May 2008.

Annexes for Members' comments (deadline 4 February 2008)	**Annex number**
Definitions (Ch. 1.1.1.)	Annex III
Diseases listed by the OIE (Ch. 1.2.3.)	Annex IV
General obligations (Ch. 1.3.1.)	Annex V
Guidelines for import risk analysis (Ch 1.4.2.)	Annex VI
Recommendations for transport (Ch 1.5.1.)	Annex VII
Infectious myonecrosis (Ch 2.3.9.)	Annex VIII
White tail disease (Ch 2.3.11.)	Annex IX
Infection with *Mikrocytos mackini* (Ch. 2.2.5.)	Annex X
Gyrodactylosis (*Gyrodactylus salaris*)	Annex XI
Introduction to the OIE Guidelines for the Welfare of Live Aquatic Animals (Ch X.X.X.)	Annex XII
Guidelines on the control of aquatic animal health hazards in aquatic animal feed (Ch. X.X.X.)	Annex XIII
Infection with *Batrachochytrium dendrobatidis* (Ch. 2.4.1.)	Annex XIV
Infection with ranavirus (Ch. 2.4.2.)	Annex XV
Guidelines on the handling and disposal of carcasses and wastes of aquatic animals (Ch X.X.X.)	Annex XVI
Guidelines for aquatic animal health surveillance (Ch. X.X.X.)	Annex XVII
Annexes for Members' information	**Annex number**
Report of the *ad hoc* Group on Aquatic Animal Feeds	Annex XVIII
Report of the *ad hoc* Group on Amphibian Diseases	Annex XIX
Work Plan	Annex XX

1. Activities and progress of *ad hoc* Groups

The Aquatic Animals Commission noted the progress made in three *ad hoc* Groups and the President thanked the chairmen of these Groups (Dr Hill and Professor Katunguka-Rwakishaya) for their contributions. The outputs of these meetings are presented in items 2.2., 2.12, 2.13 and 6.2:

- *Ad hoc* Group on Aquatic Animal Health Surveillance, 18-20 July 2007

- *Ad hoc* group on Aquatic Animal Feeds, 29-31 August 2007

- *Ad hoc* group on Amphibian Diseases, 5-7 September 2007

2. ***Aquatic Animal Health Code* (the *Aquatic Code*)**

2.1. Definitions (Chapter 1.1.1.)

Community comment
The Community has strong reservations with the proposed definition of infestation. Please, see the comments in the specific chapter.

The Aquatic Animals Commission discussed comments from the United States of America on the definition of '*infestation*' and took into account the proposed definition in the *Terrestrial Animal Health Code* (the *Terrestrial Code*) of the term '*infection*'. The Aquatic Animals Commission decided to amend the definition as proposed by the United States of America. The Aquatic Animals Commission modified several other definitions, for example to take into account the inclusion of amphibians into the remit of the OIE and suggestions by the *ad hoc* Group on Aquatic Animal Health Surveillance, and to delete definitions of terms not subsequently used in the *Aquatic Code*. Amendments made during this meeting (October 2007) are shown in the usual manner as double underline and ~~strikeout~~.The amended chapter is at Annex III for Members' comment, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

The Aquatic Animals Commission discussed recommendations of an OIE expert on improving the consistency between the *Aquatic Code* and the *Terrestrial Code*. The Aquatic Animals Commission noted that a number of modifications are proposed to definitions in the *Terrestrial Code* and decided to await endorsement of these proposals by Members before considering changes to the definitions in the *Aquatic Code*.

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

Dr Hill presented disease listing assessments carried out by the *ad hoc* Group on Amphibian Diseases.

The *ad hoc* Group had concluded that two diseases of amphibians met the OIE listing criteria: infection with *Batrachochytrium dendrobatidis* and infection with ranavirus. The assessment is provided in Annex IV of the report of the *ad hoc* Group (see full report at Annex XIX for Members' information). The Aquatic Animals Commission agreed to propose those diseases for listing. The updated chapter on diseases listed by the OIE is at Annex IV for Members' comment, with a view to proposing it them to the International Committee for adoption at the 76th General Session in May 2008. Amendments made during this meeting (October 2007) are shown in the usual manner as double underline and ~~strikeout~~.

The Aquatic Animals Commission considered Australia's comments on abalone viral mortality and on abalone viral ganglioneuritis. Dr Berthe briefed the Aquatic Animals Commission on the complexity of these diseases and suggested that an *ad hoc* Group be convened to address all related matters. The Aquatic Animals Commission agreed with this recommendation. The Aquatic Animals Commission proposed that the Director General convene such an *ad hoc* Group. The Aquatic Animals Commission decided to refer Australia's comments to this *ad hoc* Group.

A re-assessment of the three crustacean diseases still under study, necrotising hepatopancreatitis (NHP), hepatopancreatic parvovirus disease (HPVD) and Mourilyan virus disease (MoVD), will be referred to the *ad hoc* Group for the Listing of Crustacean Diseases, together with Members' comments on NHP, HPVD and MoVD. The *ad hoc* Group will also review the currently listed diseases, spherical baculovirosis, and tetrahedral baculovirosis, as to whether they still meet the criteria for listing, which had previously been questioned by Thailand.

2.3. Obligations and ethics in international trade (Section 1.3.)

The Aquatic Animals Commission considered comments submitted by an OIE expert to improve consistency between the *Aquatic Code* and the *Terrestrial Code*. The Aquatic Animals Commission noted that the two Codes are consistent as regards the principle that trade measures should only be imposed in regard to diseases that do not occur in the importing country or, in the case of diseases that occur in importing country, for diseases that are the subject of official controls. The Aquatic Animals Commission noted that several of the expert's recommendations would need to await the completion of work on restructuring the *Terrestrial Code* into two volumes. Nonetheless, the Aquatic Animals Commission amended text in Section 1.3 for consistency with the *Terrestrial Code*. Amendments made during this meeting (October 2007) are shown in the usual manner as double underline and ~~strikeout~~. The amended text is at Annex V for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

2.4. Zoning and Compartmentalisation (Chapter 1.4.4.)

2.5. Aquatic animal health measures applicable before and at departure (Chapter 1.5.2.)

2.6. Aquatic animal health measures applicable on arrival (Chapter 1.5.5.)

For these three agenda items, the Aquatic Animals Commission considered comments of an OIE expert and recent work of the Terrestrial Commission on relevant *Terrestrial Code* Chapters (Chapter 1.3.5., Chapter 1.4.1., Chapter 1.4.4.). Given the changes proposed to the structure of the *Terrestrial Code*, the Aquatic Animals Commission decided to defer detailed consideration of these chapters until its next meeting.

2.7. Risk analysis: Guidelines for import risk analysis (Chapter 1.4.2.)

The Aquatic Animals Commission considered the comments provided by an OIE expert and modified Article 1.4.2.4. accordingly. Amendments made during this meeting (October 2007) are shown in the usual manner as double underline and ~~strikeout~~. The amended text is at Annex VI for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

2.8. Recommendations for transport (Chapter 1.5.1.)

Dr Keren Bar-Yaacov (OIE Delegate for Norway) joined the meeting for this item and informed the Aquatic Animals Commission of the background to the text, drafted by Norway, on biosecurity risks during transport of fish by sea. The Aquatic Animals Commission thanked Dr Bar-Yaacov for this very helpful contribution and, after modifying some points in the draft text, agreed that this draft chapter should be sent to Members for consideration. Amendments made during this meeting (October 2007) are shown in the usual manner as double underline and ~~strikeout~~. The amended text is at Annex VII for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

2.9. Disease chapters

Community comment

The Community would agree with the proposed chapters. However, we would like that the OIE takes the comments to the specific chapters into account.

There is an increased concern on how to deal with the imports of aquaculture animals vaccinated against some of the disease listed by the OIE such as Infectious salmon anaemia or Koi carp herpes virus.

To avoid trade disruptions ensuring at the same time a high level of protection, we would suggest to the OIE AAC to include in its working programme how to deal with the trade of aquaculture animals vaccinated against any of the currently listed diseases.

2.9.1. Members' comments on draft disease chapters

The Aquatic Animals Commission discussed at some length the issue of defining and re-establishing (after a breakdown) the disease free status of a compartment. The Aquatic Animals Commission noted the EU comments but have concerns that these comments only apply in the situation where the compartment is a specific establishment as opposed to

compartments comprising several establishments. The Aquatic Animals Commission was also concerned that the proposed text does not address the need to review the biosecurity plan to obtain an understanding of why the breakdown had occurred, and to rectify the fault(s). The Aquatic Animals Commission noted this is a difficult area, and Dr Hill will develop text for discussion at its next meeting.

The Aquatic Animals Commission considered a Member's comment on the packaging of processed products for retail trade. The International Committee had adopted this text in May 2007, to provide a specific recommendation towards reducing the risk that product destined for human consumption is diverted to higher-risk usage such as feed for aquaculture or bait for recreational fishing..

The Aquatic Animals Commission noted that Members' reservations about references in the *Aquatic Code* to publications of the International Council for the Exploration of the Seas (ICES) should be largely addressed via the establishment of an Agreement between the OIE and ICES (see item 8.3.).

The Aquatic Animals Commission discussed the provision that appears in several chapters of the *Aquatic Code*, to the effect that 'importing countries should consider imposing measures to ensure that imported products are used as intended' for purposes of risk management. The Aquatic Animals Commission agreed to amend 'should' to 'may wish to', for consistency with the *Terrestrial Code*. This change will be applied across all disease chapters in the *Aquatic Code* dealing with the concept of product use.

2.9.2. Infectious myonecrosis (Chapter 2.3.9.) and White tail disease (Chapter 2.3.11.)

The Aquatic Animals Commission accepted all amendments circulated in the March 2007 Report. Members' comments submitted by 6 August were taken into consideration and the texts amended as appropriate. Minor changes were made to ensure consistency with the other disease chapters adopted in May 2007. Amendments are shown in the usual manner as double underline and ~~strikeout~~. Amendments made at this meeting (October 2007) are shown with a coloured background to distinguish them from those made previously.

The amended texts are at Annexes XIII and IX for Members' comments, with a view to proposing them to the International Committee for adoption at the 76th General Session in May 2008.

2.9.3. Crayfish plague (Chapter 2.3.7.)

For this agenda item, the Aquatic Animals Commission was joined by Dr David Alderman, an OIE expert on crayfish plague. Dr Alderman had been provided with Members' comments on the draft chapter that had been circulated with the March 2007 report. The Aquatic Animals Commission discussed with Dr Alderman the difficulties in preparing recommendations for trade in species susceptible to this disease because of its different nature compared with other diseases. Dr Alderman undertook to prepare a revised version of the chapter, in consultation with other crayfish plague experts, in time for the March 2008 meeting of the Aquatic Animals Commission.

2.9.4. Infection with *Microcytos mackini* (Chapter 2.2.5.)

The Aquatic Animals Commission considered a comment from an OIE expert and amended the text accordingly. Minor changes were made to ensure consistency with other disease chapters adopted in May 2007. Amendments made during this meeting (October 2007) are shown in the usual manner as double underline and ~~strikeout.~~ The amended text is at Annex X for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

2.9.5. Gyrodactylosis (Chapter 2.1.14.)

The *ad hoc* Group on Fish Disease Chapters for the *Aquatic Code* had considered Members' comments and had proposed appropriate amendments to the text. The Aquatic Code Commission made further amendments at its meeting and the redrafted chapter is at Annex

XI for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

The Aquatic Animals Commission considered a Member's comment that Article 2.1.14.12. is irrelevant and invited the Member to justify this comment.

2.9.6. Draft chapters for amphibian diseases

See agenda item 2.13. below.

2.9.7. Harmonisation of disease chapters

To ensure consistency with other disease chapters, minor editorial changes that had been adopted at the 75th General Session in May 2007 will be applied to other relevant disease chapters in the 2008 *Aquatic Code*.

2.10. Draft appendices on aquatic animal welfare

Community comment

The Community looks forward to the outcome of the Aquatic Animals Commission work on the OIE Guidelines for the Welfare of Life Aquatic Animals. The Community also wishes to present specific drafting comments given in the amended text of the Introduction to the Guidelines.

The Aquatic Animals Commission expressed its gratitude to the Permanent Animal Welfare Working Group and Professor Håstein for their work in developing OIE Guidelines on the Welfare of Live Aquatic Animals. However, the Aquatic Animals Commission remained concerned that the scientific basis for the guidelines on farmed fish had not yet been clearly established. The Aquatic Animals Commission also considered that the guidelines, as drafted, were still too prescriptive in some places.

The Aquatic Animals Commission decided that the Introduction to the OIE Guidelines for the Welfare of Live Aquatic Animals, which was amended on the basis of Members' comments and the views of the Aquatic Animals Commission, should be distributed to Members' for comment. In the interim, one or more members of the Aquatic Animals Commission would continue working on the Guidelines.

The amended text of the Introduction to the Guidelines is at Annex XII for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

2.11. Antimicrobial resistance in the field of aquatic animals

Dr Tomoko Ishibashi, Deputy Director of the OIE Scientific and Technical Department, joined the Aquatic Animals Commission for this item. Dr Ishibashi provided an update on developments on this file. She explained that the fourth joint FAO/WHO/OIE Meeting on Critically Important Antimicrobials, to be held on 26 November 2007, will be an important forum to discuss the appropriate balance between animal health needs and public health concerns in the use of antimicrobial products. There will also be an associated stakeholder meeting. Dr Ishibashi identified the 15 experts selected to attend the joint meeting, noting that most of these experts are not involved in aquatic animal health. The Aquatic Animals Commission thanked Dr Ishibashi for this update and decided to keep the matter under review.

2.12. Report of the meeting of the *ad hoc* Group on Aquatic Animal Feeds

Professor Katunguka-Rwakishaya presented the report of the OIE *ad hoc* Group on Aquatic Animal Feeds, which met in August 2007 to address Members' comments on the previously circulated draft Guidelines on the Control of Aquatic Animal Health Hazards in Aquatic Animal Feed. The Aquatic Animals Commission thanked Professor Katunguka-Rwakishaya for chairing this Group and commended the report. The report of the *ad hoc* Group is at Annex XVIII for Members' information.

The amended Draft Guidelines on the Control of Aquatic Animal Health Hazards in Aquatic Animal Feed are presented at Annex XIII for Members' comments, with a view to proposing them to the International Committee for adoption at the 76th General Session in May 2008. Amendments made during this meeting (October 2007) are shown in the usual manner as double underline and ~~strikeout~~, in Annex XIIIa. Because these amendments also show the numerous editorial changes, a clean version is provided in the same Annex as XIIIb, for easier reading.

2.13. Report of the meeting of the *ad hoc* Group on Amphibian Diseases

Dr Hill presented the report of the OIE *ad hoc* Group on amphibian diseases, including the assessment of the responses provided by Members' to the OIE questionnaire on this topic. The *ad hoc* Group had concluded that the data in the returned questionnaire very significantly underestimated the current international trade in live amphibians and their products and considered it essential to obtain an accurate picture. The *ad hoc* Group also recommended publication of the data obtained to increase the awareness of Members' of the potential spread of amphibian diseases with this trade. The Aquatic Animal Commission agreed to this recommendation and asked the *ad hoc* Group to submit a draft publication to the Aquatic Animal Commission.

The *ad hoc* Group drafted disease chapters for the Aquatic Code (Chapter 2.4.1. Infection with *Batrachochytrium dendrobatidis* and Chapter 2.4.2. Infection with ranavirus) which are provided in Annexes V and VI of the report of the *ad hoc* Group (see full report at Annex XIX for Members' information). The Aquatic Animal Commission made minor changes to these draft disease chapters, primarily to make them consistent with other chapters in the *Aquatic Code*. The drafts chapters are at Annexes XIV and XV for Members' comments, with a view to propose them to the International Committee for adoption at the 76th General Session in May 2008.

Subsequent to its meeting the *ad hoc* Group had drafted disease cards for these two diseases for the Aquatic Animal Commission's comment, with a view to providing finalised versions in time for the Aquatic Animal Commission's March 2008 meeting. The Aquatic Animals Commission was grateful for this initiative and noted that, if these two diseases are listed in 2008, disease chapters for the *Aquatic Manu*al would also need to be prepared as soon as possible.

The Aquatic Animals Commission agreed to maintain the Model Certificates for Amphibians/Amphibian Products in the current format as drafted by the *ad hoc* Group, pending a review of Aquatic Animal Health Certificates (see item 2.14.).

The Aquatic Commission considered the question raised by the *ad hoc* Group of the disease risks associated with transport water and international trade in aquatic plants. The Aquatic Animals Commission considered that the disease risks associated with transport water had been adequately covered in Chapter 1.5.1. (Article 1.5.1.5.). International trade in aquatic plants is outside the mandate of the OIE.

The President of the Aquatic Animals Commission commended the work of this *ad hoc* Group and thanked Dr Hill for chairing the Group.

2.14. Model Veterinary Certificates

The Aquatic Animals Commission noted a progress report from the Terrestrial Commission regarding the ongoing work of the *ad hoc* Group on Model Veterinary Certificates. The Aquatic Animals Commission confirmed that it would review the Model Aquatic Animal Health Certificates once the terrestrial equivalent has been finalised.

2.15. Guidelines on handling and disposal of carcasses and wastes of aquatic animals

The Aquatic Animals Commission thanked Professor Katunguka-Rwakishaya for reviewing this topic and preparing the draft text, which has been reformatted by the International Trade Department. The revised text is at Annex XVI for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

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

3.1. Harmonising and updating the *Aquatic Code* and the *Terrestrial Code*

Dr Kahn represented Dr Thiermann, President of the Terrestrial Commission, who was unable to attend the meeting due to travel duty. Dr Bernoth noted the progress made towards harmonisation of the two Codes. She commented that further progress on the *Aquatic Code* should await the division of the *Terrestrial Code* into two volumes as this was likely to entail the revision of some horizontal chapters in the *Terrestrial Code.*

3.2. Performance, Vision and Strategy (PVS) Tool

Dr Bar-Yaacov joined the meeting for this item. She provided the background to the proposal to modify the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool) to address aquatic animal services. Dr Bar-Yaacov mentioned that she attended the July meeting of the *ad hoc* Group on the Evaluation of Veterinary Services, which has been responsible for the development of the PVS procedures. She advised the Aquatic Animals Commission that there were some general principles to bear in mind when using the OIE PVS Tool to assess aquatic animal health services.

Dr Bernoth thanked Dr Bar-Yaacov for her valuable input on this item. The Aquatic Animals Commission noted that the OIE has received a request for evaluation of aquatic animal health services. The Aquatic Animals Commission considered that the introduction to the OIE PVS Tool should be revised to provide scope for aquatic animals to be included in an evaluation and to identify the legal basis of such evaluation (i.e. *Aquatic Code* Chapters 1.4.3.). In addition, general principles should be identified and included in the OIE PVS Tool, to guide assessors on the use of the OIE PVS Tool in the context of evaluating an aquatic animal health system.

Dr Kahn indicated that the Central Bureau will revise the introduction to the OIE PVS Tool and provide an appropriate text for the Aquatic Animals Commission to consider at its next meeting. Dr Bar-Yaacov indicated that she would develop a short text on general principles for the Aquatic Animals Commission to consider at its next meeting. Dr Kahn indicated that Dr Bar-Yaacov would be invited to participate in future OIE activities on the PVS procedures, including the next meeting of the *ad hoc* Group on the Evaluation of Veterinary Services.

4. Joint meeting with the Publications Department

4.1. Dr Pastoret, Head of OIE Publications Department, and Ms Souryi, Deputy Head of OIE Publications Department, joined the Aquatic Animals Commission for an update on progress with the upcoming publication in the *OIE Scientific and Technical Review Series* on Changing Trends in Managing Aquatic Animal Disease Emergencies. This review is due for publication in April 2008.

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

Community Comment

Climate change may be an important factor in the occurrence, distribution and severity of aquatic animal diseases. We would encourage the OIE to set up an ad-hoc working group on this specific issue to asses the relevance of climate change to the full range of OIE programs and objectives.

5.1. International meetings

5.1.1. Regional Commission Conferences

Dr Enriquez, Secretary of the AAHSC, reported on his attendance at the Second Meeting of the Inter-American Committee on Aquatic Animal Health which was held in Vancouver (Canada) in June 2007 and which was organized by the OIE Regional Commission for the Americas in collaboration with Canada as host. He reported on the Technical Resolutions adopted by the International Committee regarding aquatic animal health during the last General Session. Dr. Enriquez provided summaries of the latest developments in the *Aquatic Code* and *Aquatic Manual*. Some horizontal changes have been made to all the disease chapters of the *Aquatic Code* to ensure consistency. He also informed the meeting of the decision of the International Committee to include amphibian diseases in the OIE remit.

The Members of the Regional Commission committee will sponsor translation of the *Aquatic Manual* into Spanish and provide the funds to do so. The OIE Regional Representation for the Americas will also try to provide funding for a Spanish translation, as soon as possible, of the preliminary English version of the Aquatic Animals Commission Reports.

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

- Regional Commission for the Middle-East (29 October-1 November 2007): Dr Hill, Vice-President of the Aquatic Animals Commission.
- Regional Commission for Asia, the Far East and Oceania (Queenstown, New Zealand, 26-30 November 2007): Dr Bernoth, President of the Aquatic Animals Commission.

5.1.2. Network of Aquaculture Centres in Asia-Pacific

Dr Bernoth will represent the Aquatic Animals Commission at the Sixth Annual General Meeting of NACA Asia Regional Advisory Group on Aquatic Animal Health, 12-14 December 2007, Bangkok, Thailand. She will report on progress and further development of the *Aquatic Code* and *Aquatic Manual* and other new initiatives of the Aquatic Animals Commission.

5.1.3. Other International Conferences

Dr Bernoth has been invited to present on the activities of the OIE in the field of aquatic animal health at the 29th World Veterinary Congress, 27-31 July 2008, Vancouver, British Columbia, Canada. Several members of the Aquatic Animals Commission will attend the 7th Symposium on Diseases in Asian Aquaculture, June 22-26, 2008, Chinese Taipei.

5.2. Cooperation with FAO

The OIE Central Bureau has received a request from the FAO Fisheries and Aquaculture Department to collaborate on a one year project in the seven countries covered by the Zambezi river system (Angola, Botswana, Malawi, Mozambique, Namibia, Zambia and Zimbabwe). The project

will increase the capacity of the key national government staff (decision makers and technicians) to undertake surveillance and to diagnose the disease, and will provide the necessary information and extension material to better inform the stakeholders of the risks and of the methods for preventing spread and particularly for how to avoid the introduction of the disease into fish farms. The project would also facilitate the elaboration of a regional emergency preparedness and response strategy related to aquatic health management.

The FAO are also looking at the opportunities for organising a training workshop on aquatic animal health and trade in Eastern Europe, in early 2008, as a component of an ongoing FAO Technical Cooperation Programme project in Bosnia and would like the OIE to participate in these activities and technically contribute to the process.

The Aquatic Animals Commission noted this project and workshop and will continue to work with the OIE Central Bureau to support further strengthening of the collaboration between OIE and FAO.

6. Manual of Diagnostic Tests for Aquatic Animals

Community Comment

The Community would like to thank to the OIE AAC the efforts to be carried out to update the chapters for some not listed diseases such as IPN, Piscirickettsiosis or Spawner-isolated mortality. However, Community considers it important that the OIE AAC includes in its working programme the update o the f the BKD chapter as well.

In addition, we would like to remind that the disinfection chapters in the Aquatic Manual must contain references to disinfestation, as most of listed mollusc diseases are infestations.

6.1. Update from the Consultant Editor

For this agenda item, the Aquatic Animals Commission was joined by Dr David Alderman, Consultant Editor of the *Aquatic Manual*. Dr Alderman briefed the Aquatic Animals Commission on the status of the next version of the *Aquatic Manual*. Since the previous meeting, he had introduced a section-numbering system into the template for the disease-specific chapters so that it is easier to cross refer to sections within a chapter. The Aquatic Animals Commission reviewed the template, compared it to the template developed by the *ad hoc* Group on Aquatic Animal Health Surveillance (see item 6.2 below), and inserted a few amendments. The new template will now be sent to all the authors, including authors of chapters that were not updated in the 2006 edition, with the request that they use it to update their chapters. It is hoped to receive all the updated chapters in the first quarter of 2008, so that they can be edited and sent to Members' for comment shortly after that date. The next edition of the *Aquatic Manual* is scheduled to be published in June/July 2009.

Since the 6th edition of the *Aquatic Manual* some diseases have been de-listed from Chapter 1.2.3. of the *Aquatic Code* and some Reference Laboratories and designated experts are no longer included in the list. The Aquatic Animals Commission is of the view that there is value in updating chapters for infectious pancreatic necrosis, piscirickettsiosis (*Piscirickettsia salmonis*) and spawner-isolated mortality virus disease in the *Aquatic Manual* and seeks nominations of experts from Members' for this purpose.

The current *Aquatic Manual* chapter on disinfection of aquaculture establishments is divided into three sections: one each for fish, mollusc and crustacean farms. This means that there is some repetition as the principles and some procedures are common to all three groups. Dr Alderman agreed to rearrange the chapter such that it begins with the general principles and procedures followed by specific procedures for fish, molluscs and crustaceans, e.g. fish eggs, crustacean broodstock, etc. Dr Alderman advised the Aquatic Animals Commission that he has made some

progress with what is a substantial task and he hoped to provide the Aquatic Animals Commission with a draft chapter by December 2007.

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

Community Comment

The Community would like to contribute to the development of the disease specific surveillance guidelines with its current surveillance schemes to obtain and maintain the freedom status with regard to VHS and INH. These guidelines can be found in Commission Decision 2001/183/EC *laying down the sampling plans and diagnostic methods for the detection and confirmation of certain fish diseases.* http://eur-lex.europa.eu/pri/en/oj/dat/2001/l_067/l_06720010309en00650076.pdf

Dr Hill presented the second progress report of the OIE *ad hoc* Group on Aquatic Animal Health Surveillance. The Aquatic Animal Commission reviewed the report and commends the *ad hoc* Group for the outstanding efforts that have been made in producing the guidelines on surveillance. The Aquatic Animals Commission examined in detail the proposed appendix on aquatic animal health surveillance for the *Aquatic Code* as well as the proposed guidelines for the *Aquatic Manual* (revision of chapter 1.1.4) prepared by the *ad hoc* Group. The Aquatic Animals Commission noted that the *Terrestrial Manual* does not provide guidelines on animal health surveillance but rather this information is provided in the *Terrestrial Code*. In line with harmonising terrestrial and aquatic standards, the Aquatic Animals Commission decided to merge the information on surveillance into one set of guidelines to be appended to the *Aquatic Code*. The draft text is at Annex XVII for Members' comments, with a view to proposing it to the International Committee for adoption at the 76th General Session in May 2008.

The Aquatic Animals Commission proposed the development of a practical handbook for aquatic animal health surveillance, using the substantial work done by the *ad hoc* Group as the basis for this publication. They suggested that the *ad hoc* Group work on this publication at their next meeting. The Central Bureau indicated the possible availability of an intern to assist in the preparation of this publication.

The Aquatic Animals Commission also reviewed the further development by the *ad hoc* Group of the specific disease chapter template of the *Aquatic Manual*. The *ad hoc* Group recommended that the scientific information necessary to develop appropriate surveillance programmes for the individual diseases be formulated and included in the *Aquatic Manual* chapters. The Aquatic Animals Commission noted the large amount of epidemiological data that would be required to complete the surveillance part of each disease chapter and concluded that this would be a major task and beyond the scope of the *Aquatic Manual* chapters. Because the guidelines on surveillance are now to be appended to the *Aquatic Code* (see above), the Aquatic Animals Commission decided to limit the disease chapters in the *Aquatic Manual* to diagnostic aspects as is the case in the *Terrestrial Manual*. Disease-specific surveillance chapters would be prepared as appendices to the *Aquatic Code* as is the case in the *Terrestrial Code*.

The Aquatic Animals Commission took note of the comments by the *ad hoc* Group that the development of guidelines for individual disease chapter authors to follow in specifying the surveillance requirements for individual diseases has also become a major task. The Aquatic Animals Commission clarified that those guidelines are no longer required for the authors of the disease chapters in the *Aquatic Manual* but rather for the individual disease surveillance chapters to be added to the *Aquatic Code* and encourages the *ad hoc* Group to develop these taking into account the approach taken in the *Terrestrial Code*.

7. OIE Reference Laboratories

The Aquatic Animals Commission had received an application for OIE Reference Laboratory status for abalone viral mortality. Because there are certain unresolved scientific issues regarding this disease complex, the Aquatic Animals Commission decided to await the outcome of the forthcoming meeting of

the *ad hoc* Group on Abalone diseases, to which the proposed expert would be invited to participate (see also item 2.2.).

Following the listing of infectious myonecrosis and white tail disease in May 2007, there is now a need for OIE Reference Laboratories for these two diseases. The Aquatic Animals Commission encourages interested countries to submit applications for OIE Reference Laboratory status through the OIE Delegate. The Aquatic Animals Commission also seeks applications for an OIE Reference Laboratory for viral haemorrhagic septicaemia in North America in view of the recent outbreaks of a new form of this disease in this region.

8. Any other business

8.1. Disease cards

The Aquatic Animals Commission acknowledged the comment from Chinese Taipei on the inconsistency between the disease card and the draft disease chapter in the *Aquatic Code* for white tail disease and will correct the disease card accordingly.

The Aquatic Animals Commission confirmed its proposition from March 2007 to have disease cards only for emerging and recently listed diseases for which there is not yet an *Aquatic Manual* chapter, and to discontinue the cards for all the other diseases. Cards for infectious myonecrosis and white tail disease, diseases that were adopted for listing at the General Session in May 2007, are thus available on the web. Cards for the proposed diseases of amphibians are being developed.

8.2. Update of the Aquatic Animals Commission web pages

Dr Hill presented the amended web pages and confirmed that all the information, including the disease list and links to national contingency plans and import risk analyses, is up to date.

8.3. Update on proposed OIE agreement with the International Council for the Exploration of the Seas (ICES)

The Aquatic Animals Commission noted a draft letter of agreement between the OIE and International Council for the Exploration of the Seas (ICES). The Aquatic Animals Commission endorsed this agreement.

8.4. Review of the Aquatic Animals Commission work plan for 2007-2008

The Aquatic Animals Commission reviewed its work plan for the remainder of 2007 and 2008. The updated work plan is at Annex XX for Members' information

9. Date for next meeting

The Aquatic Animals Commission proposed to meet on 3-7 March 2008.

.../Annexes

Annex I

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 1-5 October 2007

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Annex II

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 1-5 October 2007

Adopted Agenda

1. **Activities and progress of *ad hoc* Groups**

2. ***Aquatic Animal Health Code***

   2.1. Definitions (Chapter 1.1.1.)

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

   2.3. Obligations and ethics in international trade (Chapter 1.3.1.)

   2.4. Zoning and compartmentalisation (Chapter 1.4.4.)

   2.5. Aquatic animal health measures applicable before and at departure (Chapter 1.5.2.)

   2.6. Aquatic animal health measures applicable on arrival (Chapter 1.5.5.)

   2.7. Risk analysis – Guidelines for import risk analysis (Chapter 1.4.2.)

   2.8. Recommendations for transport (Chapter 1.5.1.)

   2.9. Disease chapters

   2.10. Draft appendices on aquatic animal welfare

   2.11. Antimicrobial resistance in the field of aquatic animals

   2.12. Report of the meeting of the *ad hoc* Group on Aquatic Animal Feeds

   2.13. Report of the meeting of the *ad hoc* Group on Amphibian Diseases

   2.14. Model veterinary certificates

   2.15. Guidelines on handling and disposal of carcasses and wastes of aquatic animals

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

   3.1. Harmonising and updating the *Aquatic Code* and the *Terrestrial Code*

   3.2. Performance, Vision and Strategy (PVS) tool

4. **Joint meeting with the Publications Department**

   4.1. OIE *Scientific and Technical Review*: Issue on managing aquatic animal disease emergencies

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

   5.1. International meetings

      5.1.1. Regional Commissions Conferences

      5.1.2. Other meetings

   5.2. Cooperation with FAO

6. ***Manual of Diagnostic Tests for Aquatic Animals***

   6.1. Update from the Consultant Editor

   6.2. Report of the *Ad hoc* Group on Surveillance: Revision of chapters for the *Aquatic Code* and *Manual*

7. **OIE Reference Laboratories**

8. **Any other business**

   8.1. Disease cards

   8.2. Update of the Commission's web pages

   8.3. Update on proposed OIE agreement with the International Council for the Exploration of the Seas (ICES)

   8.4. Review of the Aquatic Animals Commission's work plan for 2007-2008

9. **Date of the next meeting**

Annex III

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1.

Community comment

The Community has strong reservations with the proposed definitions, especially with the proposed definition of infestation. If this definition is to be changed the definition of susceptible species, infection and disease should be as well subjected to discussion.

In addition, in this report, the term "vector" is used without a clear definition of what is meant by vector. A definition of vector is needed. The Community would propose the following definition:

Vector: means a species that is not susceptible to a disease but which is capable of spreading infection by conveying pathogens from one host to another.

Aquatic animals

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

~~*Area of direct transit*~~

~~means a special area established in a transit country approved by the relevant Competent Authority where aquatic animals stay for a very short time, and where water changes may be made, before further transport to their final destination when passing through the transit territory.~~

Bias

A tendency of an estimate to differ in a non-random fashion from the true value of a population parameter.

Case definition

A case definition is a set of criteria used to distinguish a case animal or *epidemiological unit* from a non-case.

Infestation

means the presence ~~in sufficient numbers of a multiplying~~ of a notifiable parasitic~~,~~ or commensal~~,~~ agent on or in a host ~~a host so as to cause damage or *disease*~~.

Community comment: Proposed definition for "Infestation".

The proposed definition supposes a major change compared to the current one as it removes the reference to the multiplication of the parasite. We would like that the OIE provides a clear explanation of the rationale of such an amendment. Otherwise, the Community would not accept the proposed new definition.

In addition, such major amendment cannot only be done in the definition of infestation. If the explanation to be provided is satisfactory, the amendment should be done in the definition of infection.

Moreover, if this definition is accepted in the General Session 2008, the definition of susceptible species and the list of susceptible species to each listed disease would be challenged.

The Community would propose the following definition for infestation:

"Means the presence of a multiplying parasitic agent on or in aquatic animals"

~~***Offal***~~

~~means visceral organs, cut-offs, condemned raw material, organs, etc. of aquatic animals.~~

Outbreak of disease

An outbreak is a substantial increase in the ~~means an~~ occurrence of *disease* ~~in an aquatic animal~~ above the expected level at a given time in a given population.

Community comment: proposed definition for "outbreak of disease"

We would retain our previous comment: in our view this is not the definition of an outbreak. This is the definition of an epidemic. Please, consider the definition laid down in the Terrestrial Code for outbreak of disease "occurrence of one or more *cases* of a *disease* in an *epidemiological unit*"

Probability sampling

A sampling strategy in which every unit has a known non-zero probability of inclusion in the sample.

Sensitivity

the proportion of true positive tests given in a diagnostic test, i.e. the number of true positive results divided by the number of true positive and false negative results.

Specificity

the probability that absence of infection will be correctly identified by a diagnostic test, i.e. the number of true negative results divided by the number of true negative and false positive results.

Study population

The population from which surveillance data are derived. This may be the same as the target population or a subset of it.

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Annex IV

CHAPTER 1.2.3.

DISEASES LISTED BY THE OIE

Community comment
The Community agrees with the proposed amendments

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 viral mortality [1].

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]

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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1. Listed according to Article 1.2.2.2.

2. Listing of this disease is under study.

— text deleted

Annex V

CHAPTER 1.3.1.

GENERAL OBLIGATIONS

Community comment

The Community agrees with the proposed amendments but would like that the OIE AAC takes into account its comments.

Article 1.3.1.1.

International trade in *aquatic animals* and *aquatic animal products* depends on a combination of health factors that should be taken into account to ensure unimpeded trade, without incurring unacceptable *risks* to human and *aquatic animal* health. ~~As a general principle, *international trade* in *aquatic animals* and their *products* from populations known to be infected with a *listed disease* and considered to be capable of transmitting the *disease* should only be done with the prior agreement of the *importing* and *exporting countries*.~~

Because of 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 Member ~~Countries~~ 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 Part 4. of the *Aquatic Code*.

Certification requirements should be exact and concise, and should clearly convey the wishes 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 signing veterinarian or other *certifying official* can, if necessary, be given a note of guidance explaining the understanding between the *Competent Authorities* involved.

When 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.

Community comment

For the sake of harmonisation with the Terrestrial Code, it would be necessary to add the following paragraph as point 4 of this article:

"The international veterinary certificate should not include requirements for disease agents or diseases 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"

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 the national level of protection. *Importing countries* should restrict their requirements to those justified for such level of protection. If these are more strict 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 pathogens or *aquatic animal diseases* that are present within the *territory* of the *importing country* and are not subject to any official control programme. The requirements applying to pathogens 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 pathogens or *diseases* by the measures applied within that country, or *zone*.

3. 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*.

Article 1.3.1.3.

Community comment

We do not understand the rationale to remove paragraph 1 f). We consider that the information on the nature of biological test and vaccines used in a country is a key element when assessing the epidemiological situation of the exporting country.

Responsibilities of the exporting country

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

   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*~~ referred to in this *Aquatic Code* including the regulations and procedures in force to maintain its free status;

   b) regular and prompt information on the occurrence of ~~transmissible listed~~ *diseases* referred to in this *Aquatic Code*;

   c) for diseases not ~~listed~~ referred to in this *Aquatic Code*, if there are new findings that are of potential epidemiological significance to other countries;

   d) details of the country's ability to apply measures to control and prevent ~~*OIE-listed diseases*~~ referred to in this *Aquatic Code*;

   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 national *territory*;~~

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

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

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

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

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

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

Article 1.3.1.4.

Community comment

As the incubation period of the listed diseases is not described in the Aquatic Code, we would kindly suggest to the OIE either:

-Either to define the recognised incubation period for each listed disease

-or to slightly modify the wording in the 2nd paragraph, replacing the reference to recognised incubation period of the disease by "reasonable period"

Responsibilities in case of an incident occurring after importation

International trade involves a continuing ethical responsibility. Therefore, if within a reasonable period ~~the recognised *infective periods* of the various *diseases*~~ 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 *Authority* to notify the *importing country*, so that the imported *aquatic animals* may be inspected or tested and appropriate action be taken to limit the spread of the *disease* should it have been inadvertently introduced.

Equally, if a *disease* condition appears in imported *aquatic animals* within a time period after importation consistent with the recognised *incubation period* of the *disease*, 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.*

In case of suspicion, on reasonable grounds, that an official 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 certificate is found to be fraudulent, every effort should be made to identify those responsible so that appropriate action can be taken according to the relevant legislation.

— text deleted

Annex VI

CHAPTER 1.4.2.

GUIDELINES FOR IMPORT RISK ANALYSIS

Community comment
The Community agrees with the proposed amendments

Article 1.4.2.1.

Introduction

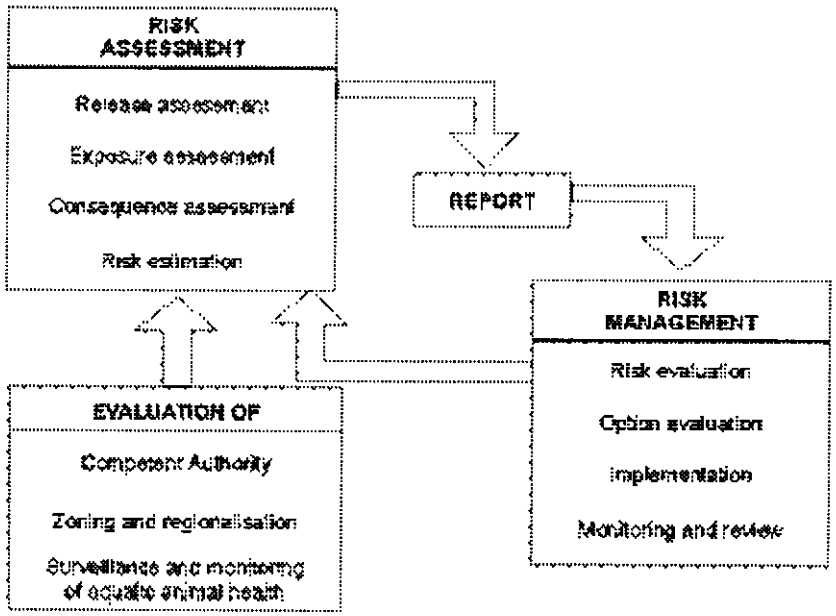
An import risk analysis begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It must be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the risk estimate, it may not be readily available, particularly where such trade is new.

Hazard identification is an essential step that must be conducted before the *risk assessment.*

The *risk assessment* process consists of four interrelated steps. These steps clarify the stages of the *risk assessment,* describing them in terms of the events necessary for the identified potential *risk(s)* to occur, and facilitate understanding and evaluation of the conclusions (or 'outputs'). The product is the *risk assessment* report, which is used in *risk communication* and *risk management.*

The relationships between *risk assessment and risk management processes* are outlined in Figure 1.

Fig. 1. ***The relationship between risk assessment and risk management processes***



Article 1.4.2.2.

Hazard identification

Hazard identification involves identifying the pathogenic agents that could potentially produce adverse consequences associated with the importation of a *commodity*.

The *hazards* identified would be those appropriate to the species being imported, or from which the *commodity* is derived, and which may be present in the *exporting country*. It is then necessary to identify whether each *hazard* is already present in the *importing country*, and whether it is an *OIE-listed disease* or is subject to control or eradication in that country and to ensure that import measures are not more trade restrictive than those applied within the country.

Hazard identification is a categorisation step, identifying biological agents dichotomously as *hazards* or not *hazards*. The *risk assessment* should be concluded if *hazard identification* fails to identify *hazards* associated with the importation.

The evaluation of the *Competent Authorities*, surveillance and control programmes, and *zoning* and regionalisation systems are important inputs for assessing the likelihood of *hazards* being present in the *aquatic animal*population of the *exporting country*.

An *importing country* may decide to permit the importation using the appropriate sanitary standards recommended in the *Aquatic Code*, thus eliminating the need for a *risk assessment*.

Article 1.4.2.3.

Principles of risk assessment

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

2. Both *qualitative* and *quantitative* risk assessment methods are valid. Although quantitative analysis is recognised to provide deeper insights into a particular problem, qualitative methods may be more relevant when available data are limited as is often the case with aquatic species.

3. The *risk assessment* should be based on the best available information that is in accord with current scientific thinking. The assessment should be well documented and supported with references to the scientific literature and other sources, including expert opinion.

4. Consistency in *risk assessment* methods should be encouraged and *transparency* is essential in order to ensure fairness and rationality, consistency in decision making and ease of understanding by all the interested parties.

5. *Risk assessments* should document the *uncertainties*, the assumptions made, and the effect of these on the final *risk* estimate.

6. *Risk* increases with increasing volume of *commodity* imported.

7. The *risk assessment* should be amenable to updating when additional information becomes available.Annex VI (contd)

Article 1.4.2.4.

Risk assessment steps

1. Release assessment

Release assessment consists of describing the biological pathway(s) necessary for an importation activity to 'release' (that is, introduce) a *hazard* into a particular environment, and estimating the likelihood of that complete process occurring. The release assessment describes the likelihood of the 'release' of each of the *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures. Examples of the kind of inputs that may be required in the release assessment are:

a) Biological factors

- Species, strain or genotype, and age of *aquatic animal*
- Strain of agent
- Tissue sites of infection and/or contamination
- Vaccination, testing, treatment and quarantine.

b) Country factors

- Incidence/prevalence
- Evaluation of *Competent Authorities,* surveillance and control programmes, and *zoning* systems of the *exporting country.*

c) Commodity factors

- Whether the *commodity* is alive or dead
- Quantity of *commodity* to be imported
- Ease of contamination
- Effect of the various processing methods on the pathogenic agent in the *commodity*
- Effect of storage and transport on the pathogenic agent in the *commodity.*

If the release assessment demonstrates no significant *risk*, the *risk assessment* does not need continue.

2. Exposure assessment

Exposure assessment consists of describing the biological pathway(s) necessary for exposure of humans and aquatic and terrestrial animals in the *importing country* to the *hazards* and estimating the likelihood of these exposure(s) occurring~~, and of the spread or establishment of the *hazard*~~.

Annex VI (contd)

The likelihood of exposure to the *hazards is* estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure, and the number, species and other characteristics of the human, *aquatic animal* or terrestrial animal populations exposed. Examples of the kind of inputs that may be required in the exposure assessment are:

a) Biological factors

- Presence of potential vectors or intermediate hosts
- Genotype of host
- Properties of the agent (e.g. virulence, pathogenicity and survival parameters).

b) Country factors

- *Aquatic animal* demographics (e.g. presence of known susceptible and carrier species, distribution)
- Human and terrestrial animal demographics (e.g. possibility of scavengers, presence of piscivorous birds)
- Customs and cultural practices
- Geographical and environmental characteristics (e.g. hydrographic data, temperature ranges, water courses).

c) Commodity factors

- Whether the *commodity* is alive or dead
- Quantity of *commodity* to be imported
- Intended use of the imported *aquatic animals* or *products* (e.g. domestic consumption, restocking, incorporation in or use as *aquaculture* feed or bait)
- Waste disposal practices.

If the exposure assessment demonstrates no significant *risk*, the *risk assessment* should conclude at this step.

3. Consequence assessment

Consequence assessment consists of identifying the potential biological, environmental and economic consequences. A causal process must exist by which exposures to a *hazard* result in adverse health, environmental or socio-economic consequences. Examples of consequences include:

a) Direct consequences

- *Aquatic animal infection, disease,* production losses and facility closures

- Adverse, and possibly irreversible, consequences to the environment
- Public health consequences. Annex VI (contd)

b) Indirect consequences

- Surveillance and control costs
- Compensation costs
- Potential trade losses
- Adverse consumer reaction.

4. Risk estimation

Risk estimation consists of integrating the results of the release assessment, exposure assessment, and consequence assessment to produce overall measures of *risks* associated with the *hazards* identified at the outset. Thus risk estimation takes into account the whole of the *risk* pathway from *hazard* identified to unwanted outcome.

For a quantitative assessment, the final outputs may include:

- The various populations of *aquatic animals* and/or estimated numbers of *aquaculture establishments* or people likely to experience health impacts of various degrees of severity over time
- Probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates
- Portrayal of the variance of all model inputs
- A sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output
- Analysis of the dependence and correlation between model inputs.

Article 1.4.2.5.

Principles of risk management

1. *Risk management* is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage *risk* appropriately to ensure that a balance is achieved between a country's desire to minimise the likelihood or frequency of *disease* incursions and their consequences and its desire to import *commodities* and fulfil its obligations under international trade agreements.

2. The international standards of the OIE are the preferred choice of *sanitary measures* for *risk management*. The application of these *sanitary measures* should be in accordance with the intentions of the standards or other recommendations of the SPS Agreement.

Article 1.4.2.6.

Risk management components

1. Risk evaluation - the process of comparing the *risk* estimated in the *risk assessment* with the Member's appropriate level of protection.

2. Option evaluation - the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the *risk* associated with an importation in line with the Member's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood and/or magnitude of adverse health and economic consequences. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the *risk assessment* and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses n technical, operational and economic factors affecting the implementation of the *risk management* options.

3. Implementation - the process of following through with the *risk management* decision and ensuring hat the *risk management* measures are in place.

4. Monitoring and review - the ongoing process by which the *risk management* measures are continuously audited to ensure that they are achieving the results intended.

Article 1.4.2.7.

Principles of risk communication

1. *Risk communication* is the process by which information and opinions regarding *hazards* and *risks* are gathered from potentially affected and interested parties during a *risk analysis,* and by which the results of the *risk assessment* and proposed *risk management* measures are communicated to the decision makers and interested parties in the *importing* and *exporting countries.* It is a multidimensional and iterative process and should ideally begin at the start of the *risk analysis* process and continue throughout.

2. A *risk communication* strategy should be put in place at the start of each *risk analysis.*

3. The *communication of risk* should be an open, interactive, iterative and transparent exchange of information that may continue after the decision on importation.

4. The principal participants in *risk communication* include the authorities in the *exporting country* and other stakeholders such as domestic aquaculturists, recreational and commercial fishermen, conservation and wildlife groups, consumer groups, and domestic and foreign industry groups.

5. The assumptions and *uncertainty* in the model, model inputs and the risk estimates of the *risk assessment* should be communicated.

6. Peer review of *risk analyses* is an essential component of *risk communication* for obtaining a scientific critique aimed at ensuring that the data, information, methods and assumptions are the best available.

— text deleted

Annex VII

CHAPTER 1.5.1.

RECOMMENDATIONS FOR TRANSPORT

Community comment

The Community agrees with the proposed amendments.

However, we would encourage the AAC to draft a specific chapter addressing the specific characteristics of the transport by land.

Finally, the Community reiterates its previous comment:

There are some references in this chapter to welfare. This chapter addresses the transport of aquatic animals including some invertebrates. Is it the intention of of the OIE AAC to draft guidelines on invertebrates' welfare? In our opinion, the title and scope of this appendix should be clarified.

Article 1.5.1.1.

Community comment

This chapter is on "Recommendations for transport". They may be used as a valuable reference when implementing measures related to transport. However, they cannot be made compulsory in all countries. We would propose to remove point 1 of this article or to replace it by the following:

1 These arrangements should be used as guidelines when member countries introduce measures to control the aquatic animal health risks related to the transport of these aquatic animals.

General arrangements

1. These arrangements should be compulsory in all countries either by legislative or regulatory texts and methods of application should be described in a manual available to all concerned.

2. *Vehicles* (or *containers*) used for the *transport* of *aquatic animals* shall be designed, constructed and fitted in such a way as to withstand the weight of the *aquatic animals* and water and to ensure their safety and welfare during *transportation. Vehicles* shall be thoroughly cleansed and disinfected before use according to the guidelines given in the *Aquatic Code.*

3. *Vehicles* (or *containers*) in which *aquatic animals* are confined during *transport* by sea or by air shall be secured to maintain optimal conditions for the *aquatic animals* during *transport*, and to allow easy access by the attendant.

Article 1.5.1.2.

Particular arrangements for containers

1. The construction of *containers* intended for *transportation* of *aquatic animals* shall be such that the accidental release of water, etc., is prevented during *transport.*

2. In the case of the *transportation* of *aquatic animals*, provision shall be made to enable preliminary observation of the contents of *containers.*

3. *Containers* in transit in which there are *aquatic animal products* shall not be opened unless the *Competent Authorities* of the *transit country* consider it necessary. If this is the case, *containers* shall be subject to precautions to prevent contamination.

4. *Containers* shall be loaded only with one kind of product or, at least, with products not susceptible to contamination by one another.

5. It rests with each country to decide on the facilities it requires for the *transport* and importation of *aquatic animals* and *aquatic animal products* in *containers*.

Article 1.5.1.3.

Particular arrangements for the transport of aquatic animals by air

1. The stocking densities for the *transport* of *aquatic animals* in *containers* should be determined by taking the following into consideration when transporting by air:

   a) the total volume of available space for each type of *aquatic animal*;

   b) the oxygenation capacity available to supply the *containers* while on the ground and during all stages of the flight.

With regard to fish, molluscs and crustaceans, the space reserved for each *aquatic animal* species in *containers* that have been fitted for the separate *transportation* of several *aquatic animals* or for the *transportation* of groups of *aquatic animals* should comply with acceptable densities specified for the species in question.

2. The OIE approved International Air Transport Association (IATA) Regulations for live animals may be adopted if they do not conflict with national legislative arrangements. (Copies of these Regulations are obtainable from the International Air Transport Association, 800 Place Victoria, P.O. Box 113, Montreal, Quebec H4Z 1M1, Canada.)

Article 1.5.1.4.

Disinfection and other sanitary measures

1. *Disinfection* and all zoo-sanitary work should be carried out in order to:

   a) avoid all unjustified inconvenience and to prevent damage or injury to the health of people and *aquatic animals*;

   b) avoid damage to the structure of the *vehicle* or its appliances;

   c) prevent, as far as possible, any damage to *aquatic animal products*.

2. On request, the *Competent Authority* shall issue the transporters with a certificate indicating the measures that have been applied to all *vehicles*, the parts of the *vehicle* that have been treated, the methods used and the reasons that led to the application of the measures.

   In the case of aircraft, the certificate may be replaced, on request, by an entry in the General Declaration of the aircraft.

3. Likewise, the *Competent Authority* shall issue on request:

a) a certificate showing the date of arrival and departure of the *aquatic animals*;

b) a certificate to the shipper or exporter, the consignee and transporter or their representatives, indicating the measures applied.

Article 1.5.1.5.

Treatment of transportation water

Water to be used for *transportation* of *aquatic animals* should be appropriately treated after transport and/or before discharge in order to minimise the *risk* of transferring pathogens. The specific recommendations are provided in the chapter of the *Aquatic Code* on disinfection.

During *transportation* of *aquatic animals*, the transporter should not be permitted to evacuate and replace the water in the transport tanks except on specifically designated sites in the national *territory*. The waste and rinsing water should not be emptied into a drainage system that is directly connected to an aquatic environment where *aquatic animals* are present. The water from the tanks should therefore either be disinfected by a recognised process (for example, 50 mg iodine or chlorine/litre for one hour), or sprayed over land that does not directly drain into waters containing *aquatic animals*. Each country shall designate the sites in their national *territories* where these operations can be carried out.

~~This Article does not apply to treatment of transport water for transport by sea.~~

Article 1.5.1.6.

Discharge of infected material

The *Competent Authority* shall take all practical measures to prevent the discharge of any untreated infective material, including transport water, into internal or territorial waters.

~~This Article does not apply to transport of *aquatic animals* by sea.~~

Article 1.5.1.7.

Particular arrangements for the transport of aquatic animals by well boat

A well boat is boat with integrated tanks to carry live fish in sea water that may operate with open valves to allow exchange of sea water. Therefore, well boats can present a biosecurity risk if the fish being carried are infected. Well boats are inherently difficult to disinfect.

1. Only healthy fish showing no clinical signs of disease on the day of loading should be transported. The well boat must have the capability of full containment of fish during its operation if so required. The stocking densities should be determined by taking both the total volume of available space for each species of fish and the oxygenation/aeration capacity available to supply the fish during all stages of transport into consideration.

2. In exceptional circumstances fish may be transported by well boat from an infected site if this is part of a disease response plan agreed to by the *Competent Authority*.

3. Provision shall be made to enable preliminary observation of the contents in the well, and monitoring equipment should be available where appropriate.

4. Access by farm staff to the vessel and from the vessel to the farm cages, including the equipment, should be restricted.

5. Well boats shall be loaded with only one type of fish at a time.

6. Well boats may operate with open valves except in designated areas in proximity to aquaculture establishments or areas with protected wild populations. The *Competent Authority* should designate the areas based upon a risk assessment.

7. Multiple deliveries of fish during the same trip should be avoided. Where unavoidable the order of deliveries should be made to the youngest year class of fish first, taking into account health status. Deliveries should be made to sites of a higher health status first, to a single aquaculture establishment, or establishments of the same health status.

8. In the event of mortality occurring during transport, a contingency plan capable of dealing with full containment and disposal of dead fish, via an approved disposal method, should be available. This plan should be prepared according to the Guidelines on handling and disposal of carcasses and wastes of aquatic animals [in preparation].

9. Well boats should not operate in adverse inclement weather conditions that may force the operation to divert from the agreed route and schedule of transport.

Annex VII (contd)

10. The well boat should be cleaned and where required disinfected to an acceptable standard before re-use. The level of disinfection should be proportional to the risk. Well boats should maintain a disinfection checklist which should be kept with the ship's log and should be open to audit. It is essential to ensure that all fish are removed from the system before cleaning. All organic matter should be removed through the process of cleaning before disinfection commences. The general principles and specific recommendations as outlined in the Aquatic Manual should be consulted for guidance.

11. When travelling between areas and zones of different health levels, cleaning and if required disinfection procedures should be followed and implemented to a standard approved by the *Competent Authority*.

— text deleted

Annex VIII

CHAPTER 2.3.9.

INFECTIOUS MYONECROSIS

Community comment

The Community agrees with the proposed amendments.

However, we would like that the OIE takes the following comments into account.

Article 2.3.9.1.

For the purposes of the *Aquatic Code*, infectious myonecrosis (IMN) means *infection* with infectious myonecrosis virus (IMNV). This virus is similar to members of the family *Totiviridae.*

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

Article 2.3.9.2.

Community comment

Two separate lists of susceptible species, one in the Code (susceptible species) and one in the Manual (other susceptible species) is misleading, as they create, in fact, two categories of susceptible species.

For the sake of clarity, we would kindly suggest to the OIE to include all susceptible species to this specific infection in this article.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp (*Penaeus vannamei*). 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 2.3.9.3.

Community comment

Litra b) should also cover dead animals intended for human consumption since there are other risk mitigation measures included in this provision namely: its intended use for human consumption, packed for direct retail trade, which implies that the likelihood of getting in contact with natural waters is very low, and finally that they will not be intended for further processing, avoiding the possible risk of spreading the disease through the effluents of the processing plants.

Before introducing the concept of vector, as it is mentioned in point 3 it is completely necessary to define what Member Countries should understand with this term.

Commodities

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

a) For the species referred to in Article 2.3.9.2. intended ~~being used~~ for any purpose:

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

~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

iii) chemically extracted chitin;

~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

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

iv~~i~~) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~IMNV~~ (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 2.3.9.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

Annex VIII (contd)

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~.

~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.~~

For the *commodities* listed in point 1b), Members ~~should~~ 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 the *commodities* of a species referred to in Article 2.3.9.2., other than those listed in point 1 of Article 2.3.9.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.9.7. to 2.3.9.11. relevant to the IMN 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 IMN of ~~any other~~ *commodity* of a species not covered in Article 2.3.9.2. but which could reasonably be expected to be a potential IMNV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of IMNV, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.9.4.

Infectious myonecrosis free country

A country may make a *self-declaration of freedom* from IMN 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 IMN if all the areas covered by the shared water are declared IMN free countries or *zones* (see

Article 2.3.9.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.9.2. is present may make a *self-declaration of freedom* from IMN 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 2.3.9.2. are present but there has ~~never~~ been no ~~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 make a *self-declaration of freedom* from IMN 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~~, for example~~ (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 IMN when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of IMNV.

OR

4. A country that has previously made a *self-declaration of freedom* from IMN but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from IMN again ~~until~~ 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IMNV; 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 ~~they~~ such part meets the conditions in point 3 of Article 2.3.9.5.

Article 2.3.9.5.

Infectious myonecrosis free zone or free compartment

Community comment
The Community would suggest to the OIE to reconsider its position as regards the issue of defining and re-establishing (after a breakdown) the disease free status of a compartment.

We would argue that for certain compartments, formed by a single establishment, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and, where appropriate fallowed, and finally restocked with aquatic animals from a certified free source.

The Community would suggest including a new point 5 in this article that would read:

" a compartment previously declared free from infectious myonecrosis but in which the disease is detected may not be declared free from that disease until the following conditions have been met:

a) the requirements in point 4, or

b) in the case that the compartment is formed by one single farm and it is supplied by water from a spring, borehole or other safe supply independent of the heath status of the surrounding waters and it is equipped with a barrier that prevents the migration of aquatic animals of susceptible species into the compartments or its water supply:

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures have been completed and followed, when necessary, by fallowing

ii) the compartment is repopulated with aquatic animals from a certified free population.

A *zone* or *compartment* within the *territory* of one or more countries not declared free from IMN 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 IMN 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 2.3.9.2. is present may be declared free from IMN 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 2.3.9.2. 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 IMN 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~~, for example~~ 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 IMN when:

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

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of IMNV.

OR

4. A *zone* previously declared free from IMN but in which the *disease* is subsequently detected may ~~not~~ be declared free from IMN again ~~until~~ 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IMNV; 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 2.3.9.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from IMN following the provisions of points 1 or 2 of Articles 2.3.9.4. or 2.3.9.5. (as relevant) may maintain its status as IMN free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from IMN following the provisions of point 3 of Articles 2.3.9.4. or 2.3.9.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as IMN free provided that conditions that are conducive to clinical expression of IMN, 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 IMN, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.9.7.

Importation of live aquatic animals from a country, zone or compartment declared free from infectious myonecrosis

When importing live *aquatic animals* of species referred to in Article 2.3.9.2. from a country, *zone* or *compartment* declared free from IMN, 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 2.3.9.4. or 2.3.9.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from IMN.

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 2.3.9.3.

Article 2.3.9.8.

Community comment

The scope of this article is unclear as there is no definition of what is meant by "new stock". Does it mean an introduction of a non-native species in a country? Further clarification is needed.

In addition, we would repeat that if the OIE AAC intention is to include a reference to the ICES Code such reference should be made to the whole ICES CODE, as a short summary might be misleading. One possible solution would be to include the web link to the whole ICES document in point 3 of this article.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.9.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first-generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of IMNV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ 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 ~~Guidelines~~ Code 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 IMNV, 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 IMNV and perform general examinations for pests and general health/*disease* status;

   g) if IMNV 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 IMN free or specific pathogen free (SPF) for IMNV;

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 2.3.9.3.

Annex VIII (contd)

Article 2.3.9.9.

Community comment
In point 1, the possible processing of the live aquatic animals is not foreseen. We would suggest to the OIE to add this option. The new proposed text would read:
1. the consignment be delivered directly to and held in isolation until processing and /or consumption; and

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

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.9.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

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

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

Members ~~should~~ 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 2.3.9.3.

Article 2.3.9.10.

Importation of aquatic animal products from a country, zone or compartment declared free from infectious myonecrosis

When importing *aquatic animal products* of species referred to in Article 2.3.9.2. from a country, *zone* or *compartment* declared free from IMN, 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 2.3.9.4. or 2.3.9.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IMN.

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 2.3.9.3.

Article 2.3.9.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from infectious myonecrosis

When importing *aquatic animal products* of species referred to in Article 2.3.9.2. from a country, *zone* or *compartment* not declared free from IMN, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.9.3.

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— text deleted

Annex IX

CHAPTER 2.3.11.

WHITE TAIL DISEASE

Community comment

The Community agrees with the proposed amendments.

However, we would like that the OIE takes the following comments into account.

Article 2.3.11.1.

For the purposes of the *Aquatic Code*, white tail disease (WTD) means *infection* with macrobrachium nodavirus (MrNV). This virus has yet to be formally classified.

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

Article 2.3.11.2.

Community comment

Two separate lists of susceptible species, one in the Code (susceptible species) and one in the Manual (other susceptible species) is misleading, as they create, in fact, two categories of susceptible species.

For the sake of clarity, we would kindly suggest to the OIE to include all susceptible species to this specific infection in this article.

Scope

The recommendations in this Chapter apply to: the giant fresh water prawn (*Macrobrachium rosenbergii*). Other common names 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 2.3.11.3.

Community comment

Litra b) should also cover dead animals intended for human consumption since there are other risk mitigation measures included in this provision such as: its intended use for human consumption, packed for direct retail trade, which implies that the likelihood of getting in contact with natural waters is very low, and finally that they will not be intended for further processing avoiding the possible risk of spreading the disease through the effluents of the processing plants.

Before introducing the concept of vector, as it is mentioned in point 3 it is completely necessary to define what Member Countries should understand with this term.

Commodities

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

   a) For the species referred to in Article 2.3.11.2. intended ~~being used~~ for any purpose:

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

~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

iii) chemically extracted chitin;

~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

iiiv) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

ivi) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~MrNV~~ (e.g. formalin or alcohol preserved samples).

b) The following products destined for human consumption from species referred to in Article 2.3.11.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

Annex IX (contd)

i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~

~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.~~

For the *commodities* listed in point 1b), Members ~~should~~ 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 the *commodities* of a species referred to in Article 2.3.11.2., other than those listed in point 1 of Article 2.3.11.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.11.7. to 2.3.11.11. relevant to the WTD 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 WTD of ~~any other~~ *commodity* of a species not covered in Article 2.3.11.2. but which could reasonably be expected to be a potential MrNV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of MrNV, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.11.4.

White tail disease free country

A country may make a *self-declaration of freedom* from WTD 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 WTD if all the areas covered by the shared water are declared WTD free countries or *zones* (see Article 2.3.11.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.11.2. is present may make a *self-*

declaration of freedom from WTD 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 2.3.11.2. are present but there has ~~never~~ been no ~~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 make a *self-declaration of freedom* from WTD 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, ~~for example~~ 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 WTD when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of MrNV.

OR

4. A country that has previously made a *self-declaration of freedom* from WTD but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from WTD again ~~until~~ 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MrNV; 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 ~~they~~ such part meets the conditions in point 3 of Article 2.3.11.5.

Article 2.3.11.5.

Community comment

The Community would suggest to the OIE to reconsider its position as regards the issue of defining and re-establishing (after a breakdown) the disease free status of a compartment.

We would argue that for certain compartments, formed by a single establishment, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and, where appropriate fallowed, and finally restocked with aquatic animals from a certified free source.

The Community would suggest including a new point 5 in this article that would read:

" a compartment previously declared free from white tail disease but in which the disease is detected may not be declared free from that disease until the following conditions have been met:

a) the requirements in point 4, or

b) in the case that the compartment is formed by one single farm and it is supplied by water from a spring, borehole or other safe supply independent of the heath status of the surrounding waters and it is equipped with a barrier that prevents the migration of aquatic animals of susceptible species into the compartments or its water supply:

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures have been completed and followed, when necessary, by fallowing

ii) the compartment is repopulated with aquatic animals from a certified free population.

White tail disease free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from WTD 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 WTD 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 2.3.11.2. is present may be declared free from WTD 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 2.3.11.2. 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 WTD 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, ~~for example~~ (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 WTD when:

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

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of MrNV.

OR

4. A *zone* previously declared free from WTD but in which the *disease* is subsequently detected may ~~not~~ be declared free from WTD again ~~until~~ 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MrNV; 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 2.3.11.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from WTD following the provisions of points 1 or 2 of Articles 2.3.11.4. or 2.3.11.5. (as relevant) may maintain its status as WTD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from WTD following the provisions of point 3 of Articles 2.3.11.4. or 2.3.11.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as WTD free provided that conditions that are conducive to clinical expression of WTD, 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 WTD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.11.7.

Importation of live aquatic animals from a country, zone or compartment declared free from white tail disease

When importing live *aquatic animals* of species referred to in Article 2.3.11.2. from a country, *zone* or *compartment* declared free from WTD, 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 2.3.11.4. or 2.3.11.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from WTD.

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 2.3.11.3.

Article 2.3.11.8.

Community comment

The scope of this article is unclear as there is no definition of what is meant by "new stock". Does it mean an introduction of a non-native species in a country? Further clarification is needed.

In addition, we would repeat that if the OIE AAC intention is to include a reference to the ICES Code such reference should be made to the whole ICES CODE, as a short summary might be misleading. One possible solution would be to include the web link to the whole ICES document in point 3 of this article.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.11.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of MrNV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ 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 ~~Guidelines~~ Code may be summarised to the following main points:

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

   b) evaluate stock's health/*disease* history;

   c) take and test samples for MrNV, 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 MrNV and perform general examinations for pests and general health/*disease* status;

   g) if MrNV 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 WTD free or specific pathogen free (SPF) for MrNV;

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 2.3.11.3.

Annex IX (contd)

Article 2.3.11.9.

Community comment

In point 1, the possible processing of the live aquatic animals is not foreseen. We would suggest to the OIE to add this option. The new proposed text would read:
1. the consignment be delivered directly to and held in isolation until processing and /or consumption

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

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.11.2. from a country, *zone* or *compartment* not declared free from WTD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

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

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

Members ~~should~~ 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 2.3.11.3.

Article 2.3.11.10.

Importation of aquatic animal products from a country, zone or compartment declared free from white tail disease

When importing *aquatic animal products* of species referred to in Article 2.3.11.2. from a country, *zone* or *compartment* declared free from WTD, 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 2.3.11.4. or 2.3.11.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WTD.

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 2.3.11.3.

Article 2.3.11.11.

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

When importing *aquatic animal products* of species referred to in Article 2.3.11.2. from a country, *zone* or

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

This Article does not apply to *commodities* listed in point 1 of Article 2.3.11.3.

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Annex X

CHAPTER 2.2.5.

INFECTION WITH *MIKROCYTOS MACKINI*

Article 2.2.5.1.

Community comment

The Community agrees with the proposed amendments.

However, we would like that the OIE takes the following comments into account.

For the purposes of the *Aquatic Code*, infection with *Mikrocytos mackini*[1] means *infection* only with *Mikrocytos mackini*.

Methods for conducting surveillance, diagnosis and confirmatory identification of infection with *Mikrocytos mackini* are provided in the *Aquatic Manual* (under study).

Article 2.2.5.2.

Community comment

Two separate lists of susceptible species, one in the Code (susceptible species) and one in the Manual (other susceptible species) is misleading, as they create, in fact, two categories of susceptible species.

For the sake of clarity, we would kindly suggest to the OIE to include all susceptible species to this specific infection in this article.

Scope

The recommendations in this Chapter apply to: European flat oyster (*Ostrea edulis*), Olympia oyster (*O. conchaphila*), Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.5.3.

Community comment

The Community would insist on its previous comment: there is no scientific evidence that proves that larvae could be considered as a safe commodity for this infestation.

Some recent studios based on the use of molecular tools, revealed infection with M. mackini in 6 months old spat (Bower et al. 2005). Therefore we lack such recent studies (using molecular tools) concerning young bivalves stages, including larva. Until these investigations are carried out, larvae should be deleted from point 1.

Bower SM, Bate K, Meyer GR (2005). Susceptible of juvenile Crassostrea gigas and resistance of Panope abrupta to M. mackini. J invertebr Pathol 88: 95-99.

Litra c) should also cover live animals intended for human consumption since there are other risk mitigation measures included in this provision such as: its intended use for human consumption, packed for direct retail trade, which implies that the likelihood of getting in contact with natural waters is very low and finally that they will not be intended for further processing avoiding the possible risk of spreading the disease through the effluents of the processing plants.

Finally, we cannot find provisions for other commodities than those listed in point 1 and for commodities of species not covered in article 2 as in the other disease chapters.

Commodities

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

   a) For the species referred to in Article 2.2.5.2. intended ~~being used~~ for any purpose:

      i) *commodities* treated in a manner that kills the host ~~(~~and ~~thereby~~ inactivates the *disease agent*~~)~~ e.g. canned or pasteurised products; chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);

      ii) larvae;

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

   b) All commodities from *Panope abrupt a*, including the live *aquatic animal*.

   c) The following *commodities* destined for human consumption from the species referred to in Article 2.2.5.2. which have been prepared and packaged for direct retail trade:

      i) off the shell (chilled or frozen).

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

Article 2.2.5.4.

***Mikrocytos mackini* free country**

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Mikrocytos mackini* if all the areas covered by the shared water are declared *Mikrocytos mackini* free *zones* (see Article 2.2.5.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.5.2. is present may make a *self-*declaration *of freedom* from *Mikrocytos mackini* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.5.2. are present but there has ~~never~~ been no ~~any~~ observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may make a *self-declaration of* freedom from *Mikrocytos mackini* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in Chapter 2.2.5. of the *Aquatic Manual*), may make a *self-declaration of freedom* from *Mikrocytos mackini* when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*.

OR

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

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

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

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*; and<u>Annex X</u> (contd)

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

   In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 2.2.5.5.

Article 2.2.5.5.

Community comment

The Community would suggest to the OIE to reconsider its position as regards the issue of defining and re-establishing (after a breakdown) the disease free status of a compartment.

We would argue that for certain compartments, <u>formed by a single establishment</u>, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and, where appropriate fallowed, and finally restocked with aquatic animals from a certified free source.

The Community would suggest including a new point 5 in this article that would read:

" a compartment previously declared free from M mackini but in which the disease is detected may not be declared free from that disease until the following conditions have been met:

a) the requirements in point 4, or

b) in the case that the compartment is formed by one single farm and it is supplied by water from a spring, borehole or other safe supply independent of the heath status of the surrounding waters and it is equipped with a barrier that prevents the migration of aquatic animals of susceptible species into the compartments or its water supply:

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures have been completed and followed, when necessary, by fallowing

ii) the compartment is repopulated with aquatic animals from a certified free population.

Mikrocytos mackini free zone or free compartment

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

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

1. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.5.2. is present may be declared free from *Mikrocytos mackini* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.5.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may be declared free from *Mikrocytos mackini* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in Chapter 2.2.5. of the *Aquatic Manual*), may be declared free from *Mikrocytos mackini* when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini.*

OR

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

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

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

c) *targeted* surveillance, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*; and

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

Article 2.2.5.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of points 1 or 2 of Articles 2.2.5.4. or 2.2.5.5. (as relevant) may maintain its status as *Mikrocytos mackini* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of point 3 of Articles 2.2.5.4. or 2.2.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Mikrocytos mackini* free provided that conditions that are conducive to clinical expression of infection with *Mikrocytos mackini*, as described in Chapter 2.2.5. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

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

Article 2.2.5.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.5.4. or 2.2.5.5. (as applicable), whether the place of production of the *commodity* is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.8.

Community comment

The scope of this article is unclear as there is no definition of what is meant by "new stock". Does it mean an introduction of a non-native species in a country? Further clarification is needed.

In addition, we would repeat that if the OIE AAC intention is to include a reference to the ICES Code such reference should be made to the whole ICES CODE, as a short summary might be misleading. One possible solution would be to include the web link to the whole ICES document in point 3 of this article.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:

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

   b) the treatment of all effluent and waste material in a manner that ensures inactivation of *Mikrocytos mackini*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as 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 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 *Mikrocytos mackini*, 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 *Mikrocytos mackini* and perform general examinations for pests and general health/disease status;

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

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

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

2. all effluent and waste material from the processing be treated in a manner that ensures *inactivation* of *Mikrocytos mackini.*

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.10.

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

When importing *aquatic animal products* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country.*

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.5.4. or 2.2.5.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Mikrocytos mackini.*

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.11.

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

When importing *aquatic animal products* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

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1. This disease does not meet the listing criteria in Chapter 1.2.2. Nevertheless, reporting requirements for non listed diseases apply in regard to significant epidemiological events (see point 1c) of Article 1.2.1.3.).

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Annex XI

CHAPTER 2.1.14.

GYRODACTYLOSIS
(*Gyrodactylus salaris*)

Article 2.1.14.1.

For the purposes of the *Aquatic Code*, gyrodactylosis means *infestation* with the viviparous freshwater ectoparasite *Gyrodactylus salaris* (*G. salaris*) (Phylum Platyhelminthes; Class Monogenea).

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

Article 2.1.14.2.

Community comment

The scope of this chapter covers all fish species that may carry the parasite and act as vectors provided G. salaris is present in the surrounding waters. In order to improve the clarity of the article, a definition of vector would be needed.

In addition, it would be necessary to clarify which is the scope of the following terms: "other salmonids" and "freshwater fish species" in the second sentence of this article.

Scope

The recommendations in this Chapter apply to: Atlantic salmon (*Salmo salar*), rainbow trout (*Oncorhynchus mykiss*), Arctic char (*Salvelinus alpinus*), North American brook trout (*Salvelinus fontinalis*), grayling (*Thymallus thymallus*), North American lake trout (*Salvelinus namaycush*) and brown trout (*Salmo trutta*). The recommendations also apply to other salmonid and freshwater fish species in waters where the parasite is present, because these species may carry the parasite and act as vectors.

Article 2.1.14.3.

Commodities

Community comment

The Community would argue that evisceration is not relevant as a measure to mitigate the risk posed by this infestation. We would propose the removal of any reference to evisceration as a risk mitigation measure in this chapter.

Litra b) should also cover fish, whether eviscerated or uneviscerated, intended for human consumption since there are other risk mitigation measures included in this provision such as: its intended use for human consumption, packed for direct retail trade, which implies that the likelihood of getting in contact with natural waters is very low and finally that they will not be intended for further processing avoiding the possible risk of spreading the disease through the effluents of the processing plants.

Before introducing the concept of vector, as it is mentioned in point 3, it is completely necessary to define what Member Countries understand with this term.

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

   a) For the species referred to in Article 2.1.14.2. intended for any purpose:

i) *commodities* treated in a manner that kills *G. salaris* e.g. leather made from fish skin, pasteurised products and ready to eat meals; and fish oil and fish meal intended for use in animal feeds;

ii) chilled products of fish, where the head, fins and skin has been removed

iii) biological samples preserved for diagnostic applications in such a manner as to inactivate *G. salaris*.

b) The following *commodities* destined for human consumption from the species referred to in Article 2.1.14.2. that have been prepared and packaged for direct retail trade:

i) *eviscerated fish* (chilled frozen);

ii) fillets or cutlets (chilled or frozen);

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

iv) smoked salmonids.

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 2.1.14.2., other than those referred to in point 1 of Article 2.1.14.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.1.14.7. to 2.1.14.11. relevant to the gyrodactylosis 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 gyrodactylosis of any live *commodity* of a species not covered in Article 2.1.14.2. but which could reasonably be expected to be a potential *G. salaris* vector, 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 2.1.14.4.

Community comment

It is well known that Atlantic salmon is the main host for *Gyrodactylus salaris* parasite. However, it is also well known that some salmon stocks are very sensitive to this parasite and others are totally resistant. In resistant strains (like Baltic salmon) this parasite does not cause clinical disease or even symptoms. Therefore, the Community considers important to add a new paragraph after "If a country shares a *zone...*".

The new paragraph could read

"If a country shares a zone with one or more other countries, it can only make a self-declaration of freedom from gyrodactylosis if all the areas covered by the shared watercourse(s) are declared gyrodactylosis free countries or zones (see Article 2.1.14.5.). ***If there is any reason to believe that the stocks of the species listed in Article 2.1.14.2. are resistant to G. salaris, freedom of a country has to be proved by targeted surveillance according to point 3.***

The Community would like that the OIE AAC explains the reason to increase the period from the standard 10 years to the proposed 25 years.

As well, the Community would like that the OIE AAC explains the reason to increase the targeted surveillance period from 2 years to 5 years in points 3 and 4 of this article.

As regards point 4.b the Community would argue that the approach taken by the OIE AAC goes beyond the requirements to consider a country as free from *G. salaris* as it deals with environmental issues. Therefore, we would propose the removal of the following wording: "*without affecting the wild or farmed host*". Point 4.b would read:

b) **infested populations have been destroyed or removed from the infested zone by means that minimise the risk of further spread of the disease, and the appropriate disinfestation procedures (see Aquatic Manual) have been completed, or the waters containing the infested fish have been treated by chemicals that kill the parasite.**

Gyrodactylosis free country

A country may make a *self-declaration of freedom* from gyrodactylosis 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 gyrodactylosis if all the areas covered by the shared watercourse(s) are declared gyrodactylosis free countries or *zones* (see Article 2.1.14.5.).

1. A country where none of the *susceptible species* referred to in Article 2.1.14.2. is present may make a *self-declaration of freedom* from gyrodactylosis 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 2.1.14.2. are present but there has been no 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 gyrodactylosis when *basic biosecurity conditions* have been continuously met 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 *infestation* 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 gyrodactylosis when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 10 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *G. salaris*.

OR

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

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

   b) infested populations have been destroyed or removed from the infested zone by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfestation* procedures (see *Aquatic Manual*) have been completed, or the waters containing the infested fish have been treated by chemicals that kill the parasite without affecting the wild or farmed host; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *G. salaris*; 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 such part meets the conditions in point 3 of Article 2.1.14.5.

Article 2.1.14.5.

Community comment

Like in Article 2.1.14.4. the Community considers important to add a new paragraph after "If a *zone* or *compartment* extends... ".

The new paragraph could read

" If a *zone* or *compartment* extends over more than one country, it can only be declared a gyrodactylosis free *zone* or *compartment* if all the *Competent Authorities* confirm that the conditions have been met. **.If there is any reason to believe that the stocks of the species listed in Article 2.1.14.2. are resistant to *G. salaris*, freedom of a zone or compartment has to be proved by targeted surveillance according to point 4".**

The Community would like that the OIE AAC explains the reason to increase the period from the standard 10 years to the proposed 25 years.

As well, the Community would like that the OIE AAC explains the reason to increase the targeted surveillance period from 2 years to 5 years in points 4 and 5 of this article.

As regards point 5.b the Community would argue that the approach taken by the OIE AAC goes beyond the requirements to consider a zone or compartment as free from *G. salaris* as it deals with environmental issues. Therefore, we would propose the removal of the following wording: "*without affecting the wild or farmed host*". Point 5.b would read:

b) **infested populations have been destroyed or removed from the infested zone by means that minimise the risk of further spread of the disease, and the appropriate disinfestation procedures (see Aquatic Manual) have been completed, or the waters containing the infested fish have been treated by chemicals that kill the parasite.**

To clarify point 3 of this article the following wording is proposed;

3. A *zone* or *compartment* supplied with seawater with a salinity of at least 25 parts per thousand and into which no live aquatic animals of species referred to in Article 2.1.14.2 have been introduced for the previous 14 days from a site of a lesser health status in relation to *G. salaris*.

Furthermore, a clear procedure to regain the freedom status in infected compartments is needed.

Finally, the Community would suggest to the OIE to reconsider its position as regards the issue of defining and re-establishing (after a breakdown) the disease free status of a compartment.

We would argue that for certain compartments, formed by a single establishment, disease free status could be regained if aquatic animal population is removed and disposed off, the establishment is properly disinfected and, where appropriate fallowed, and finally restocked with aquatic animals from a certified free source.

The Community would suggest including a new point 6 in this article that would read:

" a compartment previously declared free from Gyrodactylosis but in which the disease is detected may not be declared free from that disease until the following conditions have been met:

a) the requirements in point 5, or

b) in the case that the compartment is formed by one single farm and it is supplied by water from a spring, borehole or other safe supply independent of the heath status of the surrounding waters and it is equipped with a barrier that prevents the migration of aquatic animals of susceptible species into the compartments or its water supply:

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures have been completed and followed, when necessary, by fallowing

ii) the compartment is repopulated with aquatic animals from a certified free population.

Gyrodactylosis free zone or free compartment

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

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.1.14.2. is present may be declared free from gyrodactylosis 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 2.1.14.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from gyrodactylosis when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 10 years.

OR

3. A *zone* or *compartment* supplied with seawater with a salinity of at least 25 parts per thousand and into which no live aquatic animals of species referred to in Article 2.1.14.2 have been introduced for the previous 14 days from a site of a lesser health status.

OR

4. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 25 years, or where the *infestation* 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 gyrodactylosis when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 10 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *G. salaris*.

OR

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

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

   b) infested populations have been destroyed or removed from the *infested zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfestation* procedures (see *Aquatic Manual*) have been completed, or the waters containing the infested fish have been treated by chemicals that kill the parasite without affecting the wild or farmed host;; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *G. salaris*; 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 2.1.14.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from gyrodactylosis following the provisions of points 1 or 2 of Articles 2.1.14.4. or 2.1.14.5. (as relevant) may maintain its status as gyrodactylosis free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from gyrodactylosis following the provisions of point 3 of Articles 2.1.14.4. or 2.1.14.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as gyrodactylosis free provided that conditions that are conducive to clinical expression of gyrodactylosis, 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 infested countries and in all cases where conditions are not conducive to clinical expression of gyrodactylosis, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infestation*.

Article 2.1.14.7.

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

When importing live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* declared free from gyrodactylosis, 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 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from gyrodactylosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.8.

Community comment

The scope of this article is unclear as there is no definition of what is meant by "new stock". Does it mean an introduction of a non-native species in a country? Further clarification is needed.

In addition, we would repeat that if the OIE AAC intention is to include a reference to the ICES Code such reference should be made to the whole ICES CODE, as a short summary might be misleading. One possible solution would be to include the web link to the whole ICES document in point 3 of this article.

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

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should:a) require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that:

    i) the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days; and

    ii) no other live *aquatic animals* of the species referred to in Article 2.1.14.2. have been introduced during that period;

OR

    iii) in the case of eyed eggs, the eggs have been disinfected by a method demonstrated to be effective against *G. salaris*;

OR

b) assess the *risk* and apply risk mitigation measures such as:

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

    ii) if breeding from the imported fish, disinfection of the fertilised eggs by a method demonstrated to be effective against *G. salaris*, and complete separation of the hatched progeny from the imported animals;

iii) the treatment of all effluent and waste materials in a manner that ensures inactivation of *G. salaris*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as 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.

Annex XI (contd)

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

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

   b) evaluate stock's health/disease history;

   c) take and test samples for *G. salaris*, 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 *G. salaris* and perform general examinations for pests and general health/disease status;

   g) if *G. salaris* 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 gyrodactylosis free or specific pathogen free (SPF) for *G. salaris*;

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.9.

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

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days, and no other live fish of the species listed in Article 2.1.14.2. have been introduced during that period;

OR

2. require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.14.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that ensures inactivation of *G. salaris*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from gyrodactylosis

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that the *aquatic animals* have been held, immediately prior to export, in water with a salinity of at least 25 parts per thousand for a continuous period of at least 14 days, and no other live *aquatic animals* of the species referred to in Article 2.1.14.2. have been introduced during that period;

OR

2. require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.14.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that ensures inactivation of *G. salaris*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.11.

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

When importing *aquatic animal products* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* declared free from gyrodactylosis, 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 2.1.14.4. or 2.1.14.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from gyrodactylosis.The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Article 2.1.14.12.

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

When importing *aquatic animal products* of species referred to in Article 2.1.14.2. from a country, *zone* or *compartment* not declared free from gyrodactylosis, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate risk mitigation measures.

1. In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include:

   a) the direct delivery into and holding of the consignment in biosecure facilities for processing to one of the products referred to in point 1 of Article 2.1.14.3. or other products authorised by the *Competent Authority*;

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

OR

2. The *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued from the *Competent Authority* of the *exporting country* attesting that the product was derived from *aquatic animals* which had been held, immediately prior to processing, in water with a salinity of at least 25 parts per thousand for a continuous period of 14 days, and no other live *aquatic animals* of the species referred to in Article 2.1.14.2. have been introduced during that period.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.14.3.

Annex XII

INTRODUCTION TO OIE GUIDELINES FOR THE WELFARE OF LIVE AQUATIC ANIMALS

Article X.X.X.1.

The Community reiterates its previous comment:

The title and scope of this appendix should be clarified since the OIE Aquatic Code also includes invertebrates in the definition of aquatic animals.

Community comment:

The second bullet of the Guiding principles for aquatic animal welfare could be moved as preamble of this Introduction chapter, as follows:

"Taking into account that the use of aquatic animals in aquaculture, harvest or capture fisheries, research and for recreation (eg ornamentals and aquaria), makes a major contribution to the wellbeing of people, the following guiding principles for aquatic animal welfare should be taken into account".

Justification:

This sentence appears to be more a background than a principle for developing guidelines on animal welfare.

Guiding principles for aquatic animal welfare

Community comments:

The point "That the internationally recognised 'three Rs" (reduction in numbers of aquatic animals, refinement of experimental methods and replacement of aquatic animals with non-animal techniques) provide valuable guidance for the use of aquatic animals in science" should be reinserted in the following guiding principles for aquatic animal welfare in order to ensure consistency, where applicable, with the guiding principles for animal welfare of the Terrestrial Code.

1 That there is a critical relationship between *aquatic animal* health and *aquatic animal* welfare.

2. That the use of *aquatic animals* in aquaculture, harvest or capture fisheries, research and for recreation (eg ornamentals and aquaria), makes a major contribution to the wellbeing of people.

3. That the use of *aquatic animals* carries with it an ethical responsibility to ensure the welfare of such animals to the greatest extent practicable.

4. That improvements in *aquatic animal* welfare can often improve productivity and hence lead to economic benefits.

5. That the internationally recognised 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behaviour) provide valuable guidance in *aquatic animal* welfare.

6. That the scientific assessment of *aquatic animal* welfare involves both scientifically derived data and value-based assumptions which need to be considered together, and the process of making these assessments should be made as explicit as possible.

7. That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of *aquatic animal* welfare standards and guidelines.

Article X.X.X.2.

Scientific basis for guidelines

Community comment:

The scientific assessment of aquatic animal welfare should consider both the ability of aquatic animals to feel pain and specie-specific requirements such as water quality.

Justification:

The fulfilment of water quality parameters is crucial for ensuring the welfare of aquatic animals.

The scientific assessment of *aquatic animal* welfare has progressed rapidly in recent years and forms the basis of these guidelines. Many areas of *aquatic animal* welfare require further research to understand in full the ability of *aquatic animals* to feel pain and to be sentient. [To be developed]

Annex XIIIa

DRAFT GUIDELINES FOR THE CONTROL OF AQUATIC ANIMAL HEALTH HAZARDS IN AQUATIC ANIMAL FEEDS

Community comment

The Community appreciates that these guidelines have been drafted, which can give a valuable guidance for the control of such hazards. However, the Community would like that the OIE takes its comments into account.

1. INTRODUCTION

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

These guidelines do not for the moment ~~It does not~~ address food safety issues in detail as this is not within the mandate of the OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission).

These Guidelines should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) (Appendix containing recommendations on animal *feed*). The Food and Agriculture Organization of the United Nations (FAO) has ~~also~~ published recommendations relevant to terrestrial and aquatic animal *feed* and there is a Codex Alimentarius Commission (CAC) standard[1]. Members are encouraged to consult these publications.

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

- ~~Intensive rearing in~~ Concentration of *aquaculture establishments* and intensive rearing causes a concentration of *aquatic animals* ~~fish~~, *feed* and faecal matter in time and space and this heightens the risk of *disease* transmission, whether the pathogen enters the culture system via *feed* or other means.

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

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

- The usage of *feed* in moist, semi-moist and dry form implies different levels of risk due to the processing applied to the *feed*.

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[1] Technical Guidelines for Responsible Fisheries – Aquaculture Development: 1. Good aquaculture feed manufacturing practice. FAO 2001.

Draft Good Practices for the Animal Feed Industry – Implementing the Codex Alimentarius' Code of Practice on Good Animal Feeding, IFIF/FAO (*In preparation*).

Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

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

Annex XIIIa (contd)

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

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

2. ~~PURPOSE AND~~ SCOPE

Community comment

The scope of these guidelines remains unclear as this article includes as hazards *"pathogens that cause OIE-listed diseases and other agents that cause an adverse effect on animal and/or public health"* while article 4m) refers only to OIE listed diseases".

We are of the view that these guidelines should have a comprehensive approach and not only limited to health hazards in aquatic animal feeds limited to OIE listed diseases.

These guidelines ~~To~~ document risk mitigation measures, including traceability and certification, to deal with aquatic animal health risks associated with ~~through~~ trade in aquatic animal *feeds* and *feed ingredients*. ~~*Hazards* include *diseases* of interest i.e. *OIE-listed diseases* and any others considered to be important to aquatic animal health. This guideline~~ They recommends the control of ~~aquatic animal health~~ *hazards* through adherence to recommended practices during the production (~~procurement~~ harvest, handling, storage, processing and distribution) and use of both commercial and on-farm produced *feed* (and *feed ingredients*) for *aquatic animals*. Hazards include. While *aquatic animals* grown for food are the main focus, the same principles apply to *feed* for *aquatic animals* used for other purposes. ~~aquarium species~~.

3. DEFINITIONS

Community comment

We thank the AAC to have taken into account our previous comments. However, for the sake of clarity, we would prefer to include these definitions in Chapter 1.1.1. of the Code (Definitions).

Concerning the definition of "Meal" also algae and plant material can be used.

With regard to the definition of medicated feed, we think that it is very important to highlight that medicated feed is a veterinary medicinal product and not a feed. Therefore, medicated feed can on only be delivered and administered to aquatic animals following veterinary prescription.

In addition, we think it would be useful to keep the proposed definition on "cross contamination".

~~***Cross contamination***~~

~~Means contamination of a material or product with another material or product containing a *hazard*.~~

Dry feed

Means *feed* that has a moisture ~~dry matter~~ content ~~= or ></~~ equal to or less than ~~90~~ 15%.

Feed

Means any material (single or multiple), whether processed, semi-processed or raw that is intended to be fed directly to food-producing animals.

Feed additives

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

Feed ingredient

Means a component, part or constituent of any combination or mixture making up a *feed*, including *feed additives*, whether or not it has a nutritional value in the animal's diet. Ingredients may be of terrestrial or aquatic, plant or animal ~~or aquatic~~ origin and may be organic or inorganic substances.

Hazard

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

~~***Intra/inter species feeding***~~

~~Means feeding *aquatic animals* on products made from animals of the same species, or products made from species that are susceptible to the same pathogens as the animals receiving the *feed*.~~

Live feed

Means live farmed or wild caught animals and algae used as *feed* for *aquatic animals*. *Live feed* is often fed to aquatic animal species at an early life-stage ~~(e.g. *Artemia* cysts, rotifers, copepods)~~ and to aquatic animal species that have been cultured for a relatively short time.

Meal

Means a product derived from an aquatic animal that has been ground and heat processed to reduce the moisture content to less than 10 %.

Medicated feed

Means any *feed* which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.

Moist (or wet) feed

Means *feed* that has a moisture ~~dry matter~~ content ~~= or >~~ equal to or greater than 70 ~~30~~% ~~(e.g. frozen adult *Artemia*, whole fish or fish *offal*, molluscs, crustaceans, polychaetes for feed purposes)~~.

Semi-moist feed

Means *feed* that has a moisture ~~dry matter~~ content between 15 ~~30~~ and ~~90~~ 70%.

Fish solubles

Means a by-product of the fish oil production system, comprising the product remaining when water is drawn off (evaporated) from the residual aqueous phase.

~~***Undesirable substance***~~

~~Means a contaminant or other substance that is present in and/or on *feed* or *feed ingredients* and that constitutes a risk to animal or public health.~~

4. GENERAL PRINCIPLES

a) Roles and responsibilities

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

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

Those involved in the production and use of animal *feed* and *feed ingredients* have the responsibility to ensure that these products meet regulatory requirements[2]. All personnel involved in the ~~procurement~~ harvest, manufacture, storage and handling of *feed* and *feed ingredients* should be adequately trained and aware of their role and responsibility in preventing the spread of *hazards* ~~of animal health and public health significance~~. Appropriate contingency plans should be developed in case of a *feed*-borne *disease* outbreak. Equipment for producing, storing and transporting *feed* should be kept clean and maintained in good working order.

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

b) Regulatory standards for feed safety

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

c) Risk analysis

Internationally accepted principles and practices for ~~on~~ *risk analysis* (see Section 1.4. of the *Aquatic Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

A generic *risk analysis* framework should be applied to provide a systematic and consistent process for managing *hazards* ~~disease risks and the risk of contamination with *undesirable substances*~~.

d) Good practices

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

Where appropriate, Hazard Analysis and Critical Control Point[3] (HACCP) principles should be followed to control *hazards* that may occur in *feed*.

e) Relationship between ~~terrestrial animal disease agents~~ prions and *aquatic animal* species

Community comment

We would suggest this additional wording to the current one.

"The authorisation to use terrestrial animal by-products in the aquaculture as a means of reducing dependency on aquatic protein and lipid sources should be risk-based but at the same time taking into account the availability of control tools and structure of the industry in order to ensure the complete channelling of terrestrial animal by-products into the aquafeed production".

Scientific knowledge is lacking on the relationship between ~~certain terrestrial animal *disease agents*, notably~~ prions and *aquatic animal* species. There is no evidence to suggest that the use of terrestrial animal by-products as ingredients in aquatic animal *feeds* gives rise to *risks* in respect of prion *diseases*. More scientific information is desirable to enable *aquaculture* industries to utilise more

[2] If at the national level, there are specific food-safety or animal health regulations related to genetically modified organisms, these should be taken into account in relation to feed and feed ingredients as these products form an important part of the food chain.

[3] Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene (CAC/RCP 1-1969).

terrestrial animal by-products ~~and plant matter~~ as a means of reducing dependency on aquatic protein and lipid sources.

f) Bioaccumulation

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

g) Geographic and environmental considerations

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

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

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

h) Zoning and compartmentalisation

Feed ~~and *feed ingredients* are~~ is an important components of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 1.4.4. of the *Aquatic Code*.

i) Sampling and analysis

Community comment
We wonder whether this sampling scheme refers to live aquatic animals or to a sampling scheme in feed. We would like that the AAC clarifies this issue.

Sampling and analytical protocols should be based on scientific~~ally~~ ~~recognized~~ principles and procedures, and OIE standards where applicable.

j) Labelling

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

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

k) Design and management of inspection programmes

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

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

l) Assurance and certification

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

m) Hazards associated with aquatic animal *feed*

Community comment

It remains unclear whether the group decided to remove prions from the list of biological hazards, because they were of the view that this transmissible agents were not per se biological hazards that may occur in feed and feed ingredients for aquatic animals, or simply because as this stage, there is no prion-related disease within the list of OIE diseases for aquatic animals.

Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, ~~prions,~~ fungi and parasites. The scope of these guidelines is limited to the *OIE listed diseases of aquatic animals.*

Chemical hazards

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

Physical hazards

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

n) Cross contamination

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

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

o) Antimicrobial resistance

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

p) Management of information

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

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

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

~~5.~~ ~~HAZARDS~~

~~Biological~~

~~This document addresses the following biological hazards:~~

~~a) bacteria, virus, parasites, fungi affecting *aquatic animals*. These hazards include the *OIE-listed diseases* (Chapter 1.2.3. of the *Aquatic Code*) and other important *diseases* (including IPN and IMNV);~~

~~b) prions.~~

~~Chemical~~

~~[under study]~~

~~Physical~~

~~[under study]~~

6 5. PATHOGENS IN FEED

a) Pathogens ~~in *feed*~~ can be introduced into *feed* in the following ways ~~at two points~~:

i) ~~at source:~~ via the harvest of infected *aquatic animals*;

ii) during storage, processing and transport, ~~Contamination may occur at the manufacturing facility via~~ due to poor hygienic practices, ~~and/or~~ the presence of pests, ~~*Feed* and *feed ingredients* may be exposed to contamination during storage, manufacturing or transport, due to~~ or residues of previous batches of *feed* remaining in processing lines, containers or transport vehicles.

b) *Aquatic animals* can be exposed to pathogens in *feed* in the following ways ~~Exposure pathways include~~:

i) Direct exposure

The use of ~~raw~~ unprocessed *feed* ~~or *feed ingredients*~~ derived from *aquatic animals* to feed *aquatic animals* ~~species~~ presents a direct route ~~risk~~ of exposure, particularly when ~~to *hazards* of infectious nature~~. ~~There are risks associated with~~ feeding whole *aquatic animals* and unprocessed products of *aquatic animals* to animals of the same species. For example ~~that are susceptible to the same *diseases* as the 'fed animal' e.g.~~ feeding salmonid *offal* to salmonids or feeding rotifers or *Artemia* species to crustaceans presents a heightened risk of disease transmission.

ii) Indirect exposure

Pathogens in *feed* ~~and *feed ingredients* containing pathogenic agents~~ may be transmitted to *aquatic animals* in *aquaculture* and wild aquatic animals ~~fish~~ via contamination of the environment ~~including~~ or infection ~~contamination~~ of ~~on~~ non-target species.

6. CHEMICAL AGENTS IN *FEED*

[under study]

7. PHYSICAL AGENTS IN *FEED*

[under study]

~~7~~ 8. RECOMMENDED APPROACHES TO RISK MITIGATION

Community comment

If the OIE's intention is to keep a list of safe commodities in these guidelines, consistency between the guidelines and article 3 of the specific disease chapters would be desirable. Also products derived from plants and algae should be added as safe commodities. These products are used commonly in aquatic animal feeds.

As an example, in chapter 2.2.5. (*M. mackini*), bivalve meal is not included as a safe commodity in the proposed article 3, while in this article, bivalve meal is considered as safe commodity.

a) ***Commodities***

Safe commodities

The following *commodities* undergo extensive processing such as heat treatment, acidification, extrusion and extraction. There is a negligible risk that pathogens will survive in such products if they have been produced in accordance with normal commercial practice:

i) fish oil;

ii) crustacean oil;

iii) *fish solubles*;

iv) fish *meal*;

v) crustacean *meal*;

vi) squid meal and squid liver-meal;

vii) bivalve *meal*;

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

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

Other *commodities*

Competent Authorities should consider the following risk mitigation measures.

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

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

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

iv) use of *feed* only in *populations* that are not susceptible to the pathogen(s) in question.

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

Whole fish (fresh or frozen)

The practice of trading fresh or frozen whole marine fish for use as aquatic *feed* presents a *risk* of introducing *diseases* into *populations*. Given the difficulty of imposing effective *risk* mitigation measures, this practice is not recommended.

~~The following measures are relevant to *exporting countries*:~~

a) ~~Source of raw materials~~

~~Raw materials/ingredients should not be sourced from areas/*populations* known to be infected with significant pathogens: . It may be appropriate to adopt routine testing procedures to verify that pathogens are not present at unacceptable levels; or~~

~~When using *feed* and *feed ingredients* originating from areas known to be affected by a significant pathogen:~~

~~i) *feed* and *feed ingredients* should be delivered directly to feed manufacturing plants for processing under conditions approved by the *Competent Authority*; and~~

~~ii) effluent and other wastes from the feed manufacturing plants should be treated under conditions approved by the *Competent Authority* before discharge into the aquatic environment; or~~

~~iii) *feed* and *feed ingredients* known or suspected to be infected with significant agents pathogens should only be used and/or processed in a *zone* or *compartment* that does not contain species susceptible to the pathogen in question.~~

~~the following measures are relevant to *exporting countries*:~~

~~b)~~ **Feed production**

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

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

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

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

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

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

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

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

~~c)~~ ~~**The following measures are relevant to *Importing countries:***~~

Competent Authorities should consider the following measures:

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

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

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

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

~~8~~ 9. CERTIFICATION PROCEDURES FOR ~~AQUATIC~~ *FEEDS* OF AQUATIC ORIGIN

Community comment

The Community would repeat that articles 2.1.X.11 (importation of products from a country zone or compartment declared free) and 2.1.X.12 (importation of products from a country zone or compartment not declared free) deal with this issue. To avoid repetitions, it would be desirable to make a cross-reference to these articles in the guidelines.

~~a) The following products represent a negligible risk because of the extensive processing used to produce them:~~

~~i) fish oil;~~

~~ii) crustacean oil;~~

~~iii) *fish solubles*;~~

~~iv) fish *meal*;~~

~~v) crustacean *meal*;~~

Annex XIIIa (contd)

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

~~vii) bivalve *meal*;~~

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

~~For these products, *Competent Authorities* should not require conditions in relation to aquatic animal *diseases*, regardless of the aquatic health status of the *exporting country*, *zone* or *compartment*[4].~~

~~b) Other products~~

~~The following risk mitigation measures should be considered:~~

~~i) sourcing *feed* and *feed ingredients* from a *disease* free area; or~~

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

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4 ~~In relation to the risk associated with contamination after harvest/processing, point 4 (below) applies.~~

~~iii) treatment (e.g. by heat or acidification) of product to inactivate pathogens.~~

~~c)~~ ~~Importing country measures~~

When importing *feed* and *feed ingredients* of aquatic origin other than those mentioned in Article X.X.X. [Article with safe commodities, currently point 8], the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* (or a *certifying official* approved by the *importing country*).

This certificate should certify:

i) that *feed* and *feed ingredients* of aquatic origin were obtained ~~imported~~ from a country, *zone* or *compartment* that is free from relevant aquatic animal *diseases*[5]; or

ii) that *feed* and *feed ingredients* of aquatic origin were tested for relevant aquatic animal *diseases*[6] and shown to be free of these *diseases*; or

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

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

~~9~~ 10. RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST, ~~OF FEED INGREDIENTS AND~~ MANUFACTURE AND USE OF AQUATIC FEEDS

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

~~Some~~ *Feed ingredients* of aquatic origin used in *aquaculture*, ~~in particular of aquatic origin (e.g., krill, shrimp, fish, crab, *Artemia*)~~ can be a source of pathogens (viruses, bacteria, and parasites) ~~contamination~~ to cultured aquatic animal species. ~~These ingredients can carry live pathogens (viruses, bacteria, and parasites) and reach the aquaculture operation through different types of *feeds* (live, moist, semi-moist or dry feeds).~~ In *aquaculture establishments* ~~farms~~, ~~there are two routes of~~ pathogens in *feed* can infect the animals directly (via consumption of *feed*) or indirectly via environmental sources. ~~contamination through *aquatic animal* feeding: transmission of pathogens and contamination. **Transmission of pathogens** can take place when the *feed* itself is already infected with a pathogen. This type of contamination is more common with~~ *Live feeds* and *moist feeds* are more likely to contain pathogens because their ingredients ~~that constitute their composition~~ are either ~~kept~~ in a raw state or subject to minimal ~~in the final product (e.g., feeding tuna with wild caught fish) or at times require little~~ treatment~~(s) prior to feeding aquatic organisms~~.

~~Harvest of~~ *Feed* and *feed ingredients* ~~aquatic ingredient sources~~ harvested from infected ~~areas~~ countries, *zones*, or *compartments* ~~has~~ may have a high ~~*risk* of~~ pathogen load ~~contamination, especially if these are transported to an *aquaculture* operation without any prior treatment~~. *Feed* and *feed ingredients* from these sources should be processed (e.g. using heat or chemical treatments). ~~Processing of these ingredients places a moderate risk of contamination, and it should actually be taken as a possibility~~ to reduce, or eliminate, the pathogen load ~~risk of pathogen transmission (e.g., through heat, chemical treatments)~~. After processing care should be taken to avoid post processing contamination during storage and transportation of these commodities ~~ingredients has a low risk of contamination, but should also be considered as a direct route of pathogen contamination.~~ For example, when two or more batches of ingredients of different sanitary status are handled, stored and/or transported together without appropriate ~~any~~ biosecurity measures there is a risk of cross contamination of the *feed* ~~direct contamination to the farmed animal~~.

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5 Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

6 Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

~~**Contamination** occurs when the pathogen is introduced in a feed manufacturing facility, both through infected ingredients or finished feeds and later to the aquaculture facility. Contamination occurs with the use of *semi-moist feeds* and *dry feeds*. With these feed types, contamination can take place in the manufacturing plant during:~~

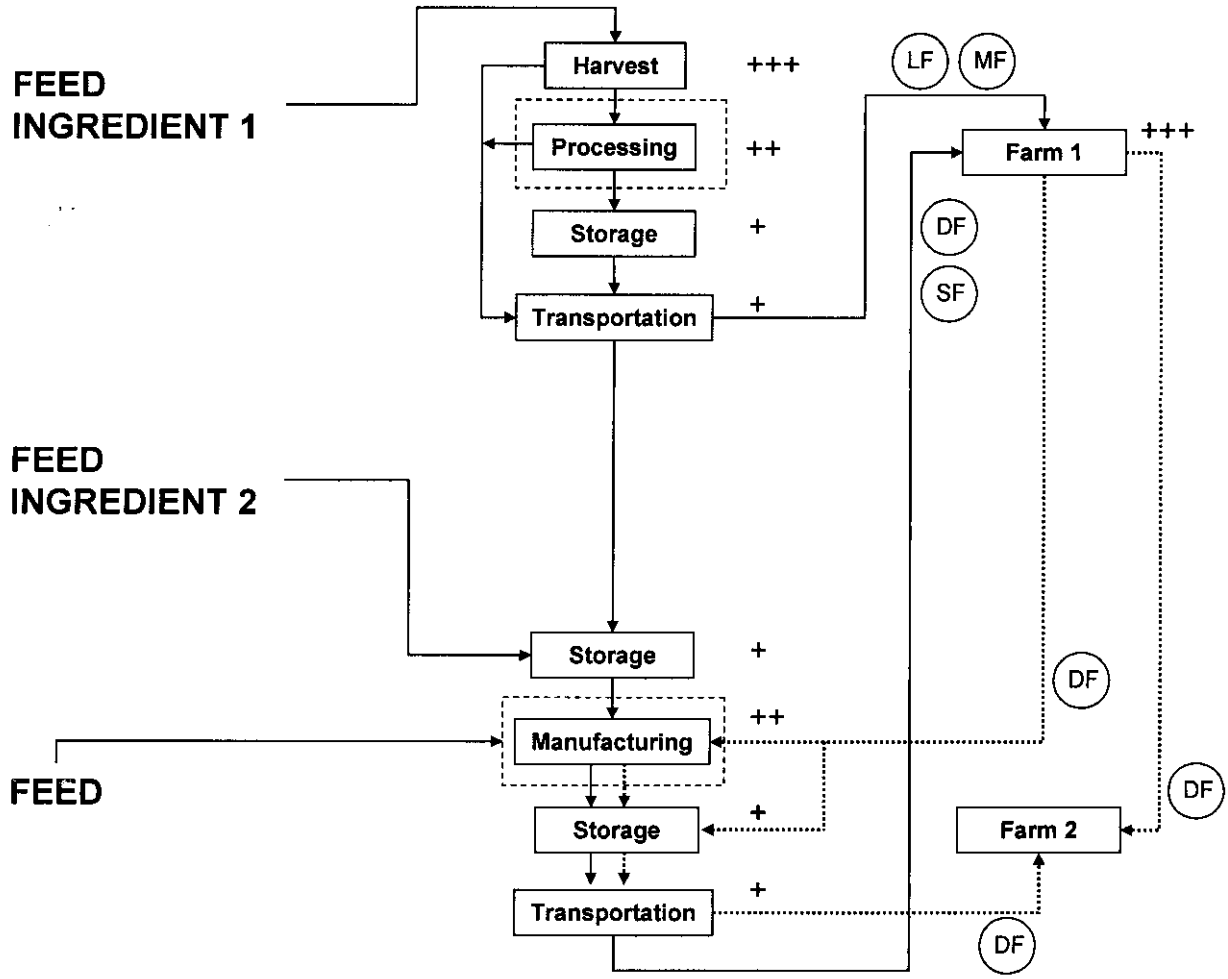
~~a) Storage of ingredients: it has a low risk of contamination, but it can take place when ingredients of different sanitary status are handled or placed together.~~

~~b) Feed manufacturing: during feed processing, ingredients are commonly subjected to heat treatment which can eliminate certain pathogens. However, use of manufacturing lines with remains of contaminated ingredients from a previous batch of feed can result in cross contamination of feeds.~~

~~c) Storage and transportation of finished feeds: it has a low risk of contamination, but when finished feeds are stored or transported together with unprocessed ingredients or with feeds of different sanitary status it can result in pathogen contamination.~~

An aquaculture facility can also be a source of pathogens ~~contamination~~ in aquatic *feeds*. ~~At this level, contamination can take place~~ For example, ~~when a finished~~ *feed* can be contaminated with pathogens through poor hygiene practices at an infected aquaculture *establishment.* ~~is delivered to a farm located in an infected area. Transmission of pathogens can occur when~~ If the *feed* is redistributed ~~withdrawn~~ from the aquaculture facility ~~and is returned~~ to the manufacturing facility for recycling, ~~for reprocessing~~ or ~~transferred~~ distributed to another farm, pathogens can be transferred to other aquaculture *establishments*.

Figure 1: **RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST, MANUFACTURE AND USE OF AQUATIC FEEDS**



[ ] feed MF: Moist feed SF: Semi-moist feed DF: Dry feed	Possibility for risk reduction
~~+++: High~~ risk of pathogen ~~contamination~~ presence ++: Moderate risk of ~~p. c.~~ pathogen presence +: Low risk of ~~p. c.~~ pathogen presence	Redistribution or recycling of finished feed

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DRAFT GUIDELINES FOR THE CONTROL OF AQUATIC ANIMAL HEALTH HAZARDS IN AQUATIC ANIMAL FEED

1. INTRODUCTION

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

These guidelines do not for the moment address food safety issues in detail as this is not within the mandate of the OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission).

These Guidelines should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) (Appendix containing recommendations on animal *feed*). The Food and Agriculture Organization of the United Nations (FAO) has published recommendations relevant to terrestrial and aquatic animal *feed* and there is a Codex Alimentarius Commission (CAC) standard[7]. Members are encouraged to consult these publications.

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

- Concentration of *aquaculture establishments* and intensive rearing causes a concentration of *aquatic animals*, *feed* and faecal matter in time and space and this heightens the risk of *disease* transmission, whether the pathogen enters the culture system via *feed* or other means.

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

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

- The usage of *feed* in moist, semi-moist and dry form implies different levels of risk due to the processing applied to the *feed*.

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

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[7] Technical Guidelines for Responsible Fisheries – Aquaculture Development: 1. Good aquaculture feed manufacturing practice. FAO 2001.

Draft Good Practices for the Animal Feed Industry – Implementing the Codex Alimentarius' Code of Practice on Good Animal Feeding, IFIF/FAO (*In preparation*).

Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

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

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

2. SCOPE

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

3. DEFINITIONS

Dry feed

Means *feed* that has a moisture content equal to or less than 15%.

Feed

Means any material (single or multiple), whether processed, semi-processed or raw that is intended to be fed directly to food-producing animals.

Feed additives

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

Feed ingredient

Means a component, part or constituent of any combination or mixture making up a *feed*, including *feed additives*, whether or not it has a nutritional value in the animal's diet. Ingredients may be of terrestrial or aquatic, plant or animal origin and may be organic or inorganic substances.

Hazard

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

Live feed

Means live farmed or wild caught animals and algae used as *feed* for *aquatic animals*. *Live feed* is often fed to aquatic animal species at an early life-stage and to aquatic animal species that have been cultured for a relatively short time.

Meal

Means a product derived from an aquatic animal that has been ground and heat processed to reduce the moisture content to less than 10 %.

Medicated feed

Means any *feed* which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.

Moist (or wet) feed

Means *feed* that has a moisture content equal to or greater than 70%.

Semi-moist feed

Means *feed* that has a moisture content between 15 and 70%.

Fish solubles

Means a by-product of the fish oil production system, comprising the product remaining when water is drawn off (evaporated) from the residual aqueous phase.

4. GENERAL PRINCIPLES

a) Roles and responsibilities

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

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

Those involved in the production and use of animal *feed* and *feed ingredients* have the responsibility to ensure that these products meet regulatory requirements[8]. All personnel involved in the harvest, manufacture, storage and handling of *feed* and *feed ingredients* should be adequately trained and aware of their role and responsibility in preventing the spread of *hazards*. Appropriate contingency plans should be developed in case of a *feed*-borne *disease* outbreak. Equipment for producing, storing and transporting *feed* should be kept clean and maintained in good working order.

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

b) Regulatory standards for feed safety

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

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[8] If at the national level, there are specific food-safety or animal health regulations related to genetically modified organisms, these should be taken into account in relation to feed and feed ingredients as these products form an important part of the food chain.

c) Risk analysis

Internationally accepted principles and practices for *risk analysis* (see Section 1.4. of the *Aquatic Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

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

d) Good practices

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

Where appropriate, Hazard Analysis and Critical Control Point[9] (HACCP) principles should be followed to control *hazards* that may occur in *feed*.

e) Relationship between prions and *aquatic animal* species

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

f) Bioaccumulation

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

g) Geographic and environmental considerations

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

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

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

h) Zoning and compartmentalisation

Feed is an important components of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 1.4.4. of the *Aquatic Code*.

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[9] Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene (CAC/RCP 1-1969).

i) Sampling and analysis

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

j) Labelling

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

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

k) Design and management of inspection programmes

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

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

l) Assurance and certification

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

m) Hazards associated with aquatic animal *feed*

Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, fungi and parasites. The scope of these guidelines is limited to the *diseases* referred to in this *Aquatic Code*.

Chemical hazards

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

Physical hazards

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

n) Cross contamination

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

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

o) Antimicrobial resistance

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

p) Management of information

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

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

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

5. PATHOGENS IN FEED

a) Pathogens can be introduced into *feed* in the following ways:

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

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

b) *Aquatic animals* can be exposed to pathogens in *feed* in the following ways:

i) Direct exposure

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

ii) Indirect exposure

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

6. CHEMICAL AGENTS IN *FEED*

[under study]

7. PHYSICAL AGENTS IN *FEED*

[under study]

8. RECOMMENDED APPROACHES TO RISK MITIGATION

a) *Commodities*

Safe *commodities*

The following *commodities* undergo extensive processing such as heat treatment, acidification, extrusion and extraction. There is a negligible risk that pathogens will survive in such products if they have been produced in accordance with normal commercial practice:

i) fish oil;

ii) crustacean oil;

iii) *fish solubles*;

iv) fish *meal*;

v) crustacean *meal*;

vi) squid meal and squid liver-meal;

vii) bivalve *meal*;

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

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

Other *commodities*

Competent Authorities should consider the following risk mitigation measures.

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

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

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

iv) use of *feed* only in *populations* that are not susceptible to the pathogen(s) in question.

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

Whole fish (fresh or frozen)

The practice of trading fresh or frozen whole marine fish for use as aquatic *feed* presents a *risk* of introducing *diseases* into *populations*. Given the difficulty of imposing effective *risk* mitigation measures, this practice is not recommended.

Feed production

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

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

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

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

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

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

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

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

Importing countries:

Competent Authorities should consider the following measures:

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

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

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

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

9. CERTIFICATION PROCEDURES FOR *FEEDS* OF AQUATIC ORIGIN

When importing *feed* and *feed ingredients* of aquatic origin other than those mentioned in Article X.X.X. [Article with safe commodities, currently point 8], the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* (or a *certifying official* approved by the *importing country*).

This certificate should certify:

i) that *feed* and *feed ingredients* of aquatic origin were obtained from a country, *zone* or *compartment* that is free from relevant aquatic animal *diseases*[10]; or

ii) that *feed* and *feed ingredients* of aquatic origin were tested for relevant aquatic animal *diseases*[11] and shown to be free of these *diseases*; or

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

Specific provisions for *diseases* referred to in this *Aquatic Code* may be found in relevant disease chapters of the *Aquatic Code*.

10. RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST, MANUFACTURE AND USE OF AQUATIC FEEDS

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

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

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

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

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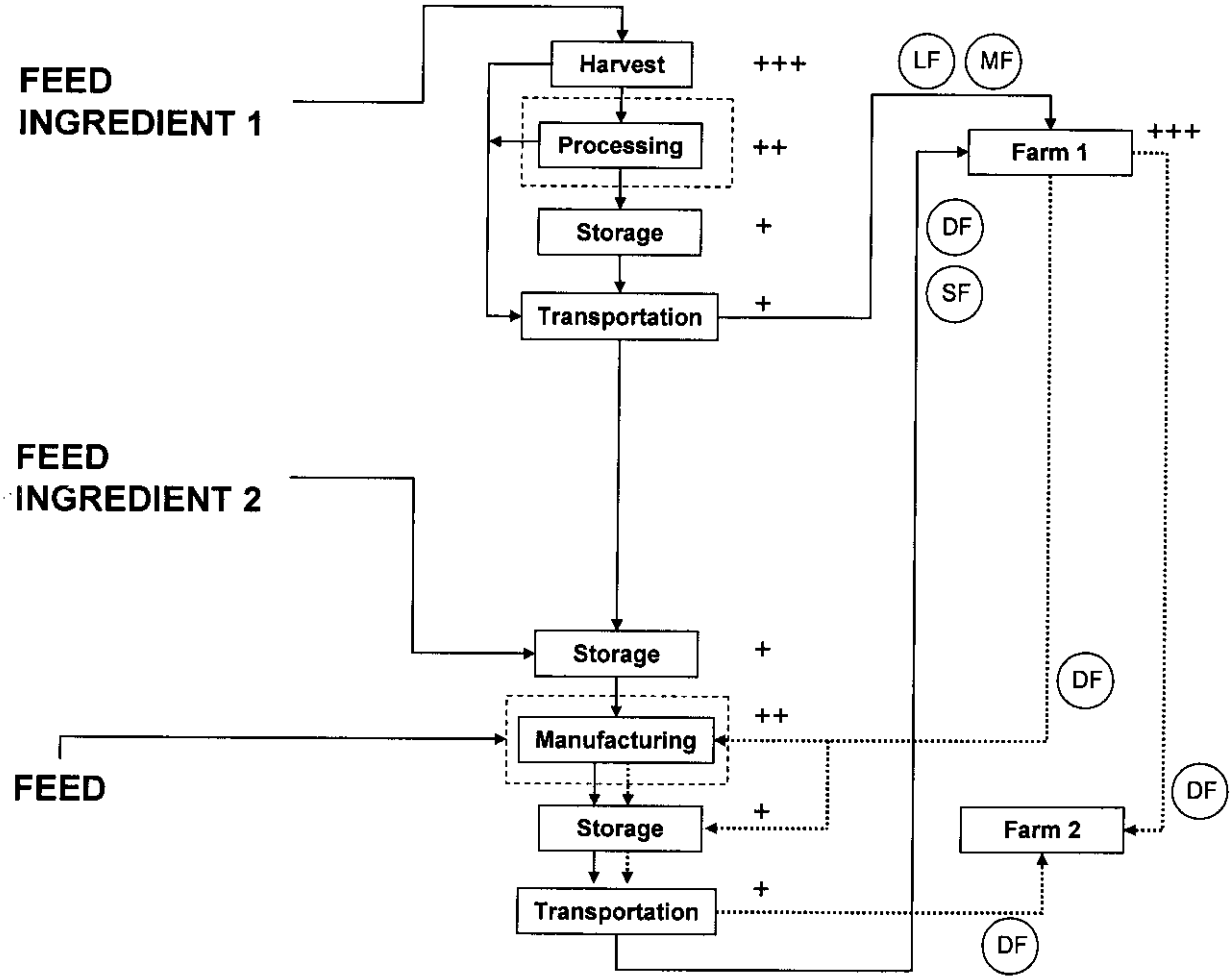
[10] Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

[11] Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

Figure 1: **RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST, MANUFACTURE AND USE OF AQUATIC FEEDS**



Feed MF: Moist feed SF: Semi-moist feed DF: Dry feed	Possibility for risk reduction
+++: High risk of pathogen presence ++: Moderate risk of pathogen presence +: Low risk of pathogen presence	Redistribution or recycling of finished feed

Annex XIV

CHAPTER 2.4.1.

INFECTION WITH *BATRACHOCHYTRIUM DENDROBATIDIS*

Community comment

The Community agrees with the proposed chapter

However, we would like that the OIE takes the following comments into account.

Article 2.4.1.1.

For the purposes of the *Aquatic Code*, infection with *Batrachochytrium dendrobatidis* means infection with the freshwater fungus *Batrachochytrium dendrobatidis* Fungi, Chytridiomycota, Rhizophydiales.

Methods for conducting surveillance and diagnosis of infection with *Batrachochytrium dendrobatidis* are provided in the *Aquatic Manual* (under development).

Article 2.4.1.2.

Community comment

Two separate lists of susceptible species, one in the Code (susceptible species) and one in the Manual (other susceptible species) is misleading, as they create, in fact, two categories of susceptible species.

For the sake of clarity, we would kindly suggest to the OIE to include all susceptible species to this specific infection in this article.

Scope

The recommendations in this Chapter apply to: all species of Anura (frogs and toads), Caudata (salamanders, newts and sirens) and Gymnophiona (caecilians). The recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.4.1.3.

Community comment
Before introducing the concept of vector, as it is mentioned in point 3 it is completely necessary to define what Member Countries should understand with this term

Commodities

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

   a) For the species referred to in Article 2.4.1.2. intended for any purpose:

      i) *commodities* treated in a manner that kills the *disease agent* e.g. canned products; leather made from amphibian skin; dried amphibian products (including air dried, flame dried and sun dried);

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 2.4.1.2. which have been prepared and packaged for direct retail trade:

i) skinned frog legs with feet removed;

ii) skinned amphibian carcasses or meat, with hands and feet removed.

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 2.4.1.2., other than those referred to in point 1 of Article 2.4.1.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.4.1.7. to 2.4.1.12. relevant to the *Batrachochytrium dendrobatidis* 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 *Batrachochytrium dendrobatidis* of any live *commodity* of a species not covered in Article 2.4.1.2. but which could reasonably be expected to be a potential *Batrachochytrium dendrobatidis* vector, 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 2.4.1.4.

Community comment
The Community would like that the OIE AAC explains the reason to increase the period from the standard 10 years to the proposed 25 years.

Batrachochytrium dendrobatidis free country

A country may make a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* 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 *Batrachochytrium dendrobatidis* if all the areas covered by the *zone* are declared *Batrachochytrium dendrobatidis* free (see Article 2.4.1.5.).

1. A country where none of the *susceptible species* referred to in Article 2.4.1.2. is present may make a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* 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 2.4.1.2. are present but there has been no 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 *Batrachochytrium dendrobatidis* when *basic biosecurity conditions* have been continuously met 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 *Batrachochytrium dendrobatidis* when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* 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 1.1.4. and X.X.X. of the *Aquatic Manual* (under development), has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*; 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 2.4.1.5.

Article 2.4.1.5.

Community comment

The Community would like that the OIE AAC explains the reason to increase the period from the standard 10 years to the proposed 25 years.

The Community would suggest to the OIE to reconsider its position as regards the issue of defining and re-establishing (after a breakdown) the disease free status of a compartment.

We would argue that for certain compartments, formed by a single establishment, disease free status could be regained if amphibian population is removed and disposed off, the establishment is properly disinfected and, where appropriate fallowed, and finally restocked with amphibians from a certified free source.

The Community would suggest including a new point 5 in this article that would read:

" a compartment previously declared free from infection with B. dendrobatidis but in which the disease is detected may not be declared free from that disease until the following conditions have been met:

a) the requirements in point 4, or

b) in the case that the compartment is formed by one single farm and it is supplied by water from a spring, borehole or other safe supply independent of the heath status of the surrounding waters and it is equipped with a barrier that prevents the migration of aquatic animals of susceptible species into the compartments or its water supply:

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures have been completed and followed, when necessary, by fallowing

ii) the compartment is repopulated with amphibians from a certified free population.

***Batrachochytrium dendrobatidis* free zone or free compartment**

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

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.4.1.2. is present may be declared free from *Batrachochytrium dendrobatidis* 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 2.4.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual* (under development), may be declared free from *Batrachochytrium dendrobatidis* when *basic biosecurity conditions* have been continuously met 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*, under development), may be declared free from *Batrachochytrium dendrobatidis* when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* (under development), has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*.

OR

4. A *zone* previously declared free from *Batrachochytrium dendrobatidis* but in which the *disease* is subsequently detected may be declared free from *Batrachochytrium dendrobatidis* 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*; 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 2.4.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Batrachochytrium dendrobatidis* following the provisions of points 1 or 2 of Articles 2.4.1.4. or 2.4.1.5. (as relevant) may maintain its status as *Batrachochytrium dendrobatidis* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Batrachochytrium dendrobatidis* following the provisions of point 3 of Articles 2.4.1.4. or 2.4.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Batrachochytrium dendrobatidis* free provided that conditions that are conducive to clinical expression of *Batrachochytrium dendrobatidis*, 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 *Batrachochytrium dendrobatidis*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.4.1.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Batrachochytrium dendrobatidis*

When importing live *aquatic animals* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*, 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 2.4.1.4. or 2.4.1.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*.

The *certificate* should be in accordance with the Model Certificate (under study) in Annex 4.X.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.8.

Community comment

If the OIE would like to introduce a scheme of treatment and testing prior to export as it is laid down in point 1a) i), the scheme should be clearly described in that chapter. Furthermore, it is unclear point 1a) ii) as we wonder where (Country, zone, compartment) susceptible species have not been introduced during that period.

A clear scientific basis should be provided to allow the movements of disinfected eggs in order to accept point 1)a) iii).

The scope of point 2 of this article is unclear as there is no definition of what is meant by "new stock". Does it mean an introduction of a non-native species in a country? Further clarification is needed.

In addition, we would repeat that if the OIE AAC intention is to include a reference to the ICES Code such reference should be made to the whole ICES CODE, as a short summary might be misleading. One possible solution would be to include the web link to the whole ICES document in point 3 of this article.

Importation of live aquatic animals for farming from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

1. When importing live aquatic animals of species referred to in Article 2.4.1.2. from a country, zone or compartment not declared free from Batrachochytrium dendrobatidis, the Competent Authority of the importing country should:

   a) require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that:

      i) the *aquatic animals* have been appropriately treated to eradicate infection and have been subsequently tested to confirm absence of the disease according to specifications provided in the relevant chapter in the *Aquatic Manual* (under development); and

      ii) no other live *aquatic animals* of the species referred to in Article 2.4.1.2. have been introduced during that period;

      OR

      iii) in the case of eggs, the eggs have been disinfected;

   OR

   b) assess the *risk* and apply risk mitigation measures such as:

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

      ii) the treatment of all effluent and waste materials in a manner that kills *Batrachochytrium dendrobatidis*.

2. For the purposes of the *Aquatic Code* the following steps should be taken if the importation is for the establishment of a new stock:

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

   b) evaluate stock's health/disease history;

   c) take and test samples for *Batrachochytrium dendrobatidis*, 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

Batrachochytrium dendrobatidis and perform general examinations for pests and general health/disease status;

g) if *Batrachochytrium dendrobatidis* 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 *Batrachochytrium dendrobatidis* free or specific pathogen free (SPF) for *Batrachochytrium dendrobatidis*;

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* not declared free from *Batrachochytrium dendrobatidis*, the *Competent Authority* of the *importing country* should require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.4.1.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that kills *Batrachochytrium dendrobatidis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.10.

Community comment

If the OIE would like to introduce a scheme of treatment and testing prior to export as it is laid down in point 1a), the scheme should be clearly described in that chapter. Furthermore, it is unclear point 1b) as we wonder where (Country, zone, compartment) susceptible species have not been introduced during that period.

In addition, a clear scientific basis should be provided to allow the movements of disinfected eggs in order to accept point 1)a) iii).

Importation of live aquatic animals intended for use in animal feed, or for agricultural, laboratory, zoo, pet trade, industrial or pharmaceutical use, from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

When importing live *aquatic animals* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* not declared free from *Batrachochytrium dendrobatidis*, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that:

   a) the *aquatic animals* have been appropriately treated to eradicate infection and have been subsequently tested to confirm absence of the diseases according to specifications provided in the relevant chapter in the *Aquatic Manual*; and

b) no other live *aquatic animals* of the species referred to in Article 2.4.1.2. have been introduced during that period;

OR

c) in the case of eggs, the eggs have been disinfected;

OR

2. assess the *risk* and apply risk mitigation measures such as:

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

b) the treatment of all effluent and waste materials in a manner that kills *Batrachochytrium dendrobatidis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.11.

Importation of aquatic animal products from a country, zone or compartment declared free from *Batrachochytrium dendrobatidis*

When importing *aquatic animal products* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*, 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 2.4.1.4. or 2.4.1.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*.

The *certificate* should be in accordance with the Model Certificate (under study) in Annex 4.X.X.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.12.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

1. When importing *aquatic animal* products of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* not declared free from *Batrachochytrium dendrobatidis*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate risk mitigation measures.

2. In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include:

a) the direct delivery into and holding of the consignment in biosecure facilities for processing to one of the products referred to in point 1 of Article 2.4.1.3. or other products authorised by the *Competent Authority*;

b) the treatment of all effluent and waste materials in a manner that kills *Batrachochytrium dendrobatidis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Annex XV

CHAPTER 2.4.2.

INFECTION WITH RANAVIRUS

Community comment

The Community agrees with the proposed chapter.

However, we would like that the OIE takes the following comments into account.

Article 2.4.2.1.

For the purposes of the *Aquatic Code*, infection with ranavirus means infection with any members of the genus *Ranavirus* in the family Iridoviridae with the exception of epizootic haematopoietic necrosis virus and European catfish virus.

Methods for conducting surveillance and diagnosis of infection with ranavirus are provided in the *Aquatic Manual*.

Article 2.4.2.2.

Community comment

Two separate lists of susceptible species, one in the Code (susceptible species) and one in the Manual (other susceptible species) is misleading, as they create, in fact, two categories of susceptible species.

For the sake of clarity, we would kindly suggest to the OIE to include all susceptible species to this specific infection in this article.

Scope

The recommendations in this Chapter apply to: all species of Anura (frogs and toads) and Caudata (salamanders and newts). The recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.4.2.3.

Community comment
Before introducing the concept of vector, as it is mentioned in point 3 it is completely necessary to define what Member Countries should understand with this term.

Commodities

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

   a) For the species referred to in Article 2.4.2.2. intended for any purpose:

      i) *commodities* treated in a manner that kills the *disease agent* e.g. canned products; leather made from amphibian skin;

iii) 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 2.4.2.2. which have been prepared and packaged for direct retail trade:

i) skinned frog legs;

ii) skinned amphibian carcasses or meat.

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 2.4.2.2., other than those referred to in point 1 of Article 2.4.2.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.4.2.7. to 2.4.2.12. relevant to the ranavirus 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 ranavirus of any live *commodity* of a species not covered in Article 2.4.2.2. but which could reasonably be expected to be a potential ranavirus vector, 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 2.4.2.4.

Community comment

Time frames in point 2 and 3 does not match.

Ranavirus free country

A country may make a *self-declaration of freedom* from ranavirus 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 ranavirus if all the areas covered by the *zone* are declared ranavirus free (see Article 2.4.2.5.).

1. A country where none of the *susceptible species* referred to in Article 2.4.2.2. is present may make a *self-declaration of freedom* from ranavirus 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 2.4.2.2. are present but there has been no observed occurrence of the *disease* for at least the past 15 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual* (under development), may make a *self-declaration of freedom* from ranavirus 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 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,* under development), may make a *self-declaration of freedom* from ranavirus when:

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

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* (under development), has been in place for at least the last 2 years without detection of ranavirus.

OR

4. A country that has previously made a *self-declaration of freedom* from ranavirus but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from ranavirus 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 1.1.4. and X.X.X. of the *Aquatic Manual* (under development), has been in place for at least the last 2 years without detection of ranavirus; 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 2.4.2.5.

Article 2.4.2.5.

Community comment

The Community would like that the OIE AAC explains the reason to increase the period from the standard 10 years to the proposed 25 years. The Community would suggest to the OIE to reconsider its position as regards the issue of defining and re-establishing (after a breakdown) the disease free status of a compartment.

We would argue that for certain compartments, formed by a single establishment, disease free status could be regained if amphibians population is removed and disposed off, the establishment is properly disinfected and, where appropriate fallowed, and finally restocked with amphibians from a certified free source.

The Community would suggest including a new point 5 in this article that would read:

" a compartment previously declared free from infection with ranavirus but in which the disease is detected may not be declared free from that disease until the following conditions have been met:

a) the requirements in point 4, or

b) in the case that the compartment is formed by one single farm and it is supplied by water from a spring, borehole or other safe supply independent of the heath status of the surrounding waters and it is equipped with a barrier that prevents the migration of aquatic animals of susceptible species into the compartments or its water supply:

i) infected populations have been safely destroyed or removed from the infected compartment by means that minimise the risk of further spread of the disease, and appropriate disinfection procedures have been completed and followed, when necessary, by fallowing

ii) the compartment is repopulated with amphibian from a certified free population.

Ranavirus free zone or free compartment

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

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.4.2.2. is present may be declared free from ranavirus 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 2.4.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual* (under development), may be declared free from ranavirus when *basic biosecurity conditions* have been continuously met 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,* under development), may be declared free from ranavirus when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual* (under development), has been in place for at least the last 2 years without detection of ranavirus.

OR

4. A *zone* previously declared free from ranavirus but in which the *disease* is subsequently detected may be declared free from ranavirus 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 1.1.4. and X.X.X. of the *Aquatic Manual* (under development), has been in place for at least the last 2 years without detection of ranavirus; 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 2.4.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from ranavirus following the provisions of points 1 or 2 of Articles 2.4.2.4. or 2.4.2.5. (as relevant) may maintain its status as ranavirus free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from ranavirus following the provisions of point 3 of Articles 2.4.2.4. or 2.4.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as ranavirus free provided that conditions that are conducive to clinical expression of ranavirus, as described in Chapter X.X.X. of the *Aquatic Manual* (under development), 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 ranavirus, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.4.2.7.

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

When importing live *aquatic animals* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* declared free from ranavirus, 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 2.4.2.4. or 2.4.2.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from ranavirus.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.X.X.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.8.

Community comment

Point 1a) of this article is unclear. Further development is needed.

The scope of point 2 of this article is unclear as there is no definition of what is meant by "new stock". Does it mean an introduction of a non-native species in a country? Further clarification is needed.

In addition, we would repeat that if the OIE AAC intention is to include a reference to the ICES Code such reference should be made to the whole ICES CODE, as a short summary might be misleading. One possible solution would be to include the web link to the whole ICES document in point 3 of this article.

Importation of live aquatic animals for farming from a country, zone or compartment not declared free from ranavirus

1. When importing live aquatic animals of species referred to in Article 2.4.2.2. from a country, zone or compartment not declared free from ranavirus, the Competent Authority of the importing country should:

   a) require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that no other live *aquatic animals* of the species referred to in Article 2.4.2.2. have been introduced during that period;

   OR

   b) assess the *risk* and apply risk mitigation measures such as:

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

      ii) the treatment of all effluent and waste materials in a manner that kills ranavirus.

2. For the purposes of the *Aquatic Code* the following steps should be taken if the importation is for the establishment of a new stock:

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

   b) evaluate stock's health/disease history;

   c) take and test samples for ranavirus, 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 ranavirus and perform general examinations for pests and general health/disease status;

   g) if ranavirus 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 ranavirus free or specific pathogen free (SPF) for ranavirus;

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.9.

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

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.4.2.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that kills ranavirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.10.

Community comment

Point 1 of this article is unclear. Further development is needed.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, laboratory, zoo, pet trade, industrial or pharmaceutical use, from a country, zone or compartment not declared free from ranavirus

When importing live *aquatic animals* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that no other live *aquatic animals* of the species referred to in Article 2.4.2.2. have been introduced during that period;

OR

2. assess the *risk* and apply risk mitigation measures such as:

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

   b) the treatment of all effluent and waste materials in a manner that kills ranavirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.11.

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

When importing *aquatic animal products* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* declared free from ranavirus, 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 2.4.2.4. or 2.4.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from ranavirus.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.X.X.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.12.

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

1. When importing *aquatic animal* products of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate risk mitigation measures.

2 In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include: Annex XV (contd)

a) the direct delivery into and holding of the consignment in biosecure facilities for processing to one of the products referred to in point 1 of Article 2.4.2.3. or other products authorised by the *Competent Authority*;

b) the treatment of all effluent and waste materials in a manner that kills ranavirus.

3. This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Annex XVI

CHAPTER X.X.X.

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

Community comment

The Community acknowledges a chapter in this area. However, the chapter needs further elaboration.

Examples of where the terminology must be clarified are "disposal plant", which is used also in the context for production of technical- or pharmaceutical products; this is not in line with the Community rules/opinion. Other examples are that "disposal treatment" and "processing" are used in an inconsistent way throughout the chapter. Furthermore, there is no justification for using different wordings in "high risk *material*" and "low risk *waste*".

As a general remark, we would like to point out that the proposed guidelines do not face the problem of the trade requirements of "high risk material" and "low risk waste". We encourage the OIE to include specific provisions to deal with this issue in future amendments of the Guidelines.

Article X.X.X.1.

Community comment

This article refers to aquatic animals dying due to disease or accidentally due to different causes during aquaculture operations. However, both possibilities do not cover the deliberate killing of animals in the case of a disease outbreak. Therefore, this article should be reworded to cover culling of animals to control a disease.

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 *Competent Authority* should be notified so that necessary steps can be taken to dispose of the dead aquatic animals in order to minimize 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.

Carcasses to be disposed of and the disposal process to be chosen should be under the supervision of 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 legislation. The guidelines should be applied in conjunction with procedures described for the killing of aquatic animals in Appendix XXXXX.

Article X.X.X.2.

Community comment

For the sake of clarity, we would prefer that the OIE includes these definitions in Chapter 1.1.1. of the Code (Definitions).

Definitions

For the purpose of these guidelines, the following definitions are relevant to the disposal of aquatic animal carcasses and their wastes:

Community comment
The definition of Aquatic animals must cover amphibians, as they are under the scope of the Aquatic Code.

- **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 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.

- **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 by means of i.e. 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 carcasses and reducing the pH in the mass by adding an organic acid. The pH must be kept below 4.0.

- **High risk 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: animal wastes 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 carcasses and processing wastes 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 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 wastes may take place after:

a) Chilling/freezing down to 4° 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*.

Article X.X.X.4.

Regulations and Jurisdiction

The legislation regulating aquatic animal health and the organisation of the Veterinary Administration should 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 wastes. Cooperation between the Veterinary Service and any other relevant bodies involved in aquatic animal health is necessary to ensure safe disposal. In this context the following aspects should be regulated:

1. right of entry to an establishment for the veterinary services and associated personnel;

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. any need to transfer ownership of dead aquatic animals to the competent authority;

5. the determining of the method and location of disposal, and the necessary equipment and facilities, by the *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 be applied near the border of a neighbouring country, the competent authorities of that country should be consulted.

Article X.X.X.5.

Community comment

To improve the clarity of this article we kindly suggest to the OIE to define what should be understood as "intermediate storage".

Collection, storage and labelling of aquatic animal carcasses/ wastes

1. On farm storage

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

Aquatic animal carcasses and waste must be stored at an appropriate temperature or pH, and in a manner that prevents leakage of infectious agents to the environment. 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 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.

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 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 must be in pursuance with regulations given by the *Competent Authority*.

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

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

Article X.X.X.6.

Community comment

With regard point 1 "High risk waste", in order to prevent in a better way the spread of aquatic animal diseases we would propose the following wording:

"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 of contagious diseases. The *Competent Authority* may give exemptions from the instructions for disposal including permission to disposal by embedment or incineration outside an approved incineration plant upon judgment as regards spread of disease, capacity of the disposal plant, availability of transporting vehicle, distance of transportation and the amount of waste. If a plant which is approved for low risk waste is used for the disposal for high risk waste the Competent Authority has to reapprove the plant for low risk waste after the disposal operation before it may be reused for low risk waste "

With regard to point 3 litra f) "Disposal methods" we propose the addition of the following sentence:

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 must depend on the pathogen in question, the number/volume of aquatic animals to be disposed and the site chosen for disposal. The choice must be based on an assessment of potential risk to public and animal health as well potential effects on the environment arising from the disposal".

Handling, storage and processing of risk 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* or according to specific regulations regarding combat of contagious diseases. The *Competent Authority* may give exemptions from the instructions for disposal including permission to disposal by embedment or incineration outside an approved incineration plant upon judgment as regards spread of 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 fur- and production animals (pigs, poultry, ruminants), technical or pharmaceutical products 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 being handled or transported together with high risk waste or being mixed with high risk waste, such waste are to be considered as high risk waste and must be treated as such.

3. Processing of high risk material

   a) Registration and labelling of batches

Disposal plants must have a system for registration and labelling of each batch 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.

b) Notification

If testing of high risk material shows that the product is not satisfactorily produced and thus may be a risk for spreading of an infectious agent, disposal plants have to report immediately to the *Competent Authority* which then may requirre additional measures to solve the problem.

Unsatisfactorily processed products must not be transported from disposal plants without permission from the *Competent Authority*.

c) Reporting

Disposal plants must report annually to the *Competent Authority* on its operations. The report 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 provisions in pursuance with the 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 spread of any infectious agent. Procedures should also be in place to avoid spread of 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 must depend on the pathogen in question, the number/volume of aquatic animals to be disposed and the site chosen for disposal.

Article X.X.X.7.

Community comment

With regard to sterilisation plants, we would like that the OIE AAC provide an explanation of the temperatures/timeframe/pressure proposed. In our experience a thermal treatment of 133 C for 20 minutes at a pressure of 3 bar gives enough certainty of sterilisation.

Conditions for approval, inspection, supervision of disposal plants and sampling

1. Approval of disposal plants

Disposal plants handling wastes of aquatic animals must be approved by the *Competent Authority*.

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

Disposal plants using low risk material 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 wastes, it must:

a) be adequately separated from the public highway and other premises such as fishfarms, fish slaugtherhouses, 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 wastes given by the *Competent Authority*;

e) fulfill requirements for handling the products as given by the *Competent Authority*.Annex XVI (contd)

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 must be localised at an adequate distance from other aquaculture enterprises such as fish slaughterhouses, processing plants and fish farms so that the risk of spread of infectious agents to such establishments is minimal.

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

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

d) The unclean section must have floors from which it is easy to collect and lead away liquids. It 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 must be in place.

f) Handling and treatment of aquatic animal waste should take place as soon as possible after being received.and it 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 must be in place.

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

j) The end product 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, must be ensiled as soon as possible after arrival.

The ensiled mass 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 40 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 must fulfil the general criteria given above. Aquatic animal waste must be incinerated as soon as possible after being received. Prior

d) Composting plants

A composting plant 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 must be composted as soon as possible after being received.

Composting 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 must not be ended until decimation of possible infectious agents have been achieved.

e) Biogas plants

A biogas plant 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 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 must be in place at the destruction plants. A general documentation system for internal control including sampling for control of critical points 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, must be kept for a given period decided upon by the *Competent Authority.* Analyses and sampling 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 carcases 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 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 carcases 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.

Community comment

The methods for handling of waste material are mainly focused on fish species. Most of them are difficult to apply to mollusc and crustaceans. We would encourage the OIE to adapt this chapter to the specific conditions of the mollusc and crustaceans.
The proposed article lists exhaustively the methods and treatments for handling of waste material without making a distinction between the two categories of waste material. The article should list for each category specifics methods and treatments.

Methods for handling of waste material (carcasses, parts of carcasses)

Disposal may 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 must be in place when transporting infectious material (carcasses/other waste material) from infected aquaculture premises to the place of pathogen inactivation/disposal handling.

Recommended methods for pathogen inactivation and disposal 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) accepted by the *Competent Authority* based on risk assessments as regards aquatic animal 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 carcasses and/or other material to be buried. It should be located at a distance from watercourses, the sea, water-supply (wells, boreholes), fish farms and proximity to areas easily accessed by the public. Fencing and restricted admittance may be necessary.

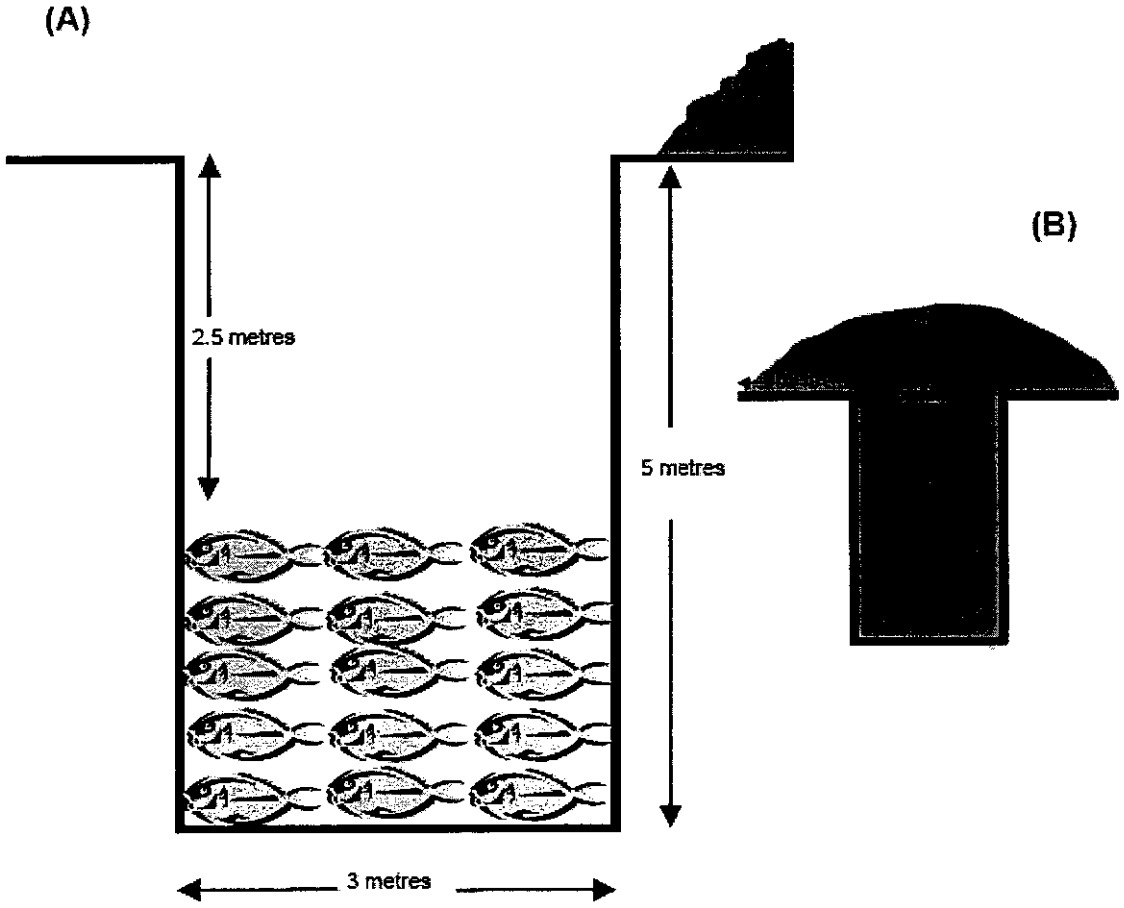
- The pit dimension depends on the volume of the fish carcasses and/or material to be buried. Furthermore, they should be constructed in such away that they are easy to fill with carcasses and other material to be buried. Fig 1 shows how a pit may be constructed (by courtesy of *AQUAVETPLAN*).

- The pit filling content should be covered with unslaken lime (CaOH) at a rate of 85 kg per 1000 kg fish material to hasten decomposition and to prevent that contaminated material to be surfaced by scavengers, etc. If necessary, such pits should be inspected in order to ensure that no leakages of infected material occur.

Whenever possible, the material should be subjected to a pathogen reducing treatment 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 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.

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 wastes

Chemical and biological treatment of carcasses/wastes 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).

4. Ensiling

Ensiling of 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 – 4 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. Ensiling of 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 for15-20 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.

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 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 concluded 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 carcasses or other organic material may be carried out by different methods, such as burning, incineration, heating (pasteurization) and sterilisation.

8. Incineration

Incineration is a controlled burning process carried out in fixed incinerators, air curtain incinerators or municipal incinerators tested and authorized by the *Competent Authority*. Air curtain incinerators are a mobile incineration system that may be brought on site. Aquatic animal carcasses/wastes may thus be burned to ashes on spot and transportation of infected material is not required.

Leak-proof transportation of input material to incinerators on fixed locations is necessary as well as requirements for subsequent disinfection of vehicles transporting carcasses/other waste material.

Incinerators for biological material are very effective for a complete disposal of carcasses/other waste material of aquatic animals/pathogens and with little or no pollution to the environment. Incinerators, however, may only be capable of handling limited volumes of biological material.

9. Pyre burning

Pyre burning is not so convenient to handle large amounts of carcasses/wastes 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 carcasses/other material to be disposed.

- *Fire management* 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 carcasses will be destroyed within 48 hours. The ashes should then be brought to a place of disposal approved by the *Competent Authority*.

10. Heating

a) Pasteurisation

Heat treatment at temperatures below 100°C can be considered as pasteurisation 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 moderate heat treatment 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 1 hr 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/ 1 hr, and a particle size below 30 mm for heating at 70°C/1 hr. Batch treatment should be used to safeguard the microbiological safety of the process and end-product.

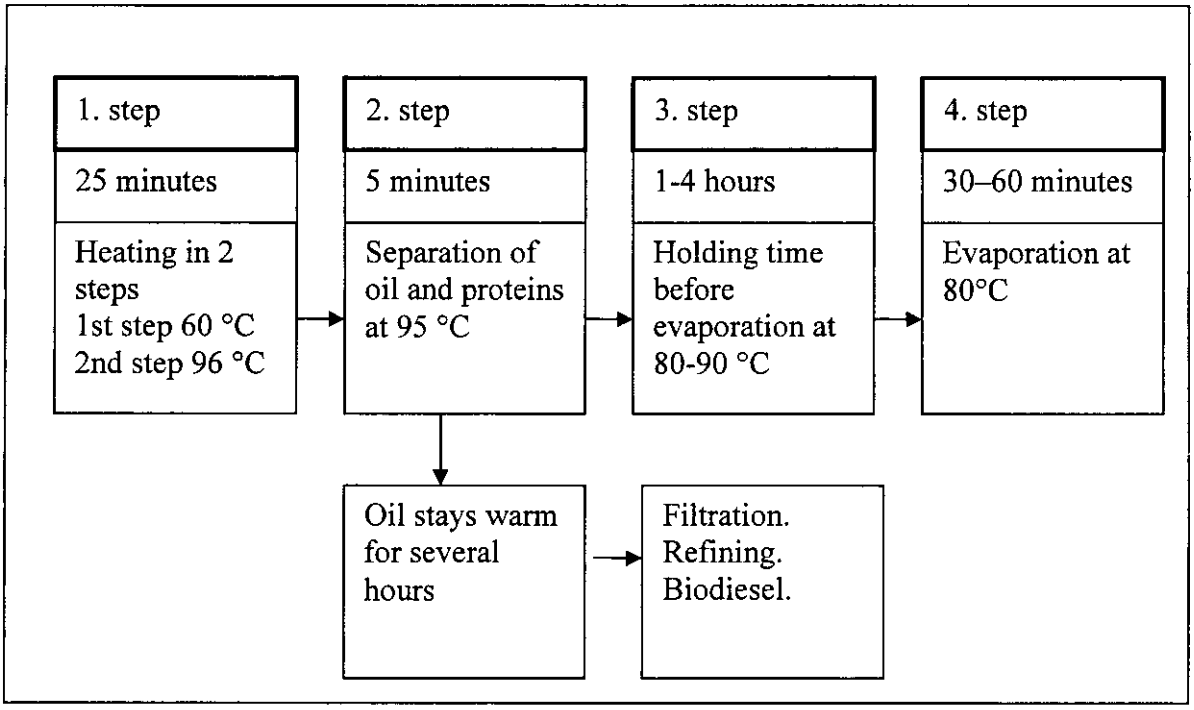
b) Sterilisation

Sterilisation of fish material based on the process described for terrestrial animals (133°C, 3 bars for 20 minutes) may lead to problems due to technological difficulties and a product that cannot be used as feed or fertiliser due to glue formation and hydrolysis of proteins ((EU – Use of by products in aquaculture).

11. Rendering

a) This is a closed system for the mechanical and thermal treatment of aquatic animal tissues leading to stable, sterilized 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

Step 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 will be decanted and purified before further processing.

* *
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APPENDIX X.X.X.

GUIDELINES FOR AQUATIC ANIMAL HEALTH SURVEILLANCE

Article x.x.x.1.

Community comment

The Community acknowledges the efforts made by the OIE AAC to draft the guidelines.

However, clarification and simplification would be desirable whether these guidelines are to be used as a reference for other disease specific surveillance guidelines.

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);

Annex XVII (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 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 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 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.

Definitions of appropriate populations should be based on the specific recommendations of the *disease* chapters of the *Aquatic Manual*.

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 Appendix 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 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 Appendix 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 Appendix.

Although not determined for many aquatic *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 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 XVII (contd)

Article x.x.x.4.

Structured 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 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, the level of confidence desired of the survey results and the performance of the tests used.

Article x.x.x.5.

Structured non-random 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

This may involve testing targeted to selected sections of the population (subpopulations), in which *disease* is more likely to be introduced or found. Examples include testing culled and dead animals, animals exhibiting clinical signs, animals located in a defined geographical area and specific age or commodity group.

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 surveillance

There is 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 (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.

Community comment

This article is focused in freedom from disease. However, with the current definitions of infection-infestation the focus is actually freedom from infection-infestation. Therefore, we would suggest that the OIE replaces "disease" with "infection-infestation".

During recent years feral marine fish have been intensively studied for viruses in Europe and North America and many fish species are found to be carriers of for example VHS strains. According to Einer-Jensen *et al.* (2004) host adaptation from marine environment/species to rainbow trout has occurred three or four times in freshwater, marine or brackish water farms. Raw, marine fish used for feeding of rainbow trout have been considered to be the main risk factor.

With the present knowledge regarding feral fish and wording in Article x.x.x.6 and x.x.x.7 it would difficult to declare e.g. VHS-freedom in marine or brackish water farms at least in some parts of Europe and North America. However, according to practical experience based on 15 years of surveillance in the Community in marine salmon and rainbow trout farms it has been shown that marine or brackish water farms are able to maintain VHS-freedom despite of the fact that several VHS strains occur in feral fish. However, it has also been shown that adaptation from wild fish to rainbow trout may occur every now and then, especially if raw marine fish is fed to farmed fish.

We agree that with the present knowledge it should not be possible to declare VHS-freedom by "Historically free" pathway (Article x.x.x.6, point 2) if there is any evidence that the pathogen occurs in wild fish. However, in order to better reflect the present knowledge and experiences the Community would like the OIE to consider deleting point 3 c) in Article x.x.x.6 and point 4 in article x.x.x.7. The Community suggests the following paragraph after point 3 in article x.x.x.7 (Maintenance of disease free status):

If there is reason to believe that the epidemiological situation in the wild population poses a significant risk for the introduction of a pathogen to the farmed population, target surveillance of the farms should not be discontinued.

Further more, targeted surveillance should not be discontinued in disease free zones or compartments in countries not declared disease free, or when fresh or frozen marine fish is fed for farmed fish.

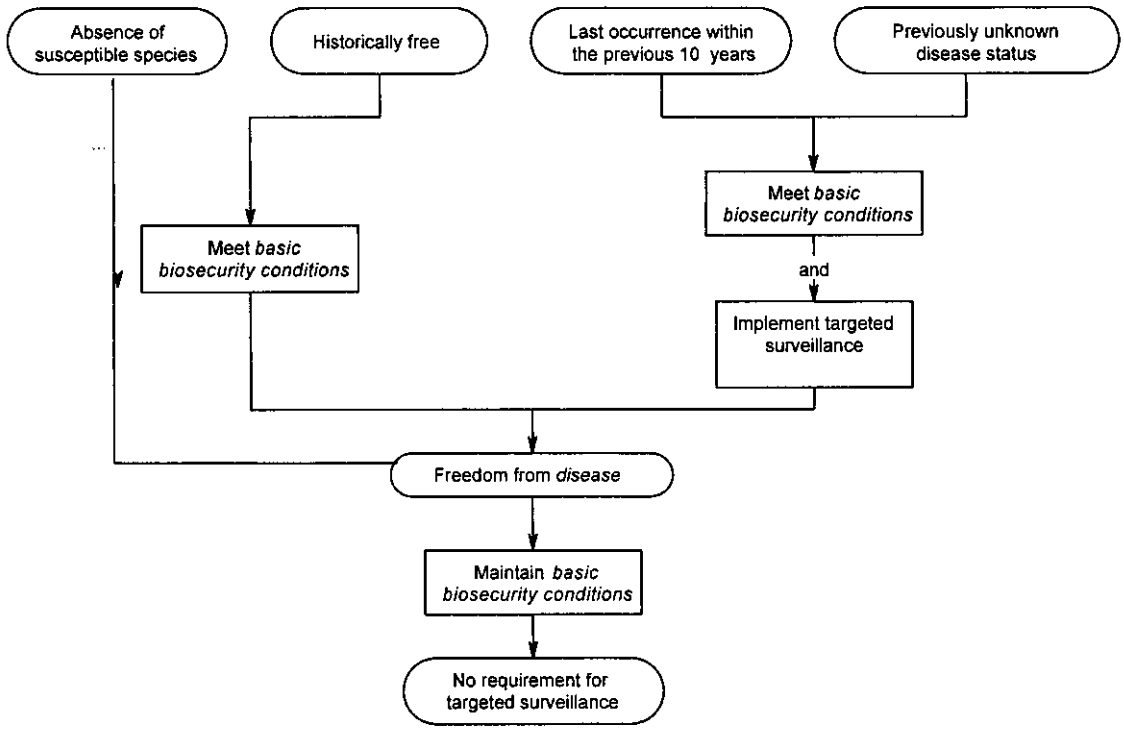
Finally, we would suggest another possibility to obtain the freedom status: certain pathogens are not able to survive in some environmental conditions. If that is the case, the country, zone or compartment may declare the freedom status with regard some specific disease, despite point 1, 2 or 3 of this article is not met. We would propose the following point 4:

4) A country, zone or compartment may be recognised as being free from disease without applying targeted surveillance if the relevant pathogen is known not to be able to survive in the country, zone or compartment and in its water source.

Pathways to demonstrate freedom from disease

The different paths to declaration of freedom from *disease* are summarised in the diagram below.

Annex XVII (contd)



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,

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, 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 and with a design prevalence at the animal and higher (i.e. pond, farm, village, etc.) levels being 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.

Community comment

The Community would encourage the OIE AAC to define the maintenance requirements for compartments.
In relation In relation to point 4, see the Community comments in previous article (x.x.x.6). The Community suggests that point 4 is deleted and the following paragraphs are added after point 3 (Maintenance of disease free status):

If there is reason to believe that the epidemiological situation in the wild population poses a significant risk for the introduction of a pathogen to the farmed population, target surveillance of the farms should not be discontinued.

Further more, targeted surveillance should not be discontinued in disease free zones or compartments in countries not declared disease free, or when fresh or frozen marine fish is fed for farmed fish.

Also, it seems unclear the need to require compulsory surveillance in the wild, when the freedom status have been achieved following option 1 ("absence of susceptible species") or option 2 ("historically free").

Therefore, we kindly suggest the OIE AAC to take into consideration the different pathways to achieve the freedom status when laying down requirements for surveillance in wild aquatic animals.

Finally, the last sentence "*A special case can be made for a compartment located in a country or zone that is not proven to be free from disease if surveillance is maintained and exposure to potential sources of disease is prevented*" is unclear as there it is not clear whether targeted surveillance may be discontinued or not. We suggest the following wording: "*for disease free zones or compartments in countries not declared disease free, targeted surveillance should be maintained but at a level commensurate with the degree of risk*"

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:

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. surveillance has demonstrated that *disease* is not present in wild aquatic animal populations of *susceptible species*.

A special case can be made for a *compartment* located in a country or *zone* that is not proven to be free from *disease* if surveillance is maintained and exposure to potential sources of *disease* is prevented.

Article x.x.x.8.

Community comment

In our opinion, three crucial factors have not been taken duly into account when designing the programmes to obtain the freedom status:

1. Historical records obtained by clinical inspections demonstrating absence of disease for several years – this is provided that the disease gives clinical symptoms on the species of consideration;

2. The susceptibility of the aquaculture animal to be sampled and the length of the surveillance programme, including that the sampling must be performed under optimal conditions (such as time of the year, temperature of the water) for the specific agent to be detected;

3. The appropriate diagnostic method, as described in the OIE Aquatic Manual and Code, is used.

Therefore, we would suggest focusing the surveillance programmes for obtaining the freedom status on the above-mentioned factors rather than focusing on random sampling.

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 Appendix.

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.

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;
- the *Competent Authority* will be able to investigate, diagnose and report *disease*, if present;
- 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.

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.Annex XVII (contd)

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. 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, 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 in the country, *zone* or *compartment*.

The sources of evidence must be fully described. In the case of 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

Annex XVII (contd)

4. Statistical methodology

Community comment

The guidelines are the best written text so far concerning aquatic animal disease surveillance. It would be, however, useful to handle the possibility of mixed infections. The situation of mixed infections by *Gyrodactylus* spp. is a practical example. There should be description of the procedure(s) to decide how many parasites must be determined to the species level in order to state freedom of infection of *Gyrodactylus salaris*. (How many parasites per sampled fish, of how many fish infected with *Gyrodactylus* spp. etc.). There probably are (and will be more in the future) other similar situations, where the problem of mixed infections complicates the surveillance.

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 (α) that the evidence observed (the results of surveillance) could have been produced under the null hypothesis that infection is present in the *population* at 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 $1-\alpha$. 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 α, including both quantitative and qualitative approaches, are acceptable as long as they are based on accepted scientific principles.

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 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 distributions 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 2%.

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*.

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.

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.

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.

Annex XVII (contd)

FreeCalc[12] 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.

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

12 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.

Design prevalence	Sensitivity (%)	Specificity (%)	Sample size	Maximum number of false +ve if the population is free
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

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.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.*

Annex XVII (contd)

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.

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, 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 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.

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.

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.

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[13].

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.

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).

13 International EpiLab, Denmark, Research Theme 1: Freedom from disease. http://www.vetinst.dk/high_uk.asp?page_id=196

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[14]. 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.

14 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.

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 × 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 × 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:

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*[15]. An example of a single farm will be used to illustrate some of the issues.

[15] 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

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:

- 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.

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.

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http://www.ausvet.com.au.

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 show 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 1 week). 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.

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:

Annex XVII (contd)

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*.

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

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[16]) is used.

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 *RandomAnimal* 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.

16 http://www.myatt.demon.co.uk/epicalc.htm

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 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

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

Original: English
August 2007

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON AQUATIC ANIMAL FEEDS
Paris, 29-31 August 2007

The OIE *ad hoc* Group on Aquatic Animal Feeds (*ad hoc* Group) met at the OIE Headquarters from 29 to 31 August 2007.

The members of the *ad hoc* Group and other participants are listed at Annex I. The Agenda adopted is given at Annex II.

Dr Kahn, on behalf of Dr Vallat, the OIE Director General, welcomed participants to the second meeting of the *ad hoc* Group. Dr Kahn thanked participants for their ongoing support of the OIE in this important area of work. She noted that one expert had been unable to attend the meeting but that he had agreed to provide comments electronically. The draft report of the meeting, including revisions proposed to the guidelines, would be sent to this member at the conclusion of the meeting and his comments taken into account via electronic circulation to all members. Professor Eli Katunguka-Rwakishaya then took over the chairmanship of the meeting. Based on the proposed terms of reference (Annex III) the *ad hoc* Group proceeded to address the comments provided by Australia, Canada, European Community (EC), Japan and New Zealand on the draft guidelines.

The following modifications to the draft guidelines were made in response to comments received. The revised draft guidelines are shown in Annex IV. Additions to the text are shown as double underlined text, with deleted text in strikeout.

The *ad hoc* Group addressed the comment of Australia on the scope of the guidelines, in particular the diseases to be addressed. Participants agreed that the guidelines should address OIE listed diseases of aquatic animals and previous references to 'significant diseases' were removed from the draft text. The *ad hoc* Group noted that some diseases are no longer listed but a disease chapter remains in the Aquatic Code (e.g., IPN). For these diseases, Members may still refer to the relevant chapters for relevant recommendations on risk mitigation in regard to aquatic animal feeds, as appropriate to the disease situation of the Member.

Annex XVIII (cont.)

The *ad hoc* Group addressed the comment of Australia on the applicability of the guidelines to small scale producers, including backyard/on-farm feed production. Noting that the scope of the guidelines specifically includes on-farm feed production, the *ad hoc* Group made some modifications to the text. Participants agreed that the general principles mentioned in the guidelines should apply to both large scale and small/back yard feed producers, including aspects that fall within the regulatory framework established by the Competent Authority (e.g. controls over the use of medicated feeds and disease-related restrictions on the disposal of aquatic animals affected by OIE listed diseases).

In relation to Australia's comment, the *ad hoc* Group clarified that the guidelines address the roles and responsibilities of the Competent Authority (in point 4), providing for the Competent Authority to decide the extent of the regulatory requirements apply.

In response to a Australia's comment on how the importing country should take account of the presence or absence of diseases in its territory in applying trade requirements, the *ad hoc* Group clarified that this raises a fundamental OIE principle. Recommendations in the Aquatic Code are based on the assumption that trade measures will only be applied in relation to diseases that are not present in the importing country or, if present, are the subject of an official disease control or eradication programme. The *ad hoc* Group extensively modified the section of the guidelines that deals with risk mitigation to clarify the responsibilities of exporting and importing countries in relation to risk mitigation for production of and international trade in feed of aquatic origin.

The *ad hoc* Group addressed Japan's recommendation that the guidelines make reference to specific risk mitigation procedures recommended for trade in feed, in regard to OIE listed diseases, in relevant disease chapters of the *Aquatic Code*. Noting that there is little scientific evidence of the introduction of diseases via feed, the *ad hoc* Group agreed in principle to the Member's proposal and amended the draft text accordingly.

In response to a Canada's recommendation that the guidelines be made more applicable to aquatic animals (not just finfish) and that algal feeds be addressed in the draft guidelines, the *ad hoc* Group modified the draft guidelines accordingly.

The *ad hoc* Group considered a New Zealand's comment that the listing of 'key considerations' was unnecessarily discursive but decided to retain all the points, as the intention was to express the difficulty of providing definitive and complete recommendations on aquaculture, which is a rapidly evolving field. New Zealand described references to the correct titles of the Terrestrial and Aquatic Codes as unnecessary verbiage. However, the *ad hoc* Group decided to retain these references until such time as the draft guidelines are included in the Aquatic Code, at which point the established abbreviations would be used.

In regard to the section on certification, the EC pointed out that specific recommendations for feed certification were not needed as articles in recently updated disease chapters of the Aquatic Code already address certification requirements for the importation of aquatic animal products (live and dead). The *ad hoc* Group accepted this point but decided to maintain a section on certification of feed of aquatic origin in the draft guidelines because the horizontal text would provide a valuable reference for countries seeking advice on feeds and not wishing to read multiple disease chapters to ascertain all the recommendations for individual diseases. Regarding the possible need to develop a new model certificate for aquatic animal feeds, the *ad hoc* Group decided to refer the question to the Aquatic Animal Health Standards Commission.

In response to the EC request for the guidelines to specifically address the risks associated with the feeding of aquaculture species on whole fish caught in the wild, the *ad hoc* Group added a further reference to this topic in the draft guidelines.

The *ad hoc* Group removed or modified several definitions in response to Members' comments. In particular, the definition of *dry feed* was modified to read '...moisture content equal to or less than 15%'. Participants agreed that the figure originally used in the definition (dry matter equal to or greater than 90%) represents an average value but accepted the EC's recommendation that 88% was a commercially accepted value. The value was adjusted to 15% based on a current reference[17]. The definition of 'semi-moist feed' was modified accordingly.

EC and Japan commented on the text on the relationship between prions and aquatic animals (points 4e and 4m in the draft guidelines). The *ad hoc* Group noted a comment about European research on transmissible spongiform encephalopathies (TSE) in fish. A long term infection study in sea bream, bass and trout is underway to investigate the transfer of prions in the gut and to examine the molecular biology of fish prion protein homologues. Although, based on previous research, the risk of TSE in fish is considered to be remote, the EC proposed to await the conclusions of the research project (at the end of 2007). The *ad hoc* Group considered that this matter should be kept under review and retained section 4e in order to provide guidance to OIE Members. However, point 4m was modified, to remove prions from the list of pathogenic agents included in the biological hazards.

The *ad hoc* Group considered comments of some Members on the lack of consistency between sections 7 and 8 of the draft guidelines and revised them accordingly. Section 9, introducing a diagrammatic representation of the pathways for pathogen distribution, was similarly revised to clarify the intent of the guidelines.

Japan commented that the draft guidelines should not address food safety and recommended a number of text modifications along these lines. The *ad hoc* Group decided not to accept these recommendations, deciding instead to seek advice from the Aquatic Animal Health Standards Commission in regard to next steps in addressing food safety issues. Dr Kahn informed the *ad hoc* Group that the OIE intends to refer the draft guidelines to the Animal Production Food Safety Working Group (APFSWG), which will hold its next meeting on 5-7 November 2007, for advice on the most appropriate way to address the food safety issue within the guidelines.

The *ad hoc* Group considered that the Terms of Reference had been completely addressed and that next step would be to refer the food safety issues to the APFSWG for further consideration.

.../Appendices

[17] Subcommittee on Fish Nutrition, National Research Council (1993). Nutrient Requirements of Fish. National Academy Press, Washington DC, 128 pp.

Annex XVIII (cont.)

Annex I

MEETING OF THE OIE *AD HOC* GROUP ON AQUATIC ANIMAL FEEDING
Paris, 29 -31 August 2007

List of participants

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Annex XVIII (cont.)

Annex II

MEETING OF THE OIE *AD HOC* GROUP ON AQUATIC ANIMAL FEEDING
Paris, 29 -31 August 2007

Adopted Agenda

1. Adoption of the Agenda
2. Terms of reference
3. Member Countries comments on the draft guidelines
4. Finalisation of the draft guidelines
5. Other business

Annex III

TERMS OF REFERENCE FOR THE OIE *AD HOC* GROUP ON AQUATIC ANIMAL FEEDS

1. Address comments received from OIE Members on the draft "Draft Guidelines for the Control of Aquatic Animal Health Hazards in Aquatic Animal Feeds".

2. Complete the work started on the draft guidelines, giving priority to work on aquatic animal pathogens.

Annex XVIII (cont.)

Annexe IV

DRAFT GUIDELINES FOR THE CONTROL OF AQUATIC ANIMAL HEALTH HAZARDS IN AQUATIC ANIMAL FEEDS

1. INTRODUCTION

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

These guidelines do not for the moment ~~It does not~~ address food safety issues in detail as this is not within the mandate of the OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission).

These Guidelines should be read in conjunction with relevant recommendations of the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) (Appendix containing recommendations on animal *feed*). The Food and Agriculture Organization of the United Nations (FAO) has ~~also~~ published recommendations relevant to terrestrial and aquatic animal *feed* and there is a Codex Alimentarius Commission (CAC) standard[18]. Members are encouraged to consult these publications.

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

- ~~Intensive rearing in~~ Concentration of *aquaculture establishments* and intensive rearing causes a concentration of *aquatic animals* ~~fish~~, *feed* and faecal matter in time and space and this heightens the risk of *disease* transmission, whether the pathogen enters the culture system via *feed* or other means.

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

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

- The usage of *feed* in moist, semi-moist and dry form implies different levels of risk due to the processing applied to the *feed*.

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[18] Technical Guidelines for Responsible Fisheries – Aquaculture Development: 1. Good aquaculture feed manufacturing practice. FAO 2001.

Draft Good Practices for the Animal Feed Industry – Implementing the Codex Alimentarius' Code of Practice on Good Animal Feeding, IFIF/FAO (*In preparation*).

Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

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

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

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

2. ~~PURPOSE AND~~ SCOPE

These guidelines ~~To~~ document risk mitigation measures, including traceability and certification, to deal with aquatic animal health risks associated with ~~through~~ trade in aquatic animal *feeds* and *feed ingredients*. ~~*Hazards* include *diseases* of interest i.e. *OIE listed diseases* and any others considered to be important to aquatic animal health~~. ~~This~~ ~~guideline~~ They recommends the control of ~~aquatic animal health~~ *hazards* through adherence to recommended practices during the production (~~procurement~~ harvest, handling, storage, processing and distribution) and use of both commercial and on-farm produced *feed* (and *feed ingredients*) for *aquatic animals*. *Hazards* include pathogens that cause *OIE-listed diseases* and other agents that cause an adverse effect on animal and/or public health. While *aquatic animals* grown for food are the main focus, the same principles apply to *feed* for *aquatic animals* used for other purposes. ~~aquarium species~~.

3. DEFINITIONS

~~***Cross contamination***~~

~~Means contamination of a material or product with another material or product containing a *hazard*.~~

Dry feed

Means *feed* that has a moisture ~~dry matter~~ content ~~= or >~~ equal to or less than ~~90~~ 15%.

Feed

Means any material (single or multiple), whether processed, semi-processed or raw that is intended to be fed directly to food-producing animals.

Feed additives

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

Feed ingredient

Means a component, part or constituent of any combination or mixture making up a *feed*, including *feed additives*, whether or not it has a nutritional value in the animal's diet. Ingredients may be of terrestrial or aquatic, plant or animal ~~or aquatic~~ origin and may be organic or inorganic substances.

Hazard

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

~~***Intra/inter species feeding***~~

~~Means feeding *aquatic animals* on products made from animals of the same species, or products made from species that are susceptible to the same pathogens as the animals receiving the *feed*.~~

Live feed

Means live farmed or wild caught animals and algae used as *feed* for *aquatic animals*. *Live feed* is often fed to aquatic animal species at an early life-stage ~~(e.g. *Artemia* cysts, rotifers, copepods)~~ and to aquatic animal species that have been cultured for a relatively short time.

Meal

Means a product derived from an aquatic animal that has been ground and heat processed to reduce the moisture content to less than 10 %.

Medicated feed

Means any *feed* which contains a veterinary drug administered to food producing animals, for therapeutic or prophylactic purposes or for modification of physiological functions.

Moist (or wet) feed

Means *feed* that has a moisture ~~dry matter~~ content ~~= or >~~ equal to or greater than 70 ~~30~~% ~~(e.g. frozen adult *Artemia*, whole fish or fish *offal*, molluscs, crustaceans, polychaetes for feed purposes)~~.

Semi-moist feed

Means *feed* that has a moisture ~~dry matter~~ content between 15 ~~30~~ and ~~90~~ 70%.

Fish solubles

Means a by-product of the fish oil production system, comprising the product remaining when water is drawn off (evaporated) from the residual aqueous phase.

~~***Undesirable substance***~~

~~Means a contaminant or other substance that is present in and/or on *feed* or *feed ingredients* and that constitutes a risk to animal or public health.~~

Annex XVIII (cont.)

Annex IV (contd)

4. GENERAL PRINCIPLES

a) Roles and responsibilities

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

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

Those involved in the production and use of animal *feed* and *feed ingredients* have the responsibility to ensure that these products meet regulatory requirements[19]. All personnel involved in the ~~procurement~~ harvest, manufacture, storage and handling of *feed* and *feed ingredients* should be adequately trained and aware of their role and responsibility in preventing the spread of *hazards* ~~of animal health and public health significance~~. Appropriate contingency plans should be developed in case of a *feed*-borne *disease* outbreak. Equipment for producing, storing and transporting *feed* should be kept clean and maintained in good working order.

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

b) Regulatory standards for feed safety

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

c) Risk analysis

Internationally accepted principles and practices for ~~on~~ *risk analysis* (see Section 1.4. of the *Aquatic Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

A generic *risk analysis* framework should be applied to provide a systematic and consistent process for managing *hazards* ~~disease risks and the risk of contamination with *undesirable substances*~~.

d) Good practices

Where national guidelines exist, good *aquaculture* practices and good manufacturing practices (including good hygienic practices) should be followed. Countries without such guidelines are encouraged to develop them. Annex XVIII (cont.)

[19] If at the national level, there are specific food-safety or animal health regulations related to genetically modified organisms, these should be taken into account in relation to feed and feed ingredients as these products form an important part of the food chain.

Where appropriate, Hazard Analysis and Critical Control Point[20] (HACCP) principles should be followed to control *hazards* that may occur in *feed.*

e) Relationship between ~~terrestrial animal disease agents~~ prions and *aquatic animal* species

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

f) Bioaccumulation

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

g) Geographic and environmental considerations

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

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

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

h) Zoning and compartmentalisation

Feed ~~and feed ingredients are~~ is an important component~~s~~ of biosecurity and need~~s~~ to be considered when defining a *compartment* or *zone* in accordance with Chapter 1.4.4. of the *Aquatic Code.*

i) Sampling and analysis

Sampling and analytical protocols should be based on scientific~~ally recognized~~ principles and procedures, and OIE standards where applicable.

[20] Hazard Analysis and Critical Control Point, as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene (CAC/RCP 1-1969).

Annex XVIII (cont.)

Annex IV (contd)

j) Labelling

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

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

k) Design and management of inspection programmes

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

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

l) Assurance and certification

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

m) Hazards associated with aquatic animal *feed*

Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, ~~prions,~~ fungi and parasites. The scope of these guidelines is limited to the *OIE listed diseases of aquatic animals.*

Chemical hazards

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

Physical hazards

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

n) Cross contamination

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

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

o) Antimicrobial resistance

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

p) Management of information

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

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

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

~~5.~~ ~~HAZARDS~~

~~Biological~~

~~This document addresses the following biological hazards:~~

~~a) bacteria, virus, parasites, fungi affecting *aquatic animals*. These hazards include the *OIE-listed diseases* (Chapter 1.2.3. of the *Aquatic Code*) and other important *diseases* (including IPN and IMNV);~~

~~b) prions.~~

~~Chemical~~

~~[under study]~~

~~Physical~~

~~[under study]~~

6 5. PATHOGENS IN FEED

a) Pathogens ~~in *feed*~~ can be introduced into *feed* in the following ways ~~at two points~~:

i) ~~at source:~~ via the harvest of infected *aquatic animals*;

Annex XVIII (cont.)

Annex IV (contd)

ii) during storage, processing and transport, ~~Contamination may occur at the manufacturing facility via~~ due to poor hygienic practices, ~~and/or~~ the presence of pests, ~~*Feed* and *feed ingredients* may be exposed to contamination during storage, manufacturing or transport, due to~~ or residues of previous batches of *feed* remaining in processing lines, containers or transport vehicles.

b) *Aquatic animals* can be exposed to pathogens in *feed* in the following ways ~~Exposure pathways include~~:

i) Direct exposure

The use of ~~raw~~ unprocessed *feed* ~~or *feed ingredients*~~ derived from *aquatic animals* to feed *aquatic animals* ~~species~~ presents a direct route ~~risk~~ of exposure, particularly when ~~to *hazards* of infectious nature~~. ~~There are risks associated with~~ feeding whole *aquatic animals* and unprocessed products of *aquatic animals* to animals of the same species. For example ~~that are susceptible to the same *diseases* as the 'fed animal' e.g.~~ feeding salmonid *offal* to salmonids or feeding rotifers or *Artemia* species to crustaceans presents a heightened risk of disease transmission.

ii) Indirect exposure

Pathogens in *feed* ~~and *feed ingredients* containing pathogenic agents~~ may be transmitted to *aquatic animals* in *aquaculture* and wild aquatic animals ~~fish~~ via contamination of the environment ~~including~~ or infection~~/contamination~~ of ~~on~~ non-target species.

6. CHEMICAL AGENTS IN *FEED*

[under study]

7. PHYSICAL AGENTS IN *FEED*

[under study]

~~7~~ 8. RECOMMENDED APPROACHES TO RISK MITIGATION

a) *Commodities*

Safe commodities

The following *commodities* undergo extensive processing such as heat treatment, acidification, extrusion and extraction. There is a negligible risk that pathogens will survive in such products if they have been produced in accordance with normal commercial practice:

i) fish oil;

ii) crustacean oil;

iii) *fish solubles*;

iv) fish *meal*;

v) crustacean *meal*;

vi) squid meal and squid liver-meal;

vii) bivalve *meal*;

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

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

Other *commodities*

Competent Authorities should consider the following risk mitigation measures.

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

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

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

iv) use of *feed* only in *populations* that are not susceptible to the pathogen(s) in question.

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

Whole fish (fresh or frozen)

The practice of trading fresh or frozen whole marine fish for use as aquatic *feed* presents a *risk* of introducing *diseases* into *populations*. Given the difficulty of imposing effective *risk* mitigation measures, this practice is not recommended.

~~The following measures are relevant to *exporting countries*:~~

~~a) Source of raw materials~~

~~Raw materials/ingredients should not be soureed from areas/*populations* known to be infected with significant pathogens: . It may be appropriate to adopt routine testing procedures to verify that pathogens are not present at unacceptable levels; or~~

~~When using *feed* and *feed ingredients* originating from areas known to be affected by a significant pathogen:~~

~~i) *feed* and *feed ingredients* should be delivered directly to feed manufacturing plants for processing under conditions approved by the *Competent Authority*; and~~

~~ii) effluent and other wastes from the feed manufacturing plants should be treated under conditions approved by the *Competent Authority* before discharge into the aquatic environment; or~~

Annex XVIII (cont.)

Annex IV (contd)

~~iii) *feed* and *feed ingredients* known or suspected to be infected with significant agents pathogens should only be used and/or processed in a *zone* or *compartment* that does not contain species susceptible to the pathogen in question.~~

~~the following measures are relevant to *exporting countries*:~~

~~b)~~ **Feed production**

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

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

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

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

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

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

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

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

~~c) The following measures are relevant to *Importing countries:*~~

Competent Authorities should consider the following measures:

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

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

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

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

~~8.~~9. CERTIFICATION PROCEDURES FOR ~~AQUATIC~~ *FEEDS* OF AQUATIC ORIGIN

~~a) The following products represent a negligible risk because of the extensive processing used to produce them:~~

~~i) fish oil;~~

~~ii) crustacean oil;~~

~~iii) *fish solubles*;~~

~~iv) fish *meal*;~~

~~v) crustacean *meal*;~~

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

~~vii) bivalve *meal*;~~

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

~~For these products, *Competent Authorities* should not require conditions in relation to aquatic animal *diseases*, regardless of the aquatic health status of the *exporting country*, *zone* or *compartment*[21].~~

~~b) Other products~~

~~The following risk mitigation measures should be considered:~~

~~i) sourcing *feed* and *feed ingredients* from a *disease* free area; or~~

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

~~iii) treatment (e.g. by heat or acidification) of product to inactivate pathogens.~~

~~c) Importing country measures~~

When importing *feed* and *feed ingredients* of aquatic origin other than those mentioned in Article X.X.X. [Article with safe commodities, currently point 8], the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* (or a *certifying official* approved by the *importing country*).

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21 ~~In relation to the risk associated with contamination after harvest/processing, point 4 (below) applies~~.

Annex XVIII (cont.)

Annex IV (contd)

This certificate should certify:

i) that *feed* and *feed ingredients* of aquatic origin were obtained ~~imported~~ from a country, *zone* or *compartment* that is free from relevant aquatic animal *diseases*[22]; or

ii) that *feed* and *feed ingredients* of aquatic origin were tested for relevant aquatic animal *diseases*[23] and shown to be free of these *diseases*; or

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

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

~~9~~ 10. RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST, ~~OF FEED INGREDIENTS AND~~ MANUFACTURE AND USE OF AQUATIC FEEDS

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

~~Some~~ *Feed ingredients* of aquatic origin used in *aquaculture*~~, in particular of aquatic origin (e.g., krill, shrimp, fish, crab, *Artemia*)~~ can be a source of pathogens (viruses, bacteria, and parasites) ~~contamination~~ to cultured aquatic animal species. ~~These ingredients can carry live pathogens (viruses, bacteria, and parasites) and reach the aquaculture operation through different types of *feeds* (live, moist, semi-moist or dry feeds).~~ In *aquaculture establishments* ~~farms~~, ~~there are two routes of~~ pathogens in *feed* can infect the animals directly (via consumption of *feed*) or indirectly via environmental sources. ~~contamination through *aquatic animal* feeding: transmission of pathogens and contamination. **Transmission of pathogens** can take place when the *feed* itself is already infected with a pathogen. This type of contamination is more common with *Live feeds* and *moist feeds*~~ are more likely to contain pathogens because their ingredients ~~that constitute their composition~~ are either ~~kept~~ in a raw state or subject to minimal ~~in the final product (e.g., feeding tuna with wild-caught fish) or at times require little~~ treatment~~(s) prior to feeding aquatic organisms~~.

~~Harvest of~~ *Feed* and *feed ingredients* ~~aquatic ingredient sources~~ harvested from infected ~~areas~~ countries, *zones*, or *compartments* ~~has~~ may have a high ~~*risk* of~~ pathogen load ~~contamination, especially if these are transported to an *aquaculture* operation without any prior treatment~~. *Feed* and *feed ingredients* from these sources should be processed (e.g. using heat or chemical treatments). ~~Processing of these ingredients places a moderate risk of contamination, and it should actually be taken as a possibility~~ to reduce, or eliminate, the pathogen load ~~risk of pathogen transmission (e.g., through heat, chemical treatments)~~. After processing care should be taken to avoid post processing contamination during storage and transportation of these commodities ~~ingredients has a low risk of contamination, but should also be considered as a direct route of pathogen contamination.~~ For example, when two or more batches of ingredients of different sanitary status are handled, stored and/or transported together without appropriate ~~any~~ biosecurity measures there is a risk of cross contamination of the *feed* ~~direct contamination to the farmed animal~~.

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[22] Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

[23] Conditions agreed between the Competent Authorities of the importing and exporting countries in accordance with the recommendations of the OIE *Aquatic Animal Health Code*.

~~**Contamination** occurs when the pathogen is introduced in a feed manufacturing facility, both through infected ingredients or finished feeds and later to the aquaculture facility. Contamination occurs with the use of *semi-moist feeds* and *dry feeds*. With these feed types, contamination can take place in the manufacturing plant during:~~

~~a) Storage of ingredients: it has a low risk of contamination, but it can take place when ingredients of different sanitary status are handled or placed together.~~

~~b) Feed manufacturing: during feed processing, ingredients are commonly subjected to heat treatment which can eliminate certain pathogens. However, use of manufacturing lines with remains of contaminated ingredients from a previous batch of feed can result in cross contamination of feeds.~~

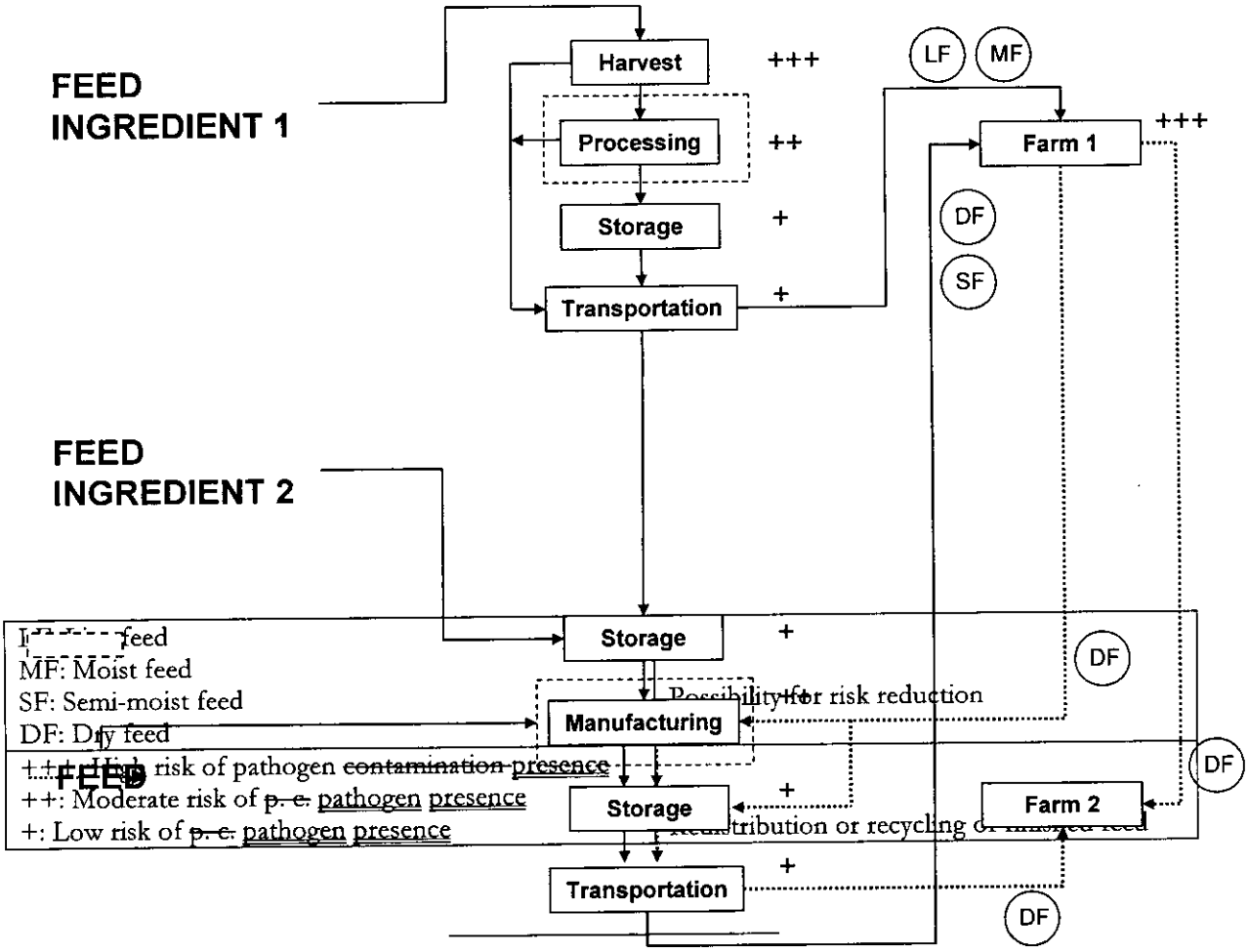
~~c) Storage and transportation of finished feeds: it has a low risk of contamination, but when finished feeds are stored or transported together with unprocessed ingredients or with feeds of different sanitary status it can result in pathogen contamination.~~

An aquaculture facility can also be a source of pathogens ~~contamination~~ in aquatic *feeds*. ~~At this level, contamination can take place~~ For example, ~~when a finished~~ *feed* can be contaminated with pathogens through poor hygiene practices at an infected aquaculture *establishment*. ~~is delivered to a farm located in an infected area. Transmission of pathogens can occur when~~ If the *feed* is redistributed ~~withdrawn~~ from the aquaculture facility ~~and is returned~~ to the manufacturing facility for recycling, ~~for reprocessing~~ or ~~transferred~~ distributed to another farm, pathogens can be transferred to other aquaculture *establishments*.

Annex XVIII (cont.)

Annex IV (contd)

Figure 1: RISK CHART OF PATHOGEN TRANSMISSION AND CONTAMINATION THROUGH HARVEST, MANUFACTURE AND USE OF AQUATIC FEEDS



Annex XIX

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

Original: English
September 2007

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON AMPHIBIAN DISEASES
Paris, 5–7 September 2007

The OIE *ad hoc* Group on Amphibian Diseases (hereinafter referred to as the *ad hoc* Group) held its meeting at the OIE Headquarters from 5 to 7 September 2007.

The members of the OIE *ad hoc* Group are listed in Annex I. The Agenda adopted is given in Annex II.

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Francesco Berlingieri, Deputy Head of the Animal Health Information Department, welcomed the members of the *ad hoc* Group and thanked them for their willingness to be involved in addressing this issue for the OIE. He stressed the good feedback received from OIE Member Countries and Territories in reply to the questionnaire. He recalled that in May 2007 the OIE International Committee had agreed to expand the remit of the OIE Aquatic Animal Health Standards Commission (Aquatic Animals Commission) to include amphibian diseases. He said that the Aquatic Animal Commission had prepared the terms of reference for the work of this *ad hoc* Group.

The Chair of the *ad hoc* Group, Dr Barry Hill, Vice-President of the Aquatic Animal Commission, introduced the agenda and the terms of reference and the position of the Aquatic Animals Commission on the issue of amphibian diseases to the *ad hoc* Group. He also presented the disease listing criteria present in Chapter 1.2.2. of the *Aquatic Animal Health Code* (the *Aquatic Code*).

1. Questionnaire on International Amphibian Trade and Diseases

The *ad hoc* Group reviewed the Members' responses to the "Questionnaire on International Amphibian Trade and Diseases" and summarized the data provided. This analysis is shown in Annex III.

2. OIE list of diseases

The *ad hoc* Group applied the listing criteria provided in Chapter 1.2.2. of the Aquatic Code to two diseases that were identified in the previous *ad hoc* Group meeting report: chytridiomycosis caused by the amphibian chytrid fungus *Batrachochytrium dendrobatidis*, and infection with a number of closely related ranaviruses that are highly pathogenic to amphibian species. Some ranaviruses can also infect fish and reptiles, resulting in morbidity and mortality. The *ad hoc* Group concluded that both "infection with Batrachochytrium *dendrobatidis*" and "infection with *Ranavirus*" meet the listing criteria and therefore should be added to the OIE list of diseases. The assessment against the listing criteria for these two diseases is shown in Annex IV of this report.

Annex XIX (contd)

3. Draft texts for the *Aquatic Animal Health Code*

a) Disease chapters

The *ad hoc* Group drafted chapters for the two diseases identified above following the template used for other recently updated disease chapters of the *Aquatic Code*. These chapters are presented in Appendices V and VI for consideration by the Aquatic Animal Commission.

b) Definitions

The *ad hoc* Group proposed an amendment to the definition of *aquatic animals* in order to include amphibians (see Annex VII). The *ad hoc* Group noted that if the definition was not modified, then changes to the two new disease chapters would need to be made accordingly.

c) Model certificates

Noting Section 4 of the *Aquatic Code*, the *ad hoc* Group considered it necessary to provide draft model certificates for trade in live amphibians and amphibian products. For this work it used as a basis the current model certificates provided in the 2007 edition of the *Aquatic Code*. These draft model certificates are presented at Appendices VIII and IX for consideration by the Aquatic Animal Commission.

d) Transport water

The *ad hoc* Group reviewed Chapter 1.5.1. on "Recommendations for Transport" of the *Aquatic Code* and noted that neither aquatic plants, nor their transport water nor their substrate was addressed. It considered these traded commodities to be a risk for transmitting amphibian diseases and possibly also fish diseases. The *ad hoc* Group advises that the Aquatic Animal Commission consider the risks and develops standards for this trade.

4. Chapters for the Manual of Diagnostic Tests for Aquatic Animals (the Aquatic Manual) and Disease cards

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

The *ad hoc* Group agreed it was essential to prepare Aquatic Manual chapters for any amphibian OIE listed diseases as soon as they are adopted by the OIE International Committee. Considering the complexity and the length of this process, the *ad hoc* Group suggested disease cards for "infection with *Batrachochytrium dendrobatidis*" and "infection with *Ranavirus*" be prepared initially to provide information to OIE Members while the Aquatic Manual chapter are being developed. The *ad hoc* Group members started to draft these and will provide a finalised version in time for the March 2008 meeting of the Aquatic Animal Commission.

.../Annexes

Annex I

MEETING OF THE OIE *AD HOC* GROUP ON AMPHIBIAN DISEASES

Paris, 5 – 7 September 2007

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Annex II

MEETING OF THE OIE *AD HOC* GROUP ON AMPHIBIAN DISEASES

Paris, 5 – 7 September 2007

Agenda

6. Adoption of the Agenda
7. Terms of reference
8. Results of the "Questionnaire on International Amphibian Trade and Diseases"
9. Identify amphibian diseases relevant to international trade that should be added to the OIE list of diseases
10. Provide rationale for the proposed new listed diseases
11. Draft Chapters for the *Aquatic Code* for the identified amphibian disease
12. *Aquatic Manual* Chapters and Disease cards

ASSESSMENT OF THE OIE MEMBER COUNTRIES AND TERRITORIES' RESPONSES TO THE QUESTIONNAIRE ON AMPHIBIAN TRADE AND DISEASES

Despite recognition by the FAO of significant growth in the global trade of amphibians for human consumption, the data collection on this and other trade in amphibians is still inadequate. The OIE *ad hoc* Group on Amphibian Diseases concluded that infectious diseases of global concern are spread by, and also affect, these trades. This concern was acknowledged by the Aquatic Animal Commission in October 2006 and a questionnaire survey was approved.

Methods

The questionnaire on international trade in amphibians and diseases was developed by the OIE *ad hoc* Group on Amphibian Diseases, approved by the Aquatic Animal Commission and circulated in 18 December 2006 to the OIE Delegates of OIE Member Countries and Territories for completion by 25 February 2007. There was no follow-up of countries that failed to respond by this date.

Data from the questionnaires were transferred to an Excel file and descriptive statistics calculated using Excel.

Results

Sixty nine countries submitted completed questionnaires, a response rate of 41% (69/168). The number of countries responding from regions and the percent response of countries for that region were Americas 13 (48%), Africa 9 (18%), Europe 33 (66%), Asia-Far East 10 (36%) and Middle East 4 (31%).

Forty five countries (64%) traded in amphibians. The type of trade in these countries included amphibians for human consumption in 28 (62%), pet trade in 30 (67%), laboratory animal trade in 22 (49%), zoo trade in 26 (58%) and other use in 1 (2%). Farming of amphibians occurred in 19 (28%) countries and varied by region with 69% of Americas, 50% of Asia-Near East and 15% of European respondents having amphibian farming. Farming was not reported in the regions of Africa or Middle East. Legislation covering the amphibian trade, other than for CITES[24] purposes, was present in 34 (49%) countries.

Of the 45 countries trading in amphibians, 31 (69%) provided quantitative data on the extent of their trade. Data was provided as weight or number of individual animals (these data are mutually exclusive), except in one case where data provided was value of the trade only. For live amphibians, 508,743 kg and 1,577,128 individuals were imported and 321,317 kg and 5,085,060 individuals were exported (Table 1). For amphibian products 3,660,971 kg and 1,522 individuals were imported and 875,451 kg were exported (Table 2). However, this is a significant underestimation since countries in all regions except the Middle East that reported an amphibian trade failed to provide quantitative data (Americas 4, Africa 1, Europe 8, Asia-Far East 1). In addition some of the major global trading countries failed to respond to the questionnaire and several of those that did, underestimated their exports and/or their imports. The *ad hoc* Group reached this conclusion using figures gathered from several sources [1, 2, 3]. They also noted that published data suggest that the global trade in amphibians in 1990 was greater that 12 million individuals [3], which is far higher than the results of the questionnaire suggest. Although reliable data on the current global trade in amphibians are not available it is known that 4.3 million frogs were imported into Hong Kong by air alone in the year 2005-2006 [1], therefore even a figure of 12 million is likely to be much lower than the actual current volume of global amphibian trade. The *ad hoc* Group therefore believes that the questionnaire data very significantly underestimate the current international trade in amphibians.

[24] CITES : Convention on International Trade of Endangered Species of Wild Fauna and Flora.

Annex XIX (contd)

Annex III (contd)

Table 1: Extent of trade in live amphibians by region as reported in the questionnaire returns. The reports in weight and in individuals are mutually exclusive. NR= None reported.

Region	Import		Export		Countries providing data (*n*)
	kg	Individual animals	kg	Individual animals	
Americas	NR	429	204,190	3,150	5
Africa	NR	1,084	NR	NR	3
Europe	250,000	160,316	115,000	5,046	14
Asia-Far East	258,743	1,409,699	2,127	5,073,364	6
Middle East	NR	5,300	NR	3,500	2
Total	508,743	1,577,128	321,317	5,085,060	30

Table 2: Extent of trade in amphibian products by region as reported in the questionnaire returns. The reports in weight and in individuals are mutually exclusive. NR= None reported

Region	Import		Export		Countries providing data (n)
	kg	Individual animals	kg	Individual animals	
Americas	22,306	NR	2,000	NR	3
Africa	303	NR	NR	NR	1
Europe	3,598,212	NR	358,300	NR	8
Asia-Far East	39,150	1,522	515,151	NR	5
Middle East	1,000	NR	NR	NR	1
Total	3,660,971	1,522	875,451	0	16

Reporting of amphibian diseases had occurred in 14 (20%) of the 69 countries. However, only 7 countries listed diseases reported and these included (with number of countries reporting in parenthesis) mycobacteriosis (2), *Aeromonas* infection (2), mucormycosis (2), chytridiomycosis (5), ranaviral disease (4), *Chryseobacterium* (*Flavobacterium*) *meningosepticum* (1).

Legislation covering amphibian diseases issues was present in 12 (17%) countries. Forty nine countries (71%) thought that amphibian diseases should be included in the remit of OIE.

Conclusion

The *ad hoc* Group considers it essential to obtain an accurate picture of international trade in amphibians and their products. The publication of these data would increase the awareness of Members of the potential spread of amphibian diseases with this trade.

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Annex XIX (contd)

Annex IV

ASSESSMENT FOR RELEVANT AMPHIBIAN DISEASES AGAINST THE LISTING CRITERIA OF CHAPTER 1.2.2. OF THE AQUATIC ANIMAL HEALTH CODE

Infection with *Batrachochytrium dendrobatidis*

No.	Parameters that support listing	Listing	Comments
A1	There are reports of significant economic losses due to *B. dendrobatidis* infection in the extensive global trade in amphibians as laboratory, ornamental or pet animals (Groff *et al.* 1991, Daszak *et al.* 1999 and Daszak *et al.* 2003).	+	Need for further data.
or			
A2	Many species of amphibians are highly susceptible and severe population declines have been reported in Europe, the Americas and Australia (Mendelson *et al.* 2006). This has resulted in an increase in the number of threatened species and has driven some species to extinction (Berger *et al.* 1998, Schloegel *et al.* 2005, Department of Environment and Heritage – Australia 2006, Lips *et al.* 2006, Skerratt *et al.* 2007). *B. dendrobatidis* has a remarkably low host specificity since it has infected at least 143 species of amphibians from 43 genera, 19 families and 2 orders, indicating that globally probably most or all species of amphibians could be infected (Department of Environment and Heritage – Australia 2006).	+	Very good evidence
Or			
A3	None	-	Never reported
and			
B4	Koch's postulates have been satisfied by multiple independent groups, published in international peer reviewed journals (Pessier *et al.* 1999, Nichols *et al.* 2001, Daszak *et al.* 2004, Berger *et al.* 2005 and Carey *et al.* 2006) and widely accepted by the scientific community.	+	Very good data
or			
B5	The aetiology is known (see B4).	-	Not applicable
and			
B6	There is strong evidence that *B. dendrobatidis* has spread internationally through the amphibian trade in Europe, the Americas and Australia (Morgan *et al.* 2007, Garner *et al.* 2006 and Fisher and Garner 2007). There is direct evidence of animals being imported with *B. dendrobatidis* infection (Mutschmann *et al.* 2000 and Parker *et al.* 2002).	+	The published scientific literature and the scale of international trade in amphibians show that there is considerable potential for further spread unless measures are taken to prevent this.
and			
B7	There are several regions were the disease hasn't been reported and which appear to be free of the disease despite the presence of susceptible species (e.g. many Caribbean Islands, Central and Eastern Europe, South and South-East Asia, Pacific Islands, West and North Africa, Middle East). However there are no countries that have performed sufficient surveillance to demonstrate the absence of the disease.	+	A lack of control is likely to result in the continuous spread into the countries and zones currently free leading to declines, and possibly to extinctions, of many species.

Annex XIX (contd)

Annex IV (contd)

No.	Parameters that support listing	Listing	Comments
	In countries where the disease has been reported, the distribution often is patchy (Garner *et al.* 2005; Speare *et al.* 2005) therefore the establishment of disease free zones may be possible (Department of Environment and Heritage – Australia 2006 and Fisher & Garner 2007).		
and			
C8	There are robust repeatable diagnostic tests with high degrees of sensitivity and specificity applicable to a range of diagnostic specimens (Hyatt *et al.* 2007 and Speare *et al.* 2005) including live and post-mortem material.	+	

Listing here:-

1	2	3	4	5	6	7	8	Insert on the OIE list?
+	+	-	+	-	+	+	+	Yes

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Infection with ranaviruses

No.	Parameters that support listing	Listing	Comments
A1	There are reports of production losses in farmed animals. (e.g. Zhang *et al.* 2001, Weng *et al.* 2002, Gallia *et al.* 2006 and Miller *et al.* 2007)	+	Good evidence
or			
A2	Ranaviruses cause mass mortality of wild amphibians (Cunningham *et al.* 1996, Daszak *et al.* 1999, Bollinger *et al.* 1999, Jancovich *et al.* 2001, Docherty *et al.* 2003, Greer *et al.* 2005 and Fox *et al.* 2006) and can be transmitted to fish and reptiles with resulting mortalities (Ariel and Owens 1997, Mao *et al.* 1999, Moody and Owens 1994 and De Voe *et al.* 2004,).	+	Very good evidence
or			
A3	None	-	Never reported
and			
B4	Koch's postulates have been satisfied by several independent groups, published in international peer reviewed journals (Wolf *et al.* 1968, Cullen *et al.* 1995, Cullen and Owens 2002, Cullen et al. 2002, Cunningham *et al.* 2007a and Cunningham *et al.* 2007b).	+	Very good data
or			
B5	The aetiology is known (see B4).	-	Not applicable
and			
B6	There is evidence that ranaviruses have been spread internationally through the amphibian trade (Hyatt et al. 2000 and Jancovich *et al.* 2005). Ranaviruses can persist on fomites and in water for several months (Speare and Smith 1992).	+	The published scientific literature and the scale of international trade in amphibian show that there is considerable potential for further spread unless measures are taken to prevent this.
and			
B7	Amphibian ranavirus infection has only been reported from a small numbers of countries (Zupanovic *et al.* 1998, Zhang *et al.* 2001, Weng *et al.* 2002, Daszak *et al.* 2003, Fox et al. 2006, Fijan *et al.* 1991). However no countries have performed sufficient surveillance to demonstrate absence of disease.	+	A lack of control is likely to result in the continuous spread into countries and zones currently free.
and			
C8	There are robust repeatable diagnostic tests as used for ranavirus diagnostics in fish as described in the OIE *Manual of Diagnostic Tests for Aquatic Animals*.	+	

Listing here:-

1	2	3	4	5	6	7	8	Add to the OIE list?
+	+	-	+	-	+	+	+	Yes

Annex IV (contd)

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Annex V

CHAPTER 2.4.1.

INFECTION WITH *BATRACHOCHYTRIUM DENDROBATIDIS*

Article 2.4.1.1.

For the purposes of the *Aquatic Code*, infection with *Batrachochytrium dendrobatidis* means infection with the freshwater fungus *Batrachochytrium dendrobatidis* Fungi, Chytridiomycota, Rhizophydiales.

Methods for conducting surveillance and diagnosis of infection with *Batrachochytrium dendrobatidis* are provided in the *Aquatic Manual*.

Article 2.4.1.2.

Scope

The recommendations in this Chapter apply to: all species of Anura (frogs and toads), Caudata (salamanders, newts and sirens) and Gymnophiona (caecilians). The recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.4.1.3.

Commodities

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

   a) For the species referred to in Article 2.4.1.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the *disease agent* e.g. canned products;

      ii) leather made from amphibian skin;

      iii) dried amphibian products (including air dried, flame dried and sun dried);

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

   b) For species other than those referred to in Article 2.4.1.2., all *aquatic animal products*.

   c) The following *commodities* destined for human consumption from the species referred to in Article 2.4.1.2. which have been prepared and packaged for direct retail trade:

      i) skinned frog legs with feet removed;

      ii) skinned amphibian carcasses or meat, with hands and feet removed.

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

Annex V (contd)

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.4.1.2., other than those referred to in point 1 of Article 2.4.1.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.4.1.7. to 2.4.1.12. relevant to the *Batrachochytrium dendrobatidis* 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 *Batrachochytrium dendrobatidis* of any live *commodity* of a species not covered in Article 2.4.1.2. but which could reasonably be expected to be a potential *Batrachochytrium dendrobatidis* vector, 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 2.4.1.4.

***Batrachochytrium dendrobatidis* free country**

A country may make a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* 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 *Batrachochytrium dendrobatidis* if all the areas covered by the *zone* are declared *Batrachochytrium dendrobatidis* free (see Article 2.4.1.5.).

1. A country where none of the *susceptible species* referred to in Article 2.4.1.2. is present may make a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* 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 2.4.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 15 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 *Batrachochytrium dendrobatidis* 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 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 *Batrachochytrium dendrobatidis* when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from *Batrachochytrium dendrobatidis* 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*; 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 2.4.1.5.

Article 2.4.1.5.

Batrachochytrium dendrobatidis free zone or free compartment

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

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.4.1.2. is present may be declared free from *Batrachochytrium dendrobatidis* 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 2.4.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from *Batrachochytrium dendrobatidis* when *basic biosecurity conditions* have been continuously met 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 *Batrachochytrium dendrobatidis* when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*.

OR

4. A *zone* previously declared free from *Batrachochytrium dendrobatidis* but in which the *disease* is subsequently detected may be declared free from *Batrachochytrium dendrobatidis* 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of *Batrachochytrium dendrobatidis*; 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 2.4.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Batrachochytrium dendrobatidis* following the provisions of points 1 or 2 of Articles 2.4.1.4. or 2.4.1.5. (as relevant) may maintain its status as *Batrachochytrium dendrobatidis* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Batrachochytrium dendrobatidis* following the provisions of point 3 of Articles 2.4.1.4. or 2.4.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Batrachochytrium dendrobatidis* free provided that conditions that are conducive to clinical expression of *Batrachochytrium dendrobatidis*, 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 *Batrachochytrium dendrobatidis*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.4.1.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Batrachochytrium dendrobatidis*

When importing live *aquatic animals* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*, 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 2.4.1.4. or 2.4.1.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.X.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.8.

Importation of live aquatic animals for farming from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

1. When importing live *aquatic animals* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* not declared free from *Batrachochytrium dendrobatidis*, the *Competent Authority* of the *importing country* should:

a) require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that:

i) the *aquatic animals* have been appropriately treated to eradicate infection and have been subsequently tested to confirm absence of the disease according to specifications provided in the relevant chapter in the *Aquatic Manual*; and

ii) no other live *aquatic animals* of the species referred to in Article 2.4.1.2. have been introduced during that period;

OR

iii) in the case of eggs, the eggs have been disinfected;

OR

b) assess the *risk* and apply risk mitigation measures such as:

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

ii) the treatment of all effluent and waste materials in a manner that kills *Batrachochytrium dendrobatidis*.

2. For the purposes of the *Aquatic Code* the following steps should be taken if the importation is for the establishment of a new stock:

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

b) evaluate stock's health/disease history;

c) take and test samples for *Batrachochytrium dendrobatidis*, 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 *Batrachochytrium dendrobatidis* and perform general examinations for pests and general health/disease status;

g) if *Batrachochytrium dendrobatidis* 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 *Batrachochytrium dendrobatidis* free or specific pathogen free (SPF) for *Batrachochytrium dendrobatidis*;

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Annex V (contd)

Article 2.4.1.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* not declared free from *Batrachochytrium dendrobatidis*, the *Competent Authority* of the *importing country* should require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.4.1.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that kills *Batrachochytrium dendrobatidis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, laboratory, zoo, pet trade, industrial or pharmaceutical use, from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

When importing live *aquatic animals* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* not declared free from *Batrachochytrium dendrobatidis*, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that:
   a) the *aquatic animals* have been appropriately treated to eradicate infection and have been subsequently tested to confirm absence of the diseases according to specifications provided in the relevant chapter in the *Aquatic Manual*; and
   b) no other live *aquatic animals* of the species referred to in Article 2.4.1.2. have been introduced during that period;

   OR

   c) in the case of eggs, the eggs have been disinfected;

OR

2. assess the *risk* and apply risk mitigation measures such as:
   a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment;
   b) the treatment of all effluent and waste materials in a manner that kills *Batrachochytrium dendrobatidis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.11.

Importation of aquatic animal products from a country, zone or compartment declared free from *Batrachochytrium dendrobatidis*

When importing *aquatic animal products* of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*, 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 2.4.1.4. or 2.4.1.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from *Batrachochytrium dendrobatidis*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.X.X.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Article 2.4.1.12.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Batrachochytrium dendrobatidis*

1. When importing *aquatic animal* products of species referred to in Article 2.4.1.2. from a country, *zone* or *compartment* not declared free from *Batrachochytrium dendrobatidis*, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate risk mitigation measures.

2. In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include:

   a) the direct delivery into and holding of the consignment in biosecure facilities for processing to one of the products referred to in point 1 of Article 2.4.1.3. or other products authorised by the *Competent Authority*;

   b) the treatment of all effluent and waste materials in a manner that kills *Batrachochytrium dendrobatidis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.1.3.

Annex VI

CHAPTER 2.4.2.

INFECTION WITH RANAVIRUS

Article 2.4.2.1.

For the purposes of the *Aquatic Code*, infection with ranavirus means infection with any members of the genus *Ranavirus* in the family Iridoviridae with the exception of epizootic haematopoietic necrosis virus and European catfish virus.

Methods for conducting surveillance and diagnosis of infection with ranavirus are provided in the *Aquatic Manual*.

Article 2.4.2.2.

Scope

The recommendations in this Chapter apply to: all species of Anura (frogs and toads) and Caudata (salamanders and newts). The recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.4.2.3.

Commodities

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

   a) For the species referred to in Article 2.4.2.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the *disease agent* e.g. canned products;

      ii) leather made from amphibian skin;

      iii) 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 2.4.2.2. which have been prepared and packaged for direct retail trade:

      i) skinned frog legs;

      ii) skinned amphibian carcasses or meat.

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

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.4.2.2., other than those referred to in point 1 of Article 2.4.2.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.4.2.7. to 2.4.2.12. relevant to the ranavirus status of the *exporting country*, *zone* or *compartment*.

Annex VI (contd)

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of ranavirus of any live *commodity* of a species not covered in Article 2.4.2.2. but which could reasonably be expected to be a potential ranavirus vector, 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 2.4.2.4.

Ranavirus free country

A country may make a *self-declaration of freedom* from ranavirus 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 ranavirus if all the areas covered by the *zone* are declared ranavirus free (see Article 2.4.2.5.).

1. A country where none of the *susceptible species* referred to in Article 2.4.2.2. is present may make a *self-declaration of freedom* from ranavirus 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 2.4.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 15 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 ranavirus 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 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 ranavirus when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of ranavirus.

OR

4. A country that has previously made a *self-declaration of freedom* from ranavirus but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from ranavirus 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of ranavirus; 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 2.4.2.5.

Article 2.4.2.5.

Ranavirus free zone or free compartment

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

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.4.2.2. is present may be declared free from ranavirus 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 2.4.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from ranavirus when *basic biosecurity conditions* have been continuously met 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 ranavirus when:

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

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of ranavirus.

OR

4. A *zone* previously declared free from ranavirus but in which the *disease* is subsequently detected may be declared free from ranavirus 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 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of ranavirus; 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 2.4.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from ranavirus following the provisions of points 1 or 2 of Articles 2.4.2.4. or 2.4.2.5. (as relevant) may maintain its status as ranavirus free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from ranavirus following the provisions of point 3 of Articles 2.4.2.4. or 2.4.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as ranavirus free provided that conditions that are conducive to clinical expression of ranavirus, 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 ranavirus, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.4.2.7.

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

When importing live *aquatic animals* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* declared free from ranavirus, 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 2.4.2.4. or 2.4.2.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from ranavirus.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.X.X.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.8.

Importation of live aquatic animals for farming from a country, zone or compartment not declared free from ranavirus

1. When importing live *aquatic animals* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should:

   a) require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that no other live *aquatic animals* of the species referred to in Article 2.4.2.2. have been introduced during that period;

OR

b) assess the *risk* and apply risk mitigation measures such as:

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

ii) the treatment of all effluent and waste materials in a manner that kills ranavirus.

2. For the purposes of the *Aquatic Code* the following steps should be taken if the importation is for the establishment of a new stock:

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

b) evaluate stock's health/disease history;

c) take and test samples for ranavirus, 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 ranavirus and perform general examinations for pests and general health/disease status;

g) if ranavirus 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 ranavirus free or specific pathogen free (SPF) for ranavirus;

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

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.9.

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

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should require that the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.4.2.3. or other products authorised by the *Competent Authority*, and all effluent and waste materials be treated in a manner that kills ranavirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, laboratory, zoo, pet trade, industrial or pharmaceutical use, from a country, zone or compartment not declared free from ranavirus

When importing live *aquatic animals* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should:

1. require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* attesting that no other live *aquatic animals* of the species referred to in Article 2.4.2.2. have been introduced during that period;

OR

2. assess the *risk* and apply risk mitigation measures such as:

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

   b) the treatment of all effluent and waste materials in a manner that kills ranavirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.11.

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

When importing *aquatic animal products* of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* declared free from ranavirus, 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 2.4.2.4. or 2.4.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from ranavirus.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.X.X.

This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Article 2.4.2.12.

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

1. When importing *aquatic animal* products of species referred to in Article 2.4.2.2. from a country, *zone* or *compartment* not declared free from ranavirus, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate risk mitigation measures.

2 In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include:

   a) the direct delivery into and holding of the consignment in biosecure facilities for processing to one of the products referred to in point 1 of Article 2.4.2.3. or other products authorised by the *Competent Authority*;

   b) the treatment of all effluent and waste materials in a manner that kills ranavirus.

3. This Article does not apply to *commodities* referred to in point 1 of Article 2.4.2.3.

Annex VII

CHAPTER 1.1.1.

DEFINITIONS

Aquatic animals

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

APPENDIX 4.X.X.

LIVE AMPHIBIANS

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

[ ] Farmed or captive [ ] Wild [ ] Adult or post-metamorphic

[ ] Eggs or spawn [ ] Larvae or tadpoles

Species:

Scientific name: .....

Common name: .....

Total weight of consignment (kg): .....

OR

Number: .....

II. Place of production/rearing or harvest prior to shipping

Country: .....

Zone: .....

Aquaculture establishment/Zone:

Name: .....

Location: .....

III. Origin of consignment (if different from II)

Country: .....

Zone: .....

Aquaculture establishment/Zone:

Name: .....

Location: .....

IV. Destination

Country: .....

Zone: .....

Aquaculture establishment/Zone:

Name: .....

Location: .....

Nature and identification of means of transport: .....

Annex VIII (contd)

V. Declaration

I, the undersigned, certify that the live amphibians and/or amphibian larvae, eggs in the present consignment have as their place of production/rearing or harvest: [ ] a Country, [ ] a Zone or [ ] an Aquaculture establishment that has been subjected to an official amphibians health surveillance scheme according to the procedures described in the OIE *Manual of Diagnostic Tests for Aquatic Animals* and that the Country, Zone or Aquaculture establishment identified in Sections II and III above has been declared free from the pathogens causing the diseases referred to in the OIE *Aquatic Animal Health Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Infection with *Batrachochytrium dendrobatidis*						
Infection with ranavirus						

Exporting country: .....

Competent Authority: .....

Stamp:

Issued at..... on

Name and address of Certifying Official

Signature:

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

Annex IX

APPENDIX 4.X.X.

AMPHIBIAN PRODUCTS

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

[ ] Meat [ ] Uneviscerated [ ] Unskinned

[ ] Farmed or captive [ ] Wild stocks [ ] Dried

Species:

Scientific name: .....

Common name: .....

Life stage: [ ]adults or postmetamorphs [ ]larvae or tadpoles [ ] eggs or spawn

Total weight (kg): .....

OR

Number: .....

II. Place of production/rearing or harvest prior to shipping

Country: .....

Zone: .....

Aquaculture establishment/Zone:

Name: .....

Location: .....

III. Origin of consignment (if different from II)

Country: .....

Zone: .....

Aquaculture establishment/Zone:

Name: .....

Location: .....

IV. Destination

Country: .....

Zone: .....

Aquaculture establishment/Zone:

Name: .....

Location: .....

Nature and identification of means of transport: .....

Annex IX (contd)

V. Declaration

I, the undersigned, certify that the live amphibians and/or amphibian larvae, eggs in the present consignment have as their place of production/rearing or harvest: [ ] a Country, [ ] a Zone or [ ] an Aquaculture establishment that has been subjected to an official amphibians health surveillance scheme according to the procedures described in the OIE *Manual of Diagnostic Tests for Aquatic Animals* and that the Country, Zone or Aquaculture establishment identified in Sections II and III above has been declared free from the pathogens causing the diseases referred to in the OIE *Aquatic Animal Health Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Infection with *Batrachochytrium dendrobatidis*						
Infection with ranavirus						

Exporting country: .....

Competent Authority: .....

Stamp:

Issued at..... on

Name and address of Certifying Official

Signature:

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

Annex XX

Aquatic Animals Commission work plan for 2007/2008

COMMISSION WORK PLAN FOR 2007/2008
Aquatic Animal Health Code
• Ongoing review of the list of diseases   • Review emerging diseases
• Finalise disease chapter for *Gyrodactylus salaris* after further Members' comments • Prepare 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*
• Review Chapter on zoning and compartmentalisation
• Prepare Appendix on Guidelines for aquatic animal health surveillance • Prepare Guidelines for surveillance for individual diseases
• Revise Aquatic Animal Health Model Certificates
• Prepare Guidelines for handling and disposal of carcasses and wastes of aquatic animals
• Finalise Guidelines for the control of aquatic animal health hazards in aquatic animal feeds
• Aquatic animal welfare guidelines
• Antimicrobial resistance in the field of aquatic animals
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 if listing is approved
Meetings
• Make presentations on the activities of the Aquatic Animals Commission at the Conferences of the OIE Regional Commissions
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 that there is scope to address the evaluation of aquatic animal health systems
• Coordination of a publication on "Changing trends in managing aquatic animal disease emergencies" under the *Rev. Sci. Tech.* series