UNION EUROPÉENNE

SANCO

19. 01. 2005

Brussels
E2 YT D(2004) /522479

Object: **Meeting of the Bureau of the Aquatic Animals Standards Commission – October 2004**

Dear Bernard,

Please find attached as an annex to this letter the Community comments on the report of the meeting of the Bureau of the Aquatic Animals Standards Commission.

The European Community again raises its concern about the consultation times the OIE gives to it Members. The OIE circulated the official report from the October meeting of the Bureau of Aquatic Animals Standards Commission on 9 December, asking for comments by 5 January. This gave the Member Countries of the OIE 15 working days to study the official report, prepare and submit comments. The European Community considers the OIE Aquatic Animal Health Code and OIE Manual of Diagnostic Tests for Aquatic Animals to be important documents concerning the international trade in aquatic animals. Any amendments to the Code and Manual should therefore be given careful considerations. The Community is of the opinion that 15 working days to consider such an important issued is not sufficient. The OIE is therefore requested to, in the future, to give OIE Member Countries more time to study the reports and proposals from the Aquatic Animals Commission, in order to be able to analyse the consequences of the proposed amendments and elaborate comments that may be properly justified. The planned meetings of the Aquatic Animals Commission must if necessary be postponed, in order to allow OIE Member Countries to submit well prepared comments.

The Community has commented on the OIE Ad hoc groups reports with respect to the assessment of the diseases listed in the 2004 Code against the listing criteria. In spite of the short time available Community experts have prepared separate reports, which challenge some of the conclusions with respect to the listing or not listing of certain diseases according to the criteria developed by the OIE. These reports on bacterial kidney disease, Koi herpes virus, infectious pancreatic necrosis and Perkinsus species are attached as annexes and the Community would ask the OIE to reassess the listing of these diseases based on this information. Furthermore, the Community would point out that it should not be the intention to carry out large scale active surveillance for diseases which are endemic in a country. Any surveillance carried out should be risk based.

The Community has also prepared a draft Chapter on the small hive beetle as requested and will submit a Community response on the SPS questionnaire in the near future.

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

Arthur Besch

Chief Veterinary Officer

Jaana Husu-Kallio

Deputy Director General

Enclosures: 1

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

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ANNEX

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

Original: English
October 2004

REPORT OF THE MEETING OF THE BUREAU OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION Paris, 11–15 October 2004

The Bureau of the OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 11 to 15 October 2004. The meeting was chaired by Dr Eva-Maria Bernoth, President of the Commission, and Dr Ricardo Enriquez, Secretary General, acted as Rapporteur.

The Commission was welcomed by Dr Bernard Vallat, Director General of the OIE. He emphasised three main objectives for the upcoming General Session of the OIE: harmonisation of chapters, to the extent possible, in the OIE *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) and the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*), development of guidelines for the implementation of compartmentalisation, and the enhancement of the disease notification system. Regarding the annual OIE/FAO/WHO questionnaires, he stressed the need for Member Countries to provide better information on aquatic animal populations and the activities of aquatic animal health services. Dr Vallat thanked the members of the Bureau for their continuing good work.

The Agenda and List of Participants are given at Appendices I and II, respectively.

Member Countries are strongly encouraged to send comments on Appendices IV, V, VIII, IX, X, XI, XII and XIV by 5 of January 2005.

1. *Aquatic Animal Health Code*

Community comment

The Community appreciates the efforts done by the OIE AAC with respect to amendments of the Code. Technical comments are included in the relevant Appendices.

The Community is however deeply concerned about what seems to be the shorter and shorter time OIE Member Countries are given to assess the reports. At the same time the OIE urges its Member Countries to submit comments. The Community believes more comments would have been received if OIE Member Countries were given sufficient time to submit their comments.

The Bureau discussed the work of various *ad hoc* Groups. One was responsible for the OIE list of aquatic diseases and others for chapters in the *Aquatic Code* and the OIE *Manual of Diagnostic Tests for Aquatic Animals* (hereafter referred to as the *Aquatic Manual*) chapters for fish, mollusc and crustacean diseases. The Bureau met with the crustacean experts from the disease list *ad hoc* group, who were meeting concurrently with the Bureau.

1.1. Revision of the OIE list of diseases

The Bureau considered the draft report produced by the *ad hoc* Group (comprising fish, mollusc and crustacean disease teams) revising the OIE list of aquatic diseases, with a view to ensuring that the terms of reference had been met and that the outputs of the three teams were harmonised. The Bureau confirmed that a detailed analysis was required only for those diseases for which the initial assessment against one or more disease listing criteria was not clear. The reports of the three teams comprising the *ad hoc* Group are at Appendix III for the information of Member Countries.

One team indicated that it had experienced difficulties in applying some criteria. The Bureau considered the indicated difficulties and decided that they did not warrant a technical change to any criterion at this time, but a minor editorial change was made to criterion 6. The proposed revised criteria are at Appendix IV for Member Countries' comment.

The Bureau decided that, based on the work of the experts, some diseases would be proposed for deletion from the current list and some not currently listed would be proposed for listing. The revised list of diseases proposed by the Bureau is at Appendix V for Member Countries' comment.

Community comment

Community experts have not been given sufficient time to fully assess the documentation put forward by the OIE. The Community therefore reserves its right to submit further comments on this topic before the General Session of the OIE in May 2005.

However, within the time limit give by the OIE, Community experts have given the report from the OIE a preliminary assessment. Based on this, the Community disagrees with the OIE on some of the recommendations from the OIE Ad hoc groups.

Therefore the Community can only support this Chapter if the changes indicated in the separate Appendixes are taken on board

1.2. Harmonisation of the structure of disease chapters for future editions of the *Aquatic Code*

The Bureau considered the draft reports produced by two *ad hoc* Groups. These contained draft disease chapters for *Marteilia refringens* and white spot disease based on templates devised by the Aquatic Animals Commission after taking into account comments received from Member Countries on its January 2004 report. These reports are at Appendices VI and VII for the information of Member Countries.

The Bureau revised the two draft disease chapters. These proposed revised chapters are presented as clean text (Appendices IX and X) for Member Countries' comment.

The Bureau drafted a chapter on epizootic haematopoietic necrosis (EHN); this proposed revised chapter is presented as clean text (Appendix VIII) for Member Countries' comment.

Community comment

In general, the Community supports the proposed amendments, provided the specific comments in Appendixes VIII, IX and X are taken into account.

1.3. Definitions

The Bureau took into account comments previously received from Canada, Australia and the European Union (EU) in revising some definitions. It also proposed a new definition for 'water catchment'. The proposed revised and new definitions are at Appendix XI for Member Countries' comment.

Community comment

The Community supports the proposed amendments provided the specific comments in Appendix XI are taken into account.

1.4. Revision of Appendix on General Recommendations on Disinfection

The Bureau revised the Appendix on General Recommendations on Disinfection to take into account comments received from Member Countries on the January 2004 report of the Aquatic Animals Commission. The revised text is at Appendix XII for Member Countries' comment.

Community comment

The Community supports the proposed amendments in Appendix XII.

2. *Manual of Diagnostic Tests for Aquatic Animals*

2.1. Revision of Chapter 1.1.4. Requirements for surveillance for international recognition of freedom from infection

The Bureau discussed the work of the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Code Commission) in developing a *Terrestrial Code* chapter on the general principles of surveillance, and the need to update Chapter 1.1.4. of the *Aquatic Manual*. Recognising the need to harmonise the *Terrestrial* and *Aquatic Codes* to the extent possible, the Bureau decided to use the draft *Terrestrial Code* chapter as a basis for developing an equivalent chapter for the *Aquatic Code*. A draft adapted to aquatic animal biology and pathology will be circulated to the members of the Aquatic Animals Commission out of session for comment. These comments, together with those received from Canada on the existing Chapter 1.1.4. of the *Aquatic Manual*, and those from Member Countries on the *Terrestrial Code* draft will be taken into account at the January 2005 joint meeting of the two Commissions in preparing a final draft for circulation to Member Countries. It is hoped that the chapter will be adopted at the 73rd General Session.

2.2. Update of disease chapters for the fifth edition of the *Aquatic Manual*, using the new template

The Bureau was briefed by Ms Sara Linnane on the timeframe of the preparation of the 5th edition (2006) of the *Aquatic Manual*. Authors will be requested to prepare their chapters, using the new template, by February 2005. Priority will be given to those diseases not proposed for removal from the list (see Agenda item 1.1.).

Community comment

The Community supports these proposals provided the specific comments in the relevant Appendices are taken into account.

3. Joint meeting with the Terrestrial Animal Health Standards Commission

The Bureau was joined by Dr Alejandro Thiermann, President of the Code Commission for this agenda item. The Bureau and Dr Thiermann discussed likely agenda items for the meeting of the two Commissions in January 2005

3.1. Continuing work on harmonisation of horizontal chapters in the *Aquatic* and *Terrestrial Codes*

The work on harmonisation will address initially the sections in Part 1 (General Provisions) of the *Aquatic Code*, in particular obligations and ethics in international trade, and import risk analysis.

3.2. Compartmentalisation

On the invitation of the Director General, an expert, Dr Yngve Torgersen from the European Commission, addressed the Bureau and the President of the Code Commission on his work on applying compartmentalisation to aquatic animals. The Bureau developed an explanatory paper on this concept, with examples illustrating the application of the concept, for the information of Member Countries (Appendix XIII). This paper will serve as the basis for a revised chapter of the *Aquatic Code* on zoning/compartmentalisation to be presented to Member Countries after the January 2005 meeting of the Commission.

The two Commissions will work together on revised chapters for each *Code* which will include explanatory guidelines to assist Member Countries in setting up and implementing zones and compartments.

3.3. OIE Working Group on Animal Welfare

The Bureau was updated on the animal welfare work of the OIE, especially the setting up of the two *ad hoc* groups on aquatic animal welfare, one to examine aquatic animal slaughter and the other transportation. It is planned that these groups would meet, if possible, in the first half of 2005 under the chairmanship of Prof. Tore Håstein and would report to the Working Group on Animal Welfare and the Aquatic Animals Commission. The Bureau was comfortable with this approach.

Community comment

The Community welcomes the work done by OIE experts.

4. Joint meeting with the Animal Health Information Department

For this agenda item, the Bureau was joined by Dr Karim Ben Jebara and Dr Julio Pinto, Head and Deputy Head respectively of the Animal Health Information Department and Dr Daniel Chaisemartin, Project Officer at the OIE.

4.1. Update on implementation of new notification system

The Bureau was updated on the implementation of the new disease notification system. Dr Ben Jebara indicated that the OIE Web interface for disease notification would be in place by July 2005, at which time information would be sought for the January-June 2005 period on diseases listed in the 2005 edition of the *Aquatic Code*. Dr Ben Jebara requested the Bureau's assistance in finalising the planned Manual for Aquatic Animal Disease Reporting, a draft of which would be forwarded to the Commission in early December 2004.

4.2. Reporting form for immediate notification or follow-up report, including control measures

Dr Ben Jebara presented the new draft form for immediate notification or follow-up of an occurrence of an aquatic animal disease or other significant epidemiological event. He also requested that the Bureau provide information on types of epidemiological units, diagnostic tests, sources of outbreaks and control measures, for inclusion in the form.

4.3. Notification and epidemiological information

The Bureau revised Chapters 1.1.2. and 1.2.1. in accordance with the new notification obligations on Member Countries. The revised text is at Appendices IV and XIV.

4.4. Update of Aquatic Animals Commission website

The Bureau discussed the need to update some of the information on the OIE Web site relevant to the Commission's work, and to minimise unnecessary duplication. Items to be deleted or amended on the AAC web pages were agreed. The Vice-President confirmed that he would be willing to continue maintaining the Commission's web pages and will make the agreed amendments as soon as possible.

Community comment

The Community supports the need to update the OIE Web-site, and would also like to draw the attention to the necessity to update Web-site of the OIE Collaboration Centre for Information of Aquatic Animal Diseases correspondingly.

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

For this agenda item, the Aquatic Animals Commission was joined by the Director General of the OIE.

5.1. Conferences of OIE Regional Commissions

The first presentation of the activities of the Aquatic Animals Commission at the regional level was made at the 23rd Conference of the OIE Regional Commission for Asia, the Far East and Oceania, held in Noumea (New Caledonia) from 25 to 28 November 2003, by the President of the Aquatic Animals Commission, Dr Eva-Maria Bernoth. Since then, this has become an item at each OIE Regional Commission Conference.

Dr Barry Hill, Vice-President, reported that his presentation at the 21st Conference of the OIE Regional Commission for Europe, which was held in Avila (Spain) from 28 September to 1 October 2004, had been well received. The Regional Commission agreed on a proposal that an OIE Seminar on aquatic animal health be held in 2005. This proposal remains to be confirmed.

During the Avila Conference, the Director General reminded the Delegates of the Recommendations of the OIE Regional Commission meeting for Asia, the Far East and Oceania. These had been endorsed by the International Committee of the OIE in May 2004. Delegates are reminded of their obligations regarding these recommendations, which are attached at Appendix XV.

Members of the Aquatic Animals Commission will give presentations during the remaining three Regional Commissions' Conferences in Panama (Americas), Khartoum (Africa) and Bahrain (Middle East). Prof. Don Lightner will give the presentation at the Panama Conference and Dr Eli Katunguka-Rwakishaya will give

the presentation at the Khartoum Conference. The Bureau agreed that Dr Barry Hill would give the presentation at the Bahrain Conference.

The Bureau discussed with Dr Vallat the progress with implementing the recommendations of the Noumea Conference. Dr Vallat indicated that he would write to all OIE Delegates asking for nominations of an 'aquatic national focal point' as a parallel recipient of Aquatic Animals Commission reports in those countries where the Veterinary Services are not responsible for aquatic animal health (see item A.7 in Appendix XV). These focal points are to coordinate all aquatic animal issues, including disease reporting and providing comments on the Commission's reports, under the authority of the Delegate.

5.2. Proposal to hold a Global Conference on Aquatic Animal Disease Emergencies in 2006

The Bureau discussed with Dr Vallat how a global conference could usefully assist with implementing the Recommendations endorsed by the International Committee (see item 5.1.). The Bureau agreed that aquatic animal disease emergencies could be part of the scope of such a global conference, but that the scope of the conference should be broadened to cover items such as involvement of veterinary services in aquatic animal health, cooperation between veterinary and fisheries authorities, and the enhancement of reporting mechanisms. Such a conference would benefit from being held in a region with significant aquaculture industries.

Member Countries are encouraged to submit to the Central Bureau proposals regarding hosting such an important event.

5.3. International meetings

Community comment
The Community supports these proposals

The Bureau agreed that Dr Ricardo Enriquez would represent the Commission at the Thirteenth Chilean Congress of Veterinary Medicine, organised by the Association of Veterinary Medicine Faculties of Chile, to be held in Valdivia (Chile) from 4 to 6 November 2004.

The President indicated that she has been invited by NACA[1] to represent the Commission at the Third Annual General Meeting of the Asia Regional Advisory Group on Aquatic Animal Health, to be held in Bangkok (Thailand) from 23 to 25 November 2004.

6. OIE Reference Laboratories

6.1. Evaluation of annual reports for 2003

The Bureau reviewed the annual reports of the activities of the OIE Reference Laboratories for aquatic animal diseases for 2003 and noted a variation in quality among the reports. The Bureau felt that in view of the change to the mandate for OIE Reference Laboratories, the current template for the annual reports needs to be amended. The Commission will propose a new template to the Central Bureau.

[1] NACA : Network of Aquaculture Centres in Asia-Pacific

6.2. Updating the list of OIE Reference Laboratories

The OIE has been notified of the following change of expert at an OIE Reference Laboratory. The Bureau of the Aquatic Animals Commission recommends its acceptance:
Bacterial kidney disease

Dr James Winton to replace Dr Ron Pascho at the Western Fisheries Research Center, 6505 N.E. 65th Street, Seattle, Washington 98115, United States of America. Tel.: (1.206) 526.65.87, Fax: (1.206) 526.66.54, E-mail: jim_winton@usgs.gov
The Bureau discussed the possible need for additional laboratories. It was agreed that it would be preferable to await the adoption of the revised list of aquatic animal diseases (Agenda item 1.1.) before further consideration.

The Commission had received a resignation from Dr M. Kent from the Reference Laboratory for Piscirickettsiosis (*Piscirickettsia salmonis*) in the USA.

Community comment
The Community supports these proposals

7. Any other business

7.1. Amphibian disease issues

The Bureau noted the recent article in *Science* discussing the worldwide decline in amphibian populations, associated with infectious diseases. The Bureau reiterated its request that Member Countries provide information on trade in amphibians (nationally and internationally) and on the occurrence of diseases of amphibians within their territory. The Bureau resolved to draft another questionnaire aimed at obtaining information on these diseases, with the view to the Commission determining the need for listing amphibian diseases and consequently drafting *Aquatic Code* and *Aquatic Manual* chapters.

7.2. Review of Aquatic Animals Commission work plan for 2005

The Commission reviewed its work plan for 2005, which is presented at Appendix XVI.

7.3. Date of the next meeting

The Aquatic Animals Commission will meet from 13 to 19 January 2005.

Community comment
The Community supports these proposals

.../Appendices

Appendix I

MEETING OF THE BUREAU OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 11–15 October 2004

Agenda

1. ***Aquatic Animal Health Code***
   - 1.1. Revision of the list of diseases
   - 1.2. Harmonisation of the structure of disease chapters for future editions of the *Aquatic Code*
   - 1.3. Definitions
   - 1.4. Revision of Appendix on General Recommendations on Disinfection
2. ***Manual of Diagnostic Tests for Aquatic Animals***
   - 2.1. Revision of Chapter 1.1.4. Requirements for surveillance for international recognition of freedom from infection
   - 2.2. Update of disease chapters for the fifth edition of the *Aquatic Manual*, using the new template
3. **Joint meeting with the Terrestrial Animal Health Standards Commission**
   - 3.1. Continuing work on harmonisation of horizontal chapters in the *Aquatic* and *Terrestrial Codes*
   - 3.2. Compartmentalisation
   - 3.3. OIE Working Group on Animal Welfare
4. **Joint meeting with the Animal Health Information Department**
   - 4.1. Update on implementation of new notification system
   - 4.2. Reporting form for immediate notification or follow-up report, including control measures
   - 4.3. Notification and epidemiological information
   - 4.4. Update of Aquatic Animals Commission website
5. **The role and activities of the OIE in the field of aquatic animals**
   - 5.1. Conferences of OIE Regional Commissions
   - 5.2. Proposal to hold a Global Conference on Aquatic Animal Disease Emergencies in 2006
   - 5.3. International meetings
6. **OIE Reference Laboratories**
   - 6.1. Evaluation of annual reports for 2003
   - 6.2. Updating the list of OIE Reference Laboratories
7. **Any other business**
   - 7.1. Amphibian disease issues
   - 7.2. Review of Aquatic Animals Commission work plan for 2005
   - 7.3. Date of the next meeting

Appendix II

MEETING OF THE BUREAU OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION
Paris, 11–15 October 2004

List of participants

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Appendix II (contd)

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Appendix III

AD HOC GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES

REPORT OF THE FINFISH TEAM

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OIE-listed fish diseases that do not appear to meet all the required listing criteria

1. INTRODUCTION

The team was asked to assess the list of diseases of fish and to conduct the work, as far as possible, through correspondence by email and to meet face-to-face when present together at a scientific meeting. In the timescale of the exercise so far, it has not proved possible for the team members to be together at any scientific meeting so all the work has been conducted by email discussion only. This has prevented detailed discussion of some of the less clear or finely balanced arguments in the assessments and means that this report may require further development in some areas to more fully justify the removal of some of the identified diseases from the OIE list.

2. APPROACH

Each of the 16 fish diseases currently listed in the 7th edition (2004) of the OIE *Aquatic Code* was evaluated independently by each team member with respect to how far they meet, or do not meet, each of the criteria for listing an aquatic animal disease as published in Article 1.1.2.1 of the *Aquatic Code*. Account was taken of information in the International Database on Aquatic Animal Diseases, in the OIE *Aquatic Manual* and in the published scientific literature. Account was also taken of the views of the Aquatic Animals Commission in their assessment presented in Appendix IX of the report of the Commission's meeting of 23-27 June 2003 on which some OIE Member Countries provided comments.

There were differences of opinion between team members on whether some criteria were or were not met for certain diseases and further discussion on these is needed. However, in the interests of obtaining comments from OIE Member Countries as early as possible, a simple summary table has been produced showing the teams assessment 'scores' against each criterion, the majority opinion of the team applying. Each of the diseases that failed to meet one or more of the criteria, and therefore a candidate for removal from the OIE list, was subjected to a more detailed evaluation. The format for presenting the detailed assessment follows directly each individual criterion as published in the Aquatic Code 7th edition (2004) Article 1.1.2.1, and includes a short summary of the reasons for compliance or lack thereof, with references that support the position stated.

Comments from OIE Member Countries will be taken into account in completing the assessments and producing a proposed amended list of fish diseases.

3. **FROM THE OIE AQUATIC ANIMAL HEALTH CODE 2004:**

CHAPTER 1.1.3.

DISEASES LISTED BY THE OIE

Article 1.1.3.1.

The following diseases of fish are listed by the OIE

- Epizootic haematopoietic necrosis
- Infectious haematopoietic necrosis
- *Oncorhynchus masou* virus disease
- Spring viraemia of carp
- Viral haemorrhagic septicaemia
- Channel catfish virus disease
- Viral encephalopathy and retinopathy
- Infectious pancreatic necrosis
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- Bacterial kidney disease (*Renibacterium salmoninarum*)
- Enteric septicaemia of catfish (*Edwardsiella ictaluri*)
- Piscirickettsiosis (*Piscirickettsia salmonis*)
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease
- White Sturgeon iridoviral disease

Article 1.1.3.2.

[...]

Article 1.1.3.3.

[...]

Appendix III (contd)

4. SUMMARY OF EVALUATIONS

Disease	Criterion 1	2	3	4	5	6	7	8	Conclusion (retain/remove)
		+	-	+	NA	+	+	+	Retain
	-								
	+	+	-	+	NA	+	+	+	Retain
OMVD	(+)	+	-	+	NA	(-)	+	+	**Remove**
SVC	+	+	-	+	NA	+	+	+	Retain
VHS	+	+	-	+	NA	+	+	+	Retain
CCVD	+	-	-	+	NA	(+)	(+)	+	**Remove**
VER	-	-	-	+	NA	+	+	+	**Remove**
IPN	(+)	-	-		NA	(+)	(-)	+	**Remove**
				+					
ISA	+	-	-	+	NA	+	+	+	Retain
EUS	+	+	-	+	NA	(+)	+	+	Retain
BKD	-	-	-	+	NA	+	(-)	+	**Remove**
ESC	(+)	-	-	+	NA	(+)	?	+	**Remove**
Piscirickettsiosis	(+)	-	-	+	NA	-	-	+	**Remove**
Gyrodactylosis	-	(+)	-	+	NA	+	(+)	+	Retain
RSBID	+	-	-	+	NA	+	+	+	Retain
WSID	-	?	-	+	NA	?	?	+	**Remove**

\+ criterion applies
(+) criterion applies but to limited circumstances
\- criterion does not apply
(-) criterion does not apply sufficiently
? insufficient information available
NA not applicable.

5. Detailed evaluation of each disease recommended for removal from the OIE list

I. Oncorhynchus masou virus disease

A. Consequences

1. Significant losses due to morbidity, mortality or product quality.

Salmonids are the only fish species susceptible to OMV infection; the order of the fish species from the most to the least susceptible is: kokanee salmon, chum salmon, masou salmon, coho salmon and rainbow trout. The age of the fish is critical and 1-month-old alevins are the most susceptible to the virus; in general, mortality rate declines with age and is negligible amongst fish 6 months old (Kimura *et al.*, 1983)

Four months after the first clinical manifestation, a varying number of surviving fish exhibit epithelioma occurring mainly around the mouth (upper and lower jaw) and, to a lesser extent, on the caudal fin, operculum and body surface. Such neoplasia may persist for up to 1 year post-infection (Kimura *et al.*, 1981) and fish disfigured in this way are of lower product quality and likely to have poor market value.

Whilst there is no doubt about morbidity and mortality affecting fry production in infected hatcheries are directly related to the agent, the overall current annual losses in Japan are not high enough to be classed as 'significant production losses at the national level'.

The disease still only affects production in one country (Japan) – no other country is affected.

2. Affects wild fish populations

Although wild populations of kokanee salmon in northern Japan are known to be persistently infected by the virus, there is no reported evidence for mortalities having an effect at the salmon population level.

3. Public health concern

None.

4. Infectious aetiology proven

No doubts about the aetiology being an infectious herpesvirus (Salmonid herpesvirus 2).

B. Spread

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

The disease is still only found in northern Japan despite over 25 years having passed since its first detection, Japan does not currently, or look likely to, export live fish or eggs of the susceptible species so there appears to be no significant likelihood of international transfer.

The most likely international trade to develop would be in eyed eggs. It is believed that the disease may be transmitted vertically via the egg (egg-associated) but the risk is

considerably reduced by use of iodophor disinfection at the eyed stage (Yoshimizu *et al.*, 1993).

7. Several countries/zones may be declared free

The oncogenic effect of the disease in survivors of outbreaks in alevins is so clinically obvious that it is possible that declaration of 'historical freedom' could be made by most countries with susceptible species of wild and/or farmed salmonids provided that the other conditions described in Chapter 1.1.4. of the OIE *Aquatic Manual* have been met.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Diagnostic tests for OMVD, as described in the OIE *Aquatic Manual*, are widely available.

Although the tests have not undergone formal standardization and validation, their routine nature and the fact that they have been in use for many years without dubious results make them acceptable. A robust case definition exists.

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II. Channel catfish virus disease

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

The disease continues to occur when channel catfish fry are held at high densities during periods of elevated water temperatures.

Loss of young fish from inventory is principal concern but economic losses are considered less than other diseases causing losses among larger fish that have increased value compared to fry.

2. Affects wild fish populations

No evidence for the disease in wild fish populations.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

No doubt about the aetiology being an infectious herpesvirus.

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

Potential for spread is present if live channel catfish are moved from endemic areas where currently there are no control programs to guarantee freedom from the virus. Most fish in endemic areas are viewed as suspect virus carriers.

However, the disease is still primarily confined to the southeastern region of the USA after more than 30 years known occurrence. Principal risk is movement of live channel catfish. Eggs are not part of any trade at present and unlikely to develop. The current trade in live channel catfish to other countries is unknown but believed to be minimal and shows no signs of potential for increase. Channel catfish have been introduced to just a few countries in the past but the farming enterprises have not become significant and no cases of CCVD have been recorded.

7. Several countries/zones may be declared free

There have been no occurrences of the disease recorded in countries other than USA except for an unsubstantiated anecdote in a scientific review publication (Plumb, 1989).

A few countries, other than the USA, where farmed populations of the susceptible species have been present for at least 25 years but no clinical cases of CCVD have been observed could possibly be declared free, provided that the biosecurity conditions, as described in Chapter 1.1.4. of the OIE *Aquatic Manual*, have been met continuously for the past 10 years. However, it is unlikely that any countries where the susceptible species exist have conducted targeted surveillance as described in the OIE *Aquatic Manual* to demonstrate absence of CCVD.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Diagnostic tests for the disease, as described in the OIE *Aquatic Manual*, are widely available. Standard virus isolation tests are effective during active outbreaks in channel catfish fry. PCR or detection of anti-CCV neutralizing antibodies in serum may identify potential virus carriers in older fish. As for most virus testing procedures for fish diseases, the methods are standardized but not formally validated. Although the tests have not undergone formal standardization, their routine nature and the fact that they have been in repeated use for many years without dubious results make them acceptable

A second distinct but related virus to ictalurid herpesvirus 1 (IcHV-1) has been found among catfish (*I. melas*) in Italy but can be readily differentiated from CCV (Hedrick *et al.*, 2003).

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III. Viral encephalopathy and retinopathy

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Viral encephalopathy and retinopathy (VER) or viral nervous necrosis (VNN) is a serious disease of larval and juvenile and sometimes older marine fish that now occurs almost world-wide, although not yet reported from any country in Africa. The disease has a wide host range and has been reported in at least 30 fish species (Munday *et al.*, 2002).

There are considerable variations in the age at which disease is first noted and the period over which mortality occurs. In general, highest mortality occurs in the earliest stages of fry development. Although disease occurrence at the juvenile stages in some species is very rare, mass mortalities often occur at juvenile to young stages in other fish species, but usually do not reach 100%, indicating the age-dependence of susceptibility (Munday et al., 2002). Mortalities have, however, been reported in production-size European sea bass (Le Breton et al., 1997) and grouper (Fukuda et al., 1996), but even in these cases, mortalities were mostly in younger fish.

2. Affects wild fish populations

No evidence for mortalities or other negative effects on wild fish at the population level.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

No doubts about the aetiology being an infectious nodavirus.

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

The disease has a worldwide distribution, affecting most, if not all, countries currently farming marine fish species. Infection is known to be present in wild fish populations and it is reasonable to assume that virus is naturally endemic in the marine environment throughout most regions of the world.

7. Several countries/zones may be declared free

It is doubtful that any country farming marine fish species is able to declare freedom form this disease using the 'absence of susceptible species' or 'historically free' options described in Chapter 1.1.4. of the OIE *Aquatic Manual*, not least because of the wide geographical distribution and large host range of the virus and inability of countries and/or individual marine fish farms to meet all of the biosecurity conditions. It is not thought that any country could declare freedom on the basis of targeted surveillance either.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Diagnostic tests for VER virus, as described in the OIE *Aquatic Manual*, are widely available.

Although the tests have not undergone formal standardization and validation, their routine nature and the fact that they have been in use for many years without dubious results make them acceptable. The pathology is very distinctive, even pathognomic, and a robust case definition can be drawn up.

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Appendix III (contd)

IV. Infectious pancreatic necrosis

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Infectious pancreatic necrosis (IPN) is a highly contagious viral disease principally of young fish of salmonid species held under intensive hatchery conditions (Wolf *et al.*, 1960; Hill, 1982; Wolf, 1988). The disease most characteristically occurs in young fry of trout, char and salmon species. Although high mortalities can occur in first-feeding fry, susceptibility generally decreases with age, with resistance to clinical disease usually being reached at about 3 months post-hatch. The economic impact of such outbreaks in such young fish is not high and, where it is endemic, the salmonid farming industry has largely learned to live with the disease, often simply discarding affected fry batches. Control methods include the implementation of hygiene practices in salmonid husbandry, through the avoidance of the introduction of fertilised eggs originating from IPNV-carrier broodstock, and the use of a protected water supply (e.g., spring or borehole) where the ingress of fish, particularly possible virus carriers, is prevented. In outbreaks, a reduction in the population density ('thinning out') can reduce the overall mortality. However, it also causes significant losses in Atlantic salmon smolts after transfer from fresh water to seawater (Smail *et al.*, 1989) but whether this is due to expression of infection acquired in freshwater or from a marine fish reservoir in the vicinity of the salmon cages is not clear.
Commercial vaccines are now available to ameliorate the losses in Atlantic salmon marine farms but there are mixed reports about their efficacy.

2. Affects wild fish populations

Although there have been many isolations of IPN virus from a wide range of wild fish species, there is no published scientific evidence that demonstrates such infections have any adverse effect at the population level, or even on the individual host.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

No doubts about the aetiology being an infectious birnavirus.

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

The biggest risk of international spread of IPN is via live fish. However, the international trade is traditionally mostly in eyed-eggs that have been subjected to a disinfection procedure. It is widely accepted that vertical transmission of IPN is a typical characteristic of the disease in trout. The published evidence for vertical transmission of

IPNV via the fertilised egg of trout species is quite comprehensive and, in the main, conclusive, but the evidence for salmon species is much less convincing.
For Atlantic salmon in Europe, there is a potential international trade in live salmon smolts to on-growing marine cage farms, delivery being by wellboat or, more rarely, by helicopter. This would introduce the potential for transfer of the virus in carrier fish but, as stated above, it is not certain that such fish are the cause of outbreaks of IPN in salmon farms rather than the source being infected local wild marine fish.

7. Several countries/zones may be declared free

The disease already has a wide geographical distribution, occurring in most major freshwater salmonid-farming countries of North and South America, Europe and Asia. However, there have been no reports of the clinical disease from countries in Oceania and it is possible that these countries could provide the evidence to justify being declared free either on historical grounds or through targeted surveillance as described in the OIE *Aquatic Manual*.

It is widespread and well-established in the marine Atlantic salmon industries of the major producer countries – only Tasmania, Australia is still believed to be free.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Diagnostic tests for IPN virus, as described in the OIE *Aquatic Manual*, are widely available.

Although the tests have not undergone formal standardization and validation, their routine nature and the fact that they have been in use for many years without dubious results make them acceptable.

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V. Bacterial kidney disease (Renibacterium salmoninarum)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

The association of *Renibacterium salmoninarum* with disease in farmed and wild salmonid fish is well established (Evelyn, 1993). The presence of the bacterium, in the absence of disease is also commonly encountered (Fryer and Lannan, 1993). Salmon with advanced cases of the bacterial kidney disease (BKD) can suffer significant mortality both in freshwater or during transition to seawater or during seawater residence (Banner *et al.*, 1986).

2. Affects wild fish populations

The impact of the disease on cultured populations of salmonids is clear but the potential effects on wild salmonids is much less clear. The presence of the bacterium in populations with no contact with hatchery-reared salmonids, indicates a potential concern for the health of wild populations of fish (Souter *et al.*, 1987) but studies to demonstrate such population impacts are not available. All salmonids, recently to include whitefish, are known hosts for the bacterium which may be present throughout the natural geographic distribution of wild and cultured salmonid fishes.

3. Public health concern

There is no evidence to suggest that the bacterium possesses any capabilities to infect homiotherms. In fact, the bacterium may be quite host specific for members of the family Salmonidae.

B. Spread

4. Infectious aetiology proven

Renibacterium salmoninarum is the proven aetiological agent of BKD and a firm association between the bacterium and disease outbreaks is established (Evelyn, 1993). What remains difficult to assess are all factors that contribute to disease as detection of the bacterium by sensitive diagnostic methods indicates a rather broad distribution of the agent in salmonid populations. A majority of these detections occur in the absence of disease.

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

The bacterium is capable of spreading via both horizontal and vertical modes with perhaps the greatest concern being transport over large distances with salmonid eggs originating from moderate to heavily infected female salmon (Evelyn, 1993; Fryer and Sanders, 1981). That the bacterium can be present within the egg and therefore not subject to surface disinfection was established by Evelyn (reviewed in Evelyn, 1993). Transport of live fish also represent a mode by which the agent may be spread over shorter distances.

7. Several countries/zones may be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the OIE *Aquatic Manual*.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Suitable screening methods as well as standardized procedures exist. A series of robust tests including antigen and DNA-based systems are available for detection of the agent or its respective antigens or nucleic acids. These tests are widely available and in some cases fully commercialized.

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VI. Enteric septicaemia of catfish (Edwardsiella ictaluri)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Enteric septicemia of catfish (ESC) is considered one of the two (the other being columnaris) most serious bacterial diseases in channel catfish culture in the southeastern USA (Wagner *et al.*, 2003). Average losses reported for ESC and columnaris range from 200–2000 lbs per outbreak as estimated from recent occurrences in catfish farms in the southeastern USA. Outbreaks require administrations of antibiotics or stock destruction with significant economic impacts to catfish growers.

2. Affects wild fish populations

Captive fish populations other than catfish have been shown to be susceptible to *Edwardsiella ictaluri* (Kent & Lyons, 1982; Plumb & Sanchez, 1983; Baxa *et al.*,.1990), but there are no reports of losses among either wild populations of catfish or other fish species.

3. Public health concern

There is no evidence to date of infections among homiotherms, although the bacterium can be propagated at temperatures of 37°C.

B. Spread

4. Infectious aetiology proven

The disease has been demonstrated to be infectious in laboratory and field trials with channel catfish (Hawke, 1979). The bacterium can spread by horizontal means to infect other catfish in the pond through two potential routes, either and oral or via infections originating in the olfactory system (Shotts *et al.*, 1986). Association of the bacterium with the disease and as the proven aetiological agent has been established (Hawke, 1979).

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

Extent of trade in live channel catfish uncertain but viewed as minimal.
Limited trade and highest risk with moving juvenile channel catfish (not commonly done internationally) make likelihood of spread to be of low risk.

7. Several countries/zones may be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the OIE *Aquatic Manual.*

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Standardized culture and biochemical identification methods remain the principal approach for screening. A real-time PCR test to identify *E. ictaluri* is available (Bilodeau *et al.*, 2003).

Appendix III (contd)

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VII. Piscirickettsiosis (Piscirickettsia salmonis)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Significant losses continue among salmonids reared in net pens in Europe, North America and Chile. New data suggests that *P. salmonis* is not restricted to salmonids and can be the cause of significant losses among certain marine fish species (Chen *et al.*, 2000, Arkush *et al.*, in press).

Demonstrated in both farmed and experimental infections of salmonids and certain non-salmonids.

The disease is considered a major and continuing problem, particularly in Chile (reviewed in Fryer & Hedrick 2003).

2. Affects wild fish populations

The increasing detection of the bacterium or closely related agents in marine fish populations may indicate a potential role for the health of wild populations but to date no reports on significant losses or impacts on wild fish population has been recorded

3. Public health concern

There is no evidence the bacterium can infect or cause disease in homiotherms. The risk to human health is therefore considered extremely low or nil.

B. Spread

4. Infectious aetiology proven

The infectious nature of the disease is proven both by experimental and natural occurrences of the disease in populations of salmon and certain non-salmonid species (reviewed in Fryer & Hedrick 2003). The increased detection in non-salmonid fish suggests a considerably wider host range than previously supposed and may in part explain occurrences in salmonid populations where trade or movement of eggs was not the source. Instead, transmission may occur from indigenous marine fish harbouring the bacterium to farmed populations of salmon.

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

The potential for spread of the bacterium with the trade in live salmonids although with increased detections other marine fish species and their transport should be considered as potential modes. Yet unresolved is the potential for transmission associated with ova. Some experimental data would suggest this possibility but most empirical data suggest otherwise (Fryer & Hedrick, 2003).

7. Several countries/zones may be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the OIE *Aquatic Manual.*

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Several tests widely available and reviewed by Fryer & Hedrick (2003). Detection of the bacterium following isolation in cell culture and or identification directly in tissues/cell cultures by IFAT are standard approaches. PCR test described but not rigorously applied or validated.

Standardized approaches but PCR not formally validated.

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VIII. White sturgeon iridoviral disease

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Losses due to WSID continue in sturgeon aquaculture both in North America and Europe. Most reports in North America are from white sturgeon (*Acipenser transmontanus*), either as part of commercial aquaculture endeavours or as part of stock enhancement programmes by state or tribal entities. In Europe losses have been associated with stocks of *Acipenser guldenstadi* and *A. naccarrii* or hybrid sturgeon (Adkison *et al.*, 1998). Significant production losses, particularly during early rearing phases are the principal impacts of the disease.

Established by epidemiological investigations on the farms and by laboratory experimental trials with the virus (Georgiadis *et al.*, 2000 and 2001 ; Hedrick *et al.*, 1992).

Economic studies of the disease have only been the partial focus of a study (Georgiadis *et al.*, 1999a, b). These studies concluded that impacts due to WSIV and or white sturgeon herpesvirus type 2 also known as *Acipenserid herpesvirus* 1 (AcHV-1) do increase costs during particular phases of production (Georgiadis *et al.*, 1999b).

2. Affects wild fish populations

Major impacts on wild fish populations are poorly understood although indirect evidence for the presence of virus in these populations is present (LaPatra *et al.*, 1994; Hedrick *et al.*, 1990). The major ecologic concerns have arisen as a result of conservation programs aimed at restoring wild sturgeon populations (*A. transmontanus*, *Scaphpirhynchus albus*, *A. naccarrii*) that have been directly impacted by losses of fish during hatchery rearing of progeny from wild adults (MacConnell *et al.*, 2000).

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

Proven in both farm and experimental laboratory trials (Hedrick *et al.*, 1992; Georgiadis *et al.*, 2000). Strong evidence for vertical transmission from adults to progeny has been obtained by spatial and temporal investigations in white sturgeon hatcheries (Georgiadis *et al.*, 2001). Virus outbreaks in white sturgeon aquaculture are often a function of fish density (LaPatra *et al.*, 1996), although several other risk factors have not been identified (Georgiadis *et al.*, 2000 and 2001).

5. Infectious agent associated but aetiology not proven

Not applicable.

6. Potential for international spread via live animals, their products and inanimate objects

Movements of live sturgeon, often larvae, continue but at a reduced level from prior years. In part, the diminished trade from sources in North America is a result of recognition of the potential for disease transfer. Considerably traffic of sturgeon from locations in central and eastern to western regions of Europe remain a concern for disease transfer.

Trading practices, particularly in Europe, make entry and establishment a likely risk.

7. Several countries/zones may be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the OIE *Aquatic Manual.*

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

Although normal procedures for standardization and validation have not been completed, a combination of virus isolation and or detection of pathognomonic cells in stained histological sections from sturgeon integument continue as the accepted diagnostic methods. Confirmation of pathognomonic cells by immunostaining with monoclonal antibodies is possible and the development of a PCR assay that should be published within the next 9 months are both considered improvements in the overall detection and confirmation of WSIV infection.

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Appendix III (contd)

REPORT OF THE MOLLUSC TEAM

[Excerpt from the Report of the Meeting of the OIE *Ad Hoc* Group on New Chapters for Mollusc Diseases. Full Report shown as Appendix VI].

AD HOC GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES MOLLUSC SUB-GROUP REPORT - JUNE 2004; AMENDED IN SEPTEMBER 2004

According to the Terms of Reference of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases, a sub-group of experts was requested to assess the diseases of molluscs that are currently listed in the OIE *Aquatic Animal Health Code* against the amended set of aquatic animal disease listing criteria and provide documented, scientific justification for any changes to the list considered to be necessary. After an initial phase of electronic correspondence, the sub-group held a meeting for further discussion, exchange of views. This report to the OIE Aquatic Animal Health Standards Commission outlines the discussions and preliminary conclusions of the mollusc sub-group in date of the June 2004 meeting and subsequent discussion in September 2004.

Appendix III (contd)

From the OIE *Aquatic Animal Health Code* 2004:

CHAPTER 1.1.3.

DISEASES LISTED BY THE OIE

Article 1.1.3.1.

[...]

Article 1.1.3.2.

The following diseases of molluscs are listed by the OIE

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosus*
- Infection with *Mikrocytos roughleyi*
- Infection with *Haplosporidium nelsoni*
- Infection with *Marteilia refringens*
- Infection with *Marteilia sydneyi*
- Infection with *Mikrocytos mackini*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni/ atlanticus*
- Infection with *Haplosporidium costale*
- Infection with *Candidatus* Xenohaliotis californiensis.

Article 1.1.3.3.

[...]

Appendix III (contd)

Current assessment

The detailed assessments are given as an appendix to the report. After reviewing scientific information available, five diseases (infection with *Bonamia roughleyi*, *Mikrocytos mackini*, *Haplosporidium costale*, *H. nelsoni* and *Marteilia sydneyi*) are proposed to be de-listed. Six of the currently listed diseases (infection with *Bonamia ostreae*, *B. exitiosa*, *P. marinus*, *P. olseni*, *Marteilia refringens* and *Xenohaliotis californiensis*) are proposed to be maintained on the OIE list. The Table below summarises evaluations and conclusions.
Discussion has particularly been long to assess two criteria: B7 for *Haplosporidium nelsoni* and B6 for *Marteilia sydneyi*.

Agent	1	2	3	4	5	6	7	8	Conclusion
B. roughleyi	-	-	-	+	N/A	-	-	+	De-list
B. exitiosa	+	+	-	+	N/A	+	+	+	Retain
B. ostreae	+	+	-	+	N/A	+	+	+	Retain
M. mackini	-	-	-	+	N/A	+	+	+	De-list
H. nelsoni	+	+	-	+	N/A	+	-	+	De-list
H. costale	-	-	-	+	N/A	+	-	+	De-list
P. marinus	+	+	-		N/A	+	+	+	Retain
P. olseni	+	+	-	+	N/A	+	+	+	Retain
M. refringens	+	+	-	+	N/A	+	+	+	Retain
M. sydneyi	+	-	-	+	N/A	-	+	+	De-list
X. californiensis	+	+	-	+	N/A	+	+	+	Retain

Remark

In several cases, conclusion of the assessment has been that disease should not be listed at a global scale while it should be given consideration for listing at a regional level.

In summary:

1. Pending on new information be provided to the group for further consideration, five diseases are proposed to be de-listed (infection with *Bonamia roughleyi*, *Mikrocytos mackini*, *Haplosporidium costale*, *H. nelsoni* and *Marteilia sydneyi*).

2. Six of the currently listed diseases are proposed to be maintained on the OIE list (infection with *Bonamia ostreae*, *B. exitiosa*, *Perkinsus marinus*, *P. olseni*, *Marteilia refringens* and *Xenohaliotis californiensis*).

Detailed assessments are provided for the five diseases proposed for delisting.

Appendix III (contd)

Infection with *Bonamia roughleyi*

No.	Meets the parameters that support listing	Listing	Comments
A1	*Bonamia roughleyi* (1) has only been reported from Sydney rock oysters (SRO), *Saccostrea glomerata*, in which it causes the disease, winter mortality. *S. glomerata* occurs along 1,400 km of the coast of New South Wales, Australia, but *B. roughleyi* is temperature limited to the coast to the south of the Georges River, near Sydney, N.S.W. There are no reliable figures on the impact of *B. roughleyi* on *S. glomerata*, because mortalities on oyster leases may be due to other diseases, such as QX disease (*Marteilia sydneyi*), herpesviruses or environmental factors. However, WM occurs at the end of winter, when salinities are high (30-35‰) and temperatures are low (<10°C) (2), and mass mortalities at this time can reasonably be attributed to WM. The incubation period is about 2.5 months and mortality does not occur in oysters <3 years old (3). The parasite does not occur where temperatures are greater than 14°C (4), and with the advent of global warming, its geographical distribution is likely to become even more restricted. Industry sources put losses due to WM at 10-40% of production to each year (Ray Tynan, Oyster Research Advisory Committee: *pers. comm.*). Mortalities of 35% (5) to <80% (6), have been reported. Peak production of 13 million dozen oysters occurred in the mid 1970s, but has now stabilised at ~8 million dozen (7), with production of 7,560,244 dozen from 1st July 2002 to 30th June 2003 (Damian Ogburn, N.S.W. Fisheries: *pers. comm.*). During that period, the industry experienced mortalities due to WM of 231,275 dozen oysters (Damian Ogburn, N.S.W. Fisheries: *pers. comm.*). This gives a mortality rate of 3%. The small percentage mortality may be because industry is able to manage around the disease by harvesting oysters before the winter, and by over-wintering smaller oysters on up-river leases at lower salinities (2). Triploid oysters are reported to have better survival rates (12.2% mortality) when exposed to the pathogen under identical conditions as diploid oysters (35% mortality) (4). However, another study found no differences in susceptibility of triploid and diploid oysters to the parasite (8). Mortalities can also be ameliorated by growing the oysters high off the benthos (5).	-	Appears to be manageable. Until now mortality rates have been largely anecdotal. Less than 20% in bad years and now less than 4%.
or			
A2	There is no apparent evidence that *B. roughleyi* causes mortalities in low density stocks of wild *S. glomerata*. The farming of SROs began as a primitive operation in the 1870s (7), but mortalities were only noticed 'a number of years' before Roughley investigated the mortalities in 1924-1925 (9). Exposure experiments have shown that *B. roughleyi* transmits directly and horizontally (4, 8), and therefore it is likely that whereas disease may occur in the crowded conditions of culture, it is much less likely to cause disease among scattered wild stocks. It therefore does not pose a threat to wild stocks. Unfortunately, so little has been published on the parasite, that virtually nothing is known about its annual pattern of infection, the histopathology of infection, or its ultrastructure.	-	Major gaps in knowledge. Generally understudied Epizootics were never reported in the wild.
or			
A3	*B. roughleyi* is not harmful to human health.	-	

Appendix III (contd)

No.	Meets the parameters that support listing	Listing	Comments
and			
B4	Direct horizontal transmission has been demonstrated during exposure experiments (4, 8), and there is currently no evidence for a spore stage.	+	Little known of epidemiology.
or			
B5	The aetiology is known (see B4). Name *Bonamia roughleyi* is given after Cochennec, *et al.* paper (1).	NA	NA
and			
B6	At present there is no threat of international spread, as SROs are not exported, only used for domestic consumption (Damian Ogburn, N.S.W. Fisheries: *pers. comm.*). However, the aim is to establish an export industry. Even if an export industry is established, there appears to be little threat of international spread of *B. roughleyi*. In Australia, *B. roughleyi* occurs in areas where Pacific oysters (*Crassostrea gigas*) and flat oysters (*Ostrea angasi*) occur, but infection of those other species has never been reported. SROs are the only known host of *B. roughleyi*, and SROs appear to occur in Australia, New Zealand and Thailand (10). They have also been reported from Pakistan, Iran, and Hong Kong, but the taxonomy of these oysters is confused (i.e. *S. glomerata* has at other times been *Saccostrea commercialis*, *Crassostrea glomerata* and *Crassostrea commercialis*). Therefore the distribution of the one susceptible host is limited. As *B. roughleyi* is restricted to waters that are below 14°C in Australia, it is extremely unlikely that it could become established in Thailand, Hong Kong, Pakistan and Iran.	-	High host affinity and given that the disease is ruled by low temperature, its potential spread is extremely limited in other areas where the host exists. No evidence of passage from *S. glomerata* to *O. angasi* although overlap exists in host and pathogen distribution.
and			
B7	The coast of N.S.W. north of the Georges River, and the coast of Queensland, that are within the geographical range of SROs, are uninfected zones because of water temperatures of >14°C. Similarly, in New Zealand, *S. glomerata* only occurs in the north of the North Island, where temperatures are >14°C, and *B. roughleyi* has not been reported from New Zealand *S. glomerata*. There appear to be no zones or other countries in which uninfected *S. glomerata* occur in waters that are <14°C.	-	It is unlikely that conditions are conducive to infection with *B. roughleyi* outside the current range of the disease.
and			
C8	Although primer sequences have been published for *B. roughleyi* (11), routine PCR has not been used to detect the parasite. Also, there has been no validation of molecular techniques. More basic techniques, such as histology and transmission electron microscopy also cannot be reliably used because the histopathology of infection has not been adequately described, and the two papers in which electron micrographs have been published (1, 3), are of poor quality.	+	Validation needed.
		De-list	

Listing here:-

1	2	3	4	5	6	7	8	
-	-	-	+	N/A	-	-	+	De-list

Appendix III (contd)

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Appendix III (contd)

Infection with *Mikrocytos mackini*

No.	Meets the parameters that support listing	Listing	Comment
A1	The impact of *Mikrocytos mackini* is unclear, as the natural beds where it occurs do not appear to be routinely monitored. Mortalities (10%) were first reported among 4-year-old Japanese (*Crassostrea gigas*) and local oysters in Pender Harbour, British Columbia, in autumn 1956 (1). In 1960, further mortalities (10%) occurred in Henry Bay, Denman Island, and 33% of oysters were found to have yellowy green pustules, regarded as pathognomic of Denman Island disease. The following month (May) 40% mortalities and <55% infection were recorded, followed by an apparent epizootic (1). Prevalence of infection is likely to have been underestimated as light infections were very difficult to detect, at that time. Epizootics have been on-going (2-5). However, since the early 1990s, losses due to mikrocytosis in enzootic areas have been insignificant (Susan Bower, Pacific Biological Station: *pers. comm.*). *M. mackini* was thought to be confined to Denman Island and surrounding islands, but it was reported from northern Washington State (USA), in 2002. Examination of the Washington beds showed that it occurred in beds of relict oysters and that its presence was therefore enzootic, and not due to recent introduction (Susan Bower: *pers. comm.*). Mortalities may economically impact oyster farmers, as the disease occurs in 4-year-old oysters, of marketable size, which appear otherwise to be in good condition (1, 6-7). However, this spring (2004) one grower has experienced ~10% mortality, and others have had product refused by processors due to 10-80% prevalence of oysters with pustules (Susan Bower: *pers. comm.*). Also, a digoxigenin *in situ* hybridisation technique has recently shown that the digestive tracts of spat are infected by *M. mackini*, which may account for mortalities among spat (Susan Bower: *pers. comm.*). This has yet to be proved.	-	Lack of quantitative data on mortalities in the wild, and it is not possible to quantify economic losses. The scale of *C. gigas* farming in waters <12°C is unknown.
Or			
A2	*M. mackini* naturally infects, and causes mortalities in wild *Crassostrea gigas*, and it naturally infects *Ostrea conchaphila* (5). It also experimentally infects *Crassostrea virginica* and *Ostrea edulis* (5, 8-10). Although the lack of host specificity might make it seem likely that *M. mackini* will spread through oyster populations, the disease is limited by temperature. Disease occurs following 3-4 months of <10°C temperatures, and does not occur at >12°C, but infections may persist for 3 months at 15°C (7, 11). Disease develops at 8°C (1). Therefore, oysters in waters that reach >12°C are not susceptible to the disease. Conversely, wild oyster populations in waters <12°C may be susceptible. Despite this, there have not been any reports of epizootics in oyster species, other than *C. gigas*	-	Only *C. gigas* in waters <12°C are susceptible.
Or			
A3	*M. mackini* is not harmful to human health.	-	
and			
B4	*Mikrocytos mackini* can be readily transmitted by inoculation of *C. gigas* with purified parasites or infected oyster homogenates, and by exposure to infected oysters (9). When uninfected oysters were exposed to infected oysters, prevalence generally increased with time, from 13% at 3 months, 7% at 3.5 months, 30% at 6 months, and 49% at 6.5 months. Disease only developed when oysters were held at low temperatures (~10°C) for prolonged periods (2.5-5.0 months) (9).	+	Although infection may occur at <12°C, disease only occurs at <10°C.

No.	Meets the parameters that support listing	Listing	Comment
Or			
B5	The aetiology is known (see B4).	NA	NA
and			
B6	Mikrocytosis can be managed in southern British Columbia by hatchery producing larvae and settling them away from infected areas, hanging culture techniques, and shortened production cycles. (Susan Bower: *pers. comm.*). Oysters are not exported from infected areas, but even if they were, there appears to be very little risk that the parasite would establish in most other countries. The oyster would have to be kept at <12°C for several months in the area into which they were introduced. This would negate spread to countries with temperate or sub-tropical climates. Although gut infections in spat suggest that *M. mackini* may be spread by spat, spat are not exported. However, the expert on *M. mackini*, Dr Susan Bower believes that the parasite could be a major problem in countries with very cold climates.	+	Spread, even if exported, appears unlikely.
and			
B7	Except for British Columbia, Canada, and the north western USA, all other countries that culture, or have wild stocks of *C. gigas*, appear to be free of *M. mackini*. Although all these countries have potentially susceptible hosts, only those in very cold regions, where temperatures do not exceed 12°C, are at risk. With global warming, the distribution of the parasite is likely to become even more restricted.	+	Zones can be established on the basis of temperature.
and			
C8	*Mikrocytos mackini* has been very difficult to detect in light infections. However, the development of imprint techniques (8), concentration (9) and purification (12) techniques, serology and PCR (13), which has been validated (14), give a robust, repeatable means of detecting the parasite.	+	
		De-list	

Listing here:-

1	2	3	4	5	6	7	8	Retain on OIE list?
-	-	-	+	N/A	+	+	+	De-list

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Appendix III (contd)

Infection with *Haplosporidium nelsoni*

No.	Meets the parameters that support listing	Listing	Comments
A1	There is very little culture because of mortality caused by *H. nelsoni* and *P. marinus.*	+	Very good data
or			
A2	Within a few years after mortality began in Delaware Bay (1957) and Chesapeake Bay (1959), over a million bushels of *Crassostrea virginica* were killed in each area (1,3). The pathogen has spread all along the east coast of the USA and into Atlantic Canada. Periodic outbreaks with high oyster losses have occurred in Long Island Sound, New York (9). The pathogen still causes high losses during drought years in Chesapeake Bay, but some resistance has apparently developed in Delaware Bay and oyster mortality from *H. nelsoni* has decreased to insignificant levels (S.E. Ford, *pers. comm.*). The pathogen infects, but does not cause significant losses in, *Crassostrea gigas* in California, Asia and France (2,4,5). *H. nelsoni* has had serious negative impact on *C. virginica* abundance in Chesapeake Bay, Delaware Bay and elsewhere along the east coast of the USA. The oyster resource at one time supported the largest oyster fishery in the world and also was of tremendous ecological importance as the dominant filter feeder. Current efforts to restore native oyster populations are driven mainly by the ecolog cal importance of oysters. *H. nelsoni* has also greatly hindered the development of oyster aquaculture in Chesapeake Bay.	+	Very good data
or			
A3	*H. nelsoni* is not harmful to human health.	-	Very confident
and			
B4	The aetiology is not proven by satisfying Koch's postulates.	-	-
or			
B5	The life cycle of *H. nelsoni* is unknown and experimental infections have never been established either by cohabitation or by injection of plasmodia or spores. Nonetheless, mortality is highly correlated with infection by *H. nelsoni*. Naïve oysters placed into *H. nelsoni*-endemic waters become infected quickly, infections develop rapidly, and mortality (>90%) occurs within 3 month of infection.	N/A	Very confident
and			
B6	There is good evidence that *H. nelsoni* was introduced to the east coast of the USA from the Pacific Ocean (2). The mechanism of the introduction is unclear, but could have been from importation of infected oysters or intermediate hosts, or from ballast water. There is circumstantial evidence that *H. nelsoni* was introduced to Atlantic Canada in ballast water. *H. nelsoni* also occurs in *C. gigas* in France, where it was likely introduced with live animals. There is international trade in both *C. gigas* and *C. virginica*.	+	Very confident
No.	**Meets the parameters that support listing**	**Listing**	**Comments**
and			

B7	*H. nelsoni* is known in *C. gigas* from Korea, Japan, France and the west coast of the USA (2,5,4), although it does not cause significant losses in *C. gigas*. It is known in *C. virginica* from the east coast of the USA and Atlantic Canada. The pathogen is not known in *C. virginica* from the Gulf of Mexico. *H. nelsoni* is not known from the southern hemisphere, but susceptibility of oysters in that region is unknown. *C. gigas* has been widespread in the world and the source of *H. nelsoni* is believed to have originated from *C. gigas* (2); from this it is considered here that *H. nelsoni* may have been transported globally and all susceptible host have already been exposed. The recent introduction in Atlantic Canada may be linked to ballast waters which broaden the possibilty that pathogen has been moved around. There are no large populations of the susceptible host similar to *C. virginica* on the east coast of the US. The parasite seems to be strongly limited by temperature which indicates that tropics wouldn't be at risk. Would a country wish to introduce for the first time *C. gigas*, risk should and ICES guidelines for introduction and transfers implemented.	-	Although widespread and only known to be pathogenic in *C. virginica*, susceptibility to southern hemisphere oysters is unknown.
and			
C8	Oysters typically are examined by paraffin histology, but this technique can miss light infections. PCR is a more sensitive technique for detecting *H. nelsoni*, and it has been validated against paraffin histology. A DNA probe is also available for *H. nelsoni* for use in *in situ* hybridization (5-8).	+	Very reliable tests
		retain	

Listing here:-

1	2	3	4	5	6	7	8	
+	+	-	+	NA	+	-	+	Retain on OIE list?
								De-list

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Appendix III (contd)

Infection with *Haplosporidium costale*

No.	Meets the parameters that support listing	Listing	Comments
A1	Evidence suggests that infections almost always progress through sporulation and that sporulation is always fatal to the oyster host, *Crassostrea virginica* (1-3). Annual mortality from *H. costale* has been reported to be as high as 60% (2). Impact of *H. costale* seems to have been reduced since 1976 by a sharp increase in *H. nelsoni* infections and oyster mortality (1). In recent years prevalence has been low and mortality likely has been insignificant.	-	Present status uncertain
or			
A2	*H. costale* has been shown to negatively affect *C. virginica* populations that are economically and ecologically important to Virginia. However, recent information suggests that the pathogen is not presently significantly affecting oyster populations. Unfortunately, surveillance for this pathogen does not occur on a regular basis. The pathogen does not seem to be causing oyster mortality in Atlantic Canada where it has recently been discovered.	-	Present status uncertain, but likely unimportant
or			
A3	*H. costale* is not harmful to human health.	-	Very confident
and			
B4	The aetiology has not been proven by satisfying Koch's postulates.	-	-
or			
B5	The life cycle of *H. costale* is unknown and experimental infections have never been established either by cohabitation or by injection of plasmodia or spores. Nonetheless, mortality is highly correlated with infection by *H. costale*.	N/A	Very confident
and			
B6	Based on experience with *H. nelsoni*, there is potential for international spread because *H. costale* parasitizes commercially important oysters.	+	Confident
and			
B7	*H. costale* is known to occur from Virginia to Maine in *C. virginica*, with recent reports from Long Island Sound, New York (5) and Atlantic Canada. The pathogen is not known in *C. virginica* south of Virginia on the east coast of the USA and it is not present on the west coast of the USA. *H. costale* is not known from the southern hemisphere, but susceptibility of oysters in that region is unknown.	-	Disease free zones exist
and			
C8	Oysters typically are examined by paraffin histology, but this technique can miss light infections. PCR is a more sensitive technique for detecting *H. costale*. A DNA probe is also available for *H. costale* for use in *in situ* hybridization (4,5).	+	PCR not validated
		De-List	

Listing here:-

1	2	3	4	5	6	7	8	Retain on OIE list?
-	-	-	+	NA	+	-	+	No

Appendix III (contd)

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Appendix III (contd)

Infection with *Marteilia sydneyi*

No.	Meets the parameters that support listing	Listing	Comments
A1	*Marteilia sydneyi* is responsible for QX disease in Sydney rock oyster, *Saccostrea glomerata*, in Australia (1,9). Infection with *M. sydneyi* leads to poor condition factor and shrunken body, often presenting as general translucency of the body of infected oysters. Death is attributed to direct blockage of the digestive gland by the parasite and consequent host starvation (15). QX disease is more commonly found in northern, warmer estuaries and was responsible for a decline in the oyster industry in southern Queensland and in northern NSW during the 1970s. As a result of this disease, production in the Tweed, Richmond and Clarence Rivers in northern NSW during the past 26 years decreased from 379,200 dozens in 1974/1975 to 168,504 dozens in 2000/2001—a drop of 56%. The disease had a devastating effect on oyster production in the Georges River which declined from 1,111,171 dozens in 1993/1994 to 62,000 dozens in 2000/2001, a drop of 94%, as the disease in this river kills up to 90% of all Sydney rock oyster annually. As the Pacific oyster is not affected by QX disease, it has partially displaced Sydney rock oysters in Georges River and now makes up 80% of the oysters on the foreshore of the upper reaches of the river (17). Outbreaks of QX disease appear to be triggered by environmental conditions (3, 11 and13). QX disease occurs annually, although the severity depends on temperature and salinity. In Georges River, NSW, infestation of oysters with QX disease parasites commences in February (summer) and most mortality occurs in April/May (autumn). Weakened survivors may die from heat stress in late spring or early summer (November/December) (17). The progeny of second-generation Sydney rock oyster breeding lines were tested for resistance to *M. sydneyi* against a non-selected control (17,18). Mortality was reduced from 85.7+/-1.5% for the controls to 63.5+/-1.2% for the most improved breeding line. This is a reduction in mortality of 22% after only two generations of selection. These partially QX disease-resistant oysters in which *M. sydneyi* was found were also 21% heavier than controls. Selection for resistance to *M. sydneyi* is feasible and may be improved through further selection.	+	very good data
or			
A2	There is no evidence of impact on wild stocks of Sydney rock oyster, *Saccostrea glomerata*, although *Marteilia sydneyi* is widely distributed in warmer parts of Australia (recent findings by use of PCR + 19); the disease seems to impede aquaculture mainly. Disease appears as a combination of crowding in culture, environmental conditions (temperature and salinity) and presence of *M. sydneyi*.	-	no clear data
or			
A3	No public health concern associated to QX.	-	robust
and			
B4	The life cycle of *M. sydneyi* is unknown and experimental infections have never been established either by cohabitation or by injection (8,12,15). Mortality is highly correlated with infection.	+	very good data

Appendix III (contd)

No.	Meets the parameters that support listing	Listing	Comments
or			
B5	Non applicable. The aetiology is known (see A1 & B4).	N/A	
and			
B6	*Marteilia sydneyi* has apparently been transferred with stocks of infected oysters (1). There is apparently no trade of Sydney rock oysters, *Saccostrea glomerata*, outside Australia. Other mollusc species exported from Australia are not known to be susceptible or vector to/of this parasite. Another species of *Saccostrea*, *S. cucullata*, is apparently not susceptible to *M. sydneyi* even exposed to it under conducive conditions (Hine & Thorne, 2000). In contrast, preliminary description of a paramyxean parasite in Thailand suggests close relationship with *M. sydneyi* in a host species closely related to *S. cucullata* (*S. forksali*-F. Berthe, *pers. comm.*); findings are not associated to mortality or disease although reported from intensive culture conditions. Survey conducted over two years show permanent low prevalence.	-	good data
and			
B7	Current information tends to show *M. sydneyi* is restricted to certain parts of Australia.	+	no clear data
and			
C8	Usually easily diagnosed, at a generic level, by applying stained tissue imprints and histology. An indirect fluorescent antibody test (IFAT) was used for *M. sydneyi* detection with polyclonal antibodies (12). Another IFAT incorporating a polyclonal antibody against *M. sydneyi* was later described (2) and proved to be specific to *M. sydneyi*. Gene probes used in the diagnosis of marteiliosis have been developed for detection of *M. sydneyi* (4,5,6) and validation partly achieved (7). *Marteilia sydneyi* can be differentiated from *M. refringens* by means of TEM (9,10).	+	Very good data
		De-list	

Listing here:-

1	2	3	4	5	6	7	8	Retain on OIE list?
+	-	-	+	N/A	-	+	+	De-list

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REPORT FROM THE CRUSTACEAN TEAM

[Excerpt from the Report of the Meeting of the OIE *Ad Hoc* Group on New Chapters for Crustacean Diseases. Full Report shown as Appendix VII].

INTRODUCTION

The *ad hoc* Group on the listing of crustacean diseases met on 4 March 2004, at the World Aquaculture 04 meeting in Honolulu (Hawaii) and subsequently from 11 to 13 October at OIE Headquarters in Paris.

The *ad hoc* Group reviewed Article 1.1.2.1. entitled "Criteria for listing an aquatic animal disease" in Chapter 1.1.2. on "Disease Listing and Notification Criteria" of the 2004 edition of the *Aquatic Animal Health Code* (hereafter referred to as the "*Aquatic Code*"). Each of the currently listed crustacean diseases (see article 1.1.3.3. and Table 1 below) was considered relative to the listing criteria. Table 1 was modified from the Table "Aquatic Animal Diseases Currently Listed in the *Aquatic Code*" which was developed by the Aquatic Animal Health Standards Commission (hereafter referred to as the "Aquatic Animals Commission") during its October 2003 meeting.

The *ad hoc* Group agreed with the Aquatic Animals Commission that the crustacean diseases which it recommended for retention on the OIE disease list (identified here by disease agent: TSV, WSSV, YHV/GAV, BP, MBV, IHHNV, and *Aphanomyces astaci*) should be retained. The *ad hoc* Group further agreed with the Aquatic Animals Commission that spawner-isolated mortality virus disease (SMV) should be removed from the list for the same reasons that were considered by the Aquatic Animals Commission.

The *ad hoc* Group considered several additional crustacean diseases for possible listing by the OIE. Five diseases were found to meet the criteria for listing and these are listed in Table 1 under the section "Suggested Changes to the List by the *ad hoc* Group".

In the section following Table 1, the *ad hoc* Group has prepared a brief summary of each of the five crustacean diseases which it has recommended for possible listing by the OIE. These are:

I. Necrotizing Hepatopancreatitis (NHB-B / bacterial)

II. Infection by Mourilyan virus (MoV)

III. Infectious Myonecrosis (IMNV)

IV. White Tail Disease (MrNV & XSV)

V. Infection by Hepatopancreatic parvovirus (HPV)

Appendix III (contd)

From the OIE *Aquatic Animal Health Code* 2004:

CHAPTER 1.1.3.

DISEASES LISTED BY THE OIE

Article 1.1.3.1.

[...]

Article 1.1.3.2.

[...]

Article 1.1.3.3.

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*)
- Spawner-isolated mortality virus disease.

Appendix III (contd)

Table 1. Working list of currently listed crustacean diseases and the recommended deletions and additions to the list by the Crustacean Disease *Ad Hoc* Group on Disease Listing

Crustacean diseases currently listed in the *Aquatic Code* (agent) AADC recommendations (top) Suggested changes (below)	Meets new disease listing criteria as published in Article 1.1.2.1. of the 7th edition of the *Aquatic Code* (2004)								OIE List (retain, add, delete)
	1	2	3	4	5	6	7	8	
Taura syndrome (TSV)	+	-	-	+	NA	+	+	+	retain
White spot disease (WSSV)	+	+/-?	-	+	NA	+	+	+	retain
Yellowhead disease (YHV/GAV)	+	-	-	+	NA	+	+	+	retain
Tetrahedral baculovirosis (*Baculovirus penaei* /BP)	+	-	-	+	NA	+	+	+	retain
Spherical baculovirosis (*P. monodon*-type baculovirus/MBV)	+	-	-	+	NA	+	+	+	retain
Infectious hypodermal and haematopoietic necrosis (IHHNV)	+	+	-	+	NA	+	+	+	retain
Crayfish plague (*Aphanomyces astaci* / fungus)	+	+	-	+	NA	+	+	+	retain
Suggested Changes to the List by the Ad Hoc Group									
Spawner-isolated mortality virus disease (SMV)	-	-	-	-	-	+	+/-	-	delete
Necrotizing Hepatopancreatitis (NHP-B / bacterial)	+	-	-	+	NA	+	+	+	add
Infection by Mourilyan virus (MoV)	+	-	-	-/?	+	+	+	+	add
Infectious Myonecrosis (IMNV)	+	-	-	+	NA	+	+	+	add
White Tail Disease (MrNV & XSV)	+	-	-	+	NA	+	+	+	add
Infection by HPV	+ /-	-/ ?	-	+	N/A	+	+	+/-	add

Appendix III (contd)

GENERAL STATEMENT ON THE CURRENT DISEASE LIST

The crustacean team discussed the current list of crustacean diseases as shown in the 2004 edition of the *Aquatic Code*.

In consideration of the disease listing criteria as provided in Chapter 1.1.2. of the 2004 edition of the *Aquatic Code*, the crustacean team recommends to the Aquatic Animals Commission that the following diseases remain listed:

- Taura syndrome (TSV)
- White spot disease (WSSV)
- Yellowhead disease (YHV/GAV)
- Tetrahedral baculovirosis (*Baculovirus penaei* /BP)
- Spherical baculovirosis (*P. monodon*-type baculovirus/MBV)
- Infectious hypodermal and haematopoietic necrosis (IHHNV)
- Crayfish plague (*Aphanomyces astaci* / fungus).

Of the currently listed diseases, the crustacean team recommends that the disease caused by the infection with SMV be removed from the list.

The crustacean team also recommends the addition of five diseases to the OIE list.

DETAILED EVALUATION OF EACH DISEASE RECOMMENDED FOR REMOVAL FROM THE OIE LIST

I. Spawner-isolated mortality virus disease (SMV)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Although originally isolated from diseased shrimp in which mortalities had occurred, there is no evidence that SMV is a pathogenic agent. SMV infection may cause reduced postlarval survival but there is insufficient documentation of economic impact to justify listing.

2. Affects wild fish populations

There is no report of any impact, economic or ecological, on wild populations.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

There is insufficient evidence that SMV is the cause of any known disease.

5. Infectious agent associated but aetiology not proven

SMV isolated from diseased shrimp but other agents (e.g. gill-associated virus) also present and so aetiology not proven.

6. Potential for international spread via live animals, their products and inanimate objects

a. International trade in susceptible species exists or likely to develop

SMV occurs in healthy wild and farmed populations of *Penaeus monodon* and *Cherax quadricarinatus* in Australia and has been detected in farmed *P. monodon* in the Philippines. International trade exists in each of these susceptible species.

b. Trading practices make entry and establishment a likely risk

Yes.

7. Several countries/zones may be declared free

No countries, zones or compartments have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the *Aquatic Manual*. Potential for declaration of freedom does exist, particularly for zones or compartments if diagnostic test becomes widely available.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

a. Widely available test

Test procedures (*PCR* and ISH) not published and positive control materials not available.

b. Formal standardization and validation

PCR and ISH tests not formally validated.

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Appendix III (contd)

JUSTIFICATION FOR LISTING

I. Necrotizing Hepatopancreatitis (NHP-B / an alpha proteobacteria)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Where NHP occurs, it causes significant production losses in shrimp farms, which may approach 100% if not correctly diagnosed and treated. The occurrence of NHP disease seems to be dependent upon a combination of high temperature and high salinity, with the disease most often tending to occur in regions where the disease is enzootic during the dry season when water temperatures and salinity are near or greater than 30°C and 30 ppt, respectively. In some epizootics of NHP, entire shrimp farming regions are severely impacted with significant crop losses.
While NHP can be treated with medicated feeds containing certain antibiotics to which the causative bacterium is sensitive, cultured stocks with developing infections by NHP are often not diagnosed before going off feed and becoming difficult or impossible to treat.

2. Affects wild crustacean populations

NHP has been detected in wild penaeid shrimp in areas where the disease also occurs in farms.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

The aetiology of NHP disease is proven. NHP disease is caused by an alpha proteobacterium that has not formally been named but is generally referred to as NHP-B.

5. Infectious agent associated but aetiology not proven

N/A.

6. Potential for international spread via live animals, their products and inanimate objects

a. International trade in susceptible species exists or likely to develop
Yes.

b. Trading practices make entry and establishment a likely risk
Yes.
NHP has been reported from cultured penaeid shrimp in Texas (USA), Mexico, Central America (Belize, Guatemala, Nicaragua, Costa Rica, and Panama), Peru, Ecuador, Colombia, Venezuela, and Brazil. It was documented to have been transferred to Eritrea (northeast Africa) with imported *Penaeus vannamei* from Mexico, where within one year of its introduction it caused such severe disease losses that the importing facility was depopulated and disinfected to eradicate the disease.

Appendix III (contd)

Despite numerous introductions into east and southeast Asia of *P. vannamei* and *P. stylirostris* from affected regions in the Americas, NHP has not been reported in these importing countries.

7. Several countries/zones could be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4 of the *Aquatic Manual.* Some compartments in USA have declared freedom from NHP-B.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

a. Widely available test

***Classical methods*:** NHP can be tentatively diagnosed using simple wet-mounts of tissue squashes of the hepatopancreas by demonstration of reduce stored lipid droplets in the HP, and by distinctive pathological changes to the HP tubules. Definitive diagnosis is accomplished using routine paraffin/H&E methods.

Antibody-based methods: Monoclonal antibodies to NHP have been developed and these are expected to be commercially available by late 2004.

Molecular methods: Standard PCR and real-time PCR methods, and non-radioactive DNA probe methods are available for the detection of NHP-B, the bacterial agent of NHP.

b. Formal standardization and validation

Standardized approaches but PCR, ISH, and antibody based diagnostic methods have not been formally validated.

D. Source of expertise

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II. Mourilyan virus (MoV)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

MoV occurs commonly at low levels in wild and farmed populations of healthy *Penaeus monodon* and healthy farmed *Penaeus japonicus* in eastern Australia. Elevated MoV levels, as detected by PCR and ISH, have accompanied mass mortalities in farmed *P. japonicus*. Elevated MoV levels (together with elevated GAV levels) have been detected in moribund *P. monodon* affected by Mid-crop mortality syndrome (MCMS). Elevated MoV (and GAV) levels occur in susceptible shrimp injected with inocula derived from MCMS outbreaks. MCMS has caused significant economic impact on *P. monodon* farming in Australia.

2. Affects wild crustacean populations

There is evidence of infection in wild populations but there is no report of any impact, economic or ecological.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

None.

5. Infectious agent associated but aetiology not proven

Transmission experiments have demonstrated MoV is infectious but not proven MoV as a cause of disease, specifically MCMS with which it (together with GAV) is strongly associated.

6. Potential for international spread via live animals, their products and inanimate objects

a. International trade in susceptible species exists or likely to develop

MoV occurs in healthy wild and farmed populations of *Penaeus monodon* and *P. japonicus* in Australia and has been detected in farmed *P. monodon* in the Thailand, Malaysia, Fiji and Vietnam. International trade exists in each of these susceptible species.

b. Trading practices make entry and establishment a likely risk

Yes.

7. Several countries/zones could be declared free

No countries, zones or compartments have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the *Aquatic Manual*. Potential for declaration of freedom does exist, particularly for zones or compartments.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

a. Widely available test

PCR test available as a commercial kit. PCR and ISH test procedures submitted for publication.

b. Formal standardization and validation

PCR and ISH tests not formally validated.

D. Source of expertise

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III. Infectious Myonecrosis (IMNV)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Infectious myonecrosis (IMN) is a recently identified disease in cultured *Penaeus vannamei* in northeast Brazil. IMN causes significant disease and mortalities in juvenile and subadult pond-reared stocks of *P. vannamei*. In 2003, IMN was estimated to have caused $20 million in losses to the affected farms in Brazil. In 2004, the losses to the industry are expected to be greater than $20 million.

IMN presents as a disease with an acute onset of gross signs and elevated mortalities, but it progresses with a more chronic course accompanied by persistent low level mortalities. To date, IMN appears to be limited to northeast Brazil, but shrimp with similar gross signs have been also reported from other countries where *P. vannamei* are cultured.

2. Affects wild shrimp populations

Not known.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

Infectious myonecrosis (IMN) has been demonstrated to be caused by the virus IMNV, a 40 nm unenveloped dsRNA virus tentatively placed in the *Totiviridae*.

5. Infectious agent associated but aetiology not proven

N/A.

6. Potential for international spread via live animals, their products and inanimate objects

Since the disease was first recognized in 2002 in Piaui state in northeast Brazil, the disease spread in 2003 into the states of Cera and Rio Grande do Norte. By August 2004, the range of the disease had expanded to include shrimp farms in the states of Paraiba and Pernambuco.

The principal species of shrimp farmed in Brazil is *P. vannamei*. This species is not native to Brazil and all stocks grown in Brazil have been imported. Brazil imposed a ban on imports of live penaeid shrimp in about 1998. Consequently, it developed its large shrimp farming industry using shrimp stocks in the country prior to the import ban. The stocks of *P. vannamei* developed and cultured in Brazil are not deemed to be superior to those cultured elsewhere in Latin America. Hence, Brazilian stocks of live *P. vannamei* have not been exported from Brazil for development elsewhere. Nonetheless, frozen farm raised shrimp (90,000 tons) were exported from Brazil in 2003, and live shrimp (broodstock, nauplii, or post-larvae) might be exported from Brazil to other countries in Latin America for commercial development.

IMNV is known to cause persistent infections in apparently healthy animals which facilitate spread of infection.

7. Several countries/zones could be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the *Aquatic Manual*. Some compartments in the USA have declared freedom from IMNV.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

a. Widely available test

Classical methods: Acute IMN disease can be tentatively diagnosed from gross signs of multifocal to generalized muscle necrosis visible as opaque muscles. Definitive diagnosis is accomplished using routine paraffin/H&E methods by the demonstration of myonecrosis and significant hypertrophy of the lymphoid organ (LO) with the formation of spheroids (LOS), which may also commonly occur at sites distant to the LO (ectopic LOS).

Molecular methods: Standard one step RT-PCR, nested RT- PCR and non-radioactive DNA probe methods are available for the detection of IMNV, the viral agent of IMN.

b. Formal standardization and validation

Standardized approaches but PCR not formally validated.

D. Source of expertise

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IV. White Tail Disease (WTD caused by infection by MrNV {a nodavirus} & XSV {a very small ssRNA virus})

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

WTD is a disease of *Macrobrachium rosenbergii*, the giant freshwater prawn. WTD has been reported from freshwater shrimp hatcheries in Guadeloupe (French West Indies, Caribbean), Puerto Rico, Taiwan, China, and India). The disease has been especially significant in China and India where it has been responsible for significant crop and economic losses in farmed prawns.

2. Affects wild shrimp populations

Not known.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

Yes. Two viruses have been isolated from diseased prawns with WTD. These have been characterized and named Macrobrachium nodavirus (MrNV) and extra small virus (XSV).

Note (from J.R. Bonami): "About this criterion, it is for the moment difficult to say what is the role of each virus in the disease. What we know is: as the XSV genome codes only for capsid proteins and does not possess a RNA polymerase gene, it should need the help of MrNV-RdRp to replicate. Experimental transmission of the disease was accomplished using a mix of MrNV and XSV".

5. Infectious agent associated but aetiology not proven

N/A.

6. Potential for international spread via live animals, their products and inanimate objects

Transfer of the disease was documented to have occurred with the movement of infected postlarval *M. rosenbergii* from Guadeloupe to Puerto Rico.

The sudden appearance of the disease in regions of China, Bangladesh (Nair, personal communication) and India suggests that it was introduced. However, the disease has not been reported from southeast Asia, where major industries are present that culture *M. rosenbergii.*

a. International trade in susceptible species exists or likely to develop

Yes.

b. Trading practices make entry and establishment a likely risk

Yes.

7. Several countries/zones could be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the *Aquatic* Manual.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

a. Widely available test

Classical methods: Acute WTD disease can be tentatively diagnosed from gross signs of mutifocal to generalized muscle necrosis visible as opaque muscles which give affected PLs white tails.

Antibody-based methods: An ELISA test for WMD has been developed (commercial availability unknown; availability from potential Reference Laboratory(s) unknown).

Molecular methods: Standard one step RT-PCR and non-radioactive DNA probe methods are available for the detection of MrNV and XSV.

b. Formal standardization and validation

Standardized approaches but PCR not formally validated.

D. Source of expertise

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V. Disease caused by infection with Hepatopancreatic parvovirus (HPV)

A. Consequences

1. Significant losses due to morbidity, mortality or product quality

Disease due to hepatopancreatic parvovirus (HPV) infection has been associated with significant disease losses, including high mortality rates, in postlarval and early juvenile stages of *Penaeus chinensis* and *P. monodon* in the nursery phase of culture when high stocking densities are employed.

In an epidemiological study of significant diseases of pond-reared *P. monodon* in Thailand, HPV was linked to reduced growth and poor culture performance resulting in significantly reduced crop production.

HPV is known to infect a number of penaeid species in many geographic regions including:

Asia: *Penaeus chinensis*, *P. merguiensis*, *P. indicus*, *P. japonicus* and *P. monodon.*

Australia: *P. esculentus*, *P. merguiensis* and *P. japonicus*

East Africa & the Middle: *East*: *P. monodon* and *P. semisulcatus*

Americas: *P. vannamei*, *P. stylirostris* and *P. schmitti.*

2. Affects wild shrimp populations

Not known.

3. Public health concern

None.

B. Spread

4. Infectious aetiology proven

HPV has been shown to adversely affect its host species.

The virus has been successfully passed from infected to uninfected hosts.

Virions of HPV are small, un-enveloped, ~22 nm diameter icosahedrons with a 5 kb ssDNA genome. The virus is considered to belong to the *Densovirinae.*

At least three distinct strains/types of HPV have been shown to exist using molecular methods.

5. Infectious agent associated but aetiology not proven

N/A.

6. Potential for international spread via live animals, their products and inanimate objects

HPV poses a significant risk for international spread via trade in live nauplii, postlarvae and broodstock of the susceptible penaeid species. The existence of genetically distinct

strains of the virus (some of which may not be detected by some published PCR or ISH methods) may complicate detection and certification issues between trading partners.

7. Several countries/zones could be declared free

No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the *Aquatic Manual*. Some compartments in the USA have declared freedom from HPV.

C. Diagnosis

8. A repeatable and robust means of detection/diagnosis exists

a. Widely available test

***Classical methods*:** Acute HPV infections can be tentatively diagnosed from stained or unstained wet-mount preparations of the hepatopancreas (HP) by demonstration of characteristic intranuclear inclusion bodies in hypertrophied nuclei of especially e-cells in the HP tubules. Histopathology may be employed to provide a definitive diagnosis of HPV infection by demonstration of pathognomonic HPV intranuclear inclusion bodies in the HP tubule epithelium.

Molecular methods: Standard one step PCR, nested PCR, real-time PCR, and non-radioactive DNA probe methods (especially ISH) are available for the detection of HPV. Commercial kits are available for PCR detection. Different strains may be distinguished by use of certain primer sets or by ISH with certain DIG-labeled probes. A "group-specific" PCR method that detects all of the known HPV strains is available, as is a "group-specific" ISH probe method.

b. Formal standardization and validation

Standardized approaches but PCR not formally validated.

D. Source of expertise

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Appendix IV

CHAPTER 1.1.2.

DISEASE LISTING AND NOTIFICATION CRITERIA

Article 1.1.2.1.

Community comment

The Community agrees with the proposed amendments provided our principle comment delivered in relation to the report from the October 2003 meeting are taken into account in relation to criterion 1.

The Community propose to include in the explanatory note to criterion 1: "or causes significant increase in production costs due to the high cost of control measures"

Criteria for listing an aquatic animal disease

Diseases proposed for listing must meet all of the relevant parameters set for each of the criteria, namely A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a *disease* must have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8.

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
		A. Consequences	
1.		The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in *susceptible*[1] *species*, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.
2.	Or	The disease has been shown to or scientific evidence indicates that it is likely to negatively affect wild aquatic animal populations that are an asset worth protecting for economic or ecological reasons.	Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, the asset could be ecological or environmental in nature, for example, if the population consists of an endangered species of aquatic animal or an aquatic animal potentially endangered by the disease.
3.	Or	The agent is of public health concern.	
		And	
		B. Spread	
4.		Infectious aetiology of the disease is proven.	

[1] 'Susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
5.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
6.	And	Potential for international spread, including via live animals, their products ~~and~~ or inanimate objects.	International trade in aquatic animal species *susceptible* to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is a likely risk.
7.	And	Several countries or countries with *zones* may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 as well as the relevant disease chapter of the *Aquatic Manual*.	*Free countries/zones* could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible, however, individual countries that run a control programme on such a disease can demand its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of *broodstock* from widespread diseases, or the protection of the last remaining *free zones* from a widespread disease.
		And	
		C. Diagnosis	
8.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see OIE *Manual of Diagnostic Tests for Aquatic Animals*) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

Article 1.1.2.2.

Criteria for ~~urgent~~ immediate notification of aquatic animal diseases

	A. For listed diseases
1.	First occurrence or re-occurrence of a disease in a country or zone of a country, if the country or zone of the country was previously considered to be free of that particular disease; or
2.	Occurrence in a new host species; or
3.	New pathogen strain or new disease manifestation; or
4.	Potential for international spread of the disease; or
5.	Zoonotic potential.
	B. For non-listed diseases
1.	Emerging disease/pathogenic agent if there are findings that are of epidemiological significance to other countries.

— text deleted

Appendix V

CHAPTER 1.1.3.

DISEASES LISTED BY THE OIE

Article 1.1.3.1.

Community comment

Based in the assessment of the OIE expert group for fish diseases (report in Appendix III) the Community could preliminary agree to the proposal for amendments to the listing of fish diseases with respect to the de-listing of :
-*Oncorhynchus masou* virus disease,
-Channel catfish virus disease,
-Viral encephalopathy and retinopathy,
-Enteric septicaemia of catfish (*Edwardsiella ictaluri*),
-Piscirickettsiosis (*Piscirickettsia salmonis*)
-White Sturgeon iridoviral disease.

However, the Community will reiterate its comment to the report of the October 2003 meeting of the AAC, with respect to the claim that BKD and IPN complies with the listing criteria.

Although not being invited to do so, the Community would ask the OIE to consider Koi Herpes Virus infection to be listed.

Justifications are forwarded as an Annex to this report.

The Community reserves its right to submit further detailed comments after the deadline and before the General Session 2005, due to the short consultation times given by the OIE.

The following diseases of fish are listed by the OIE:

- Epizootic haematopoietic necrosis
- Infectious haematopoietic necrosis
- ~~*Oncorhynchus masou* virus disease~~
- Spring viraemia of carp
- Viral haemorrhagic septicaemia
- ~~Channel catfish virus disease~~
- ~~Viral encephalopathy and retinopathy~~
- ~~Infectious pancreatic necrosis~~
- Infectious salmon anaemia
- Epizootic ulcerative syndrome

- ~~Bacterial kidney disease (*Renibacterium salmoninarum*)~~
- ~~Enteric septicaemia of catfish (*Edwardsiella ictaluri*)~~
- ~~Piscirickettsiosis (*Piscirickettsia salmonis*)~~
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease
- ~~White Sturgeon iridoviral disease.~~

Article 1.1.3.2.

Community comment

Based in the assessment of the OIE expert group for mollusc diseases (report in Appendix III) the Community could preliminary agree to the proposal for amendments to the listing of mollusc diseases with respect to the de-listing of :
-Infection with *Mikrocytos roughleyi*
-Infection with *Haplosporidium nelsoni*
-Infection with *Marteilia Sydney*
-Infection with *Haplosporidium costale*

Furthermore, the Community will reiterate its comment to the report of the October 2003 meeting of the AAC, with respect to the claim that infection with *Microcytos mackini* should REMAIN listed, and that *Perkinus olseni/atlanticus* should NOT be listed.

Justifications are forwarded as an Annex to this report.

However, the Community reserves its right to submit further comments after the deadline and before the General Session 2005, due to the short consultation times given by the OIE.

The following diseases of molluscs are listed by the OIE:

- Infection with *Bonamia ostreae*
- Infection with *Bonamia ~~exitiosus~~ exitiosa*
- ~~Infection with *Mikrocytos roughleyi*~~
- ~~Infection with *Haplosporidium nelsoni*~~
- Infection with *Marteilia refringens*
- ~~Infection with *Marteilia Sydney*~~
- ~~Infection with *Mikrocytos mackini*~~
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni/atlanticus*
- ~~Infection with *Haplosporidium costale*~~
- Infection with Candidatus Xenohaliotis californiensis.

Article 1.1.3.3.

Community comment

Based in the assessment of the OIE expert group for crustacean diseases (report in Appendix III) the Community could preliminary agree to the de-listing of Spawner-isolated mortality virus disease

However, the Community CANNOT agree to the proposal for addition of 5 diseases to the listing of crustacean diseases.

The major reason for this is the inconsistent use/interpretation of several of the listing criteria by the

crustacean specialist group when comparing with the reports of the fish- and mollusc expert groups.

Some examples:

NHP-B: NHP could, according to the assessment in relation to criterion 1, cause 100% mortality if not diagnosed and treated. Several other non-listed diseases would also case high mortalities if they were not diagnosed or treated. This justification cannot be used for compliance with criterion 1. Furthermore, according to criterion 6 (b) numerous introductions into Asia from affected regions have not resulted in transmission of disease. With respect to criterion 7, the fact that a few compartments in the United States of America could demonstrate freedom does not justify OIE listing.

MoV fails to meet criterion 4 or 5.

IMNV fails to meet criterion 7, the fact that a few compartments in the United States of America could demonstrate freedom do not justify OIE listing.

HPV fails (partly) to meet both criterion 1 and 8. The latter is a compulsory requirement.

The Community reserves its right to submit comments after the deadline and before the General Session 2005, due to the short consultation times given by the OIE.

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*)
- ~~Spawner-isolated mortality virus disease~~
- = Necrotising hepatopancreatitis
- = Infection with Mourilyan virus
- = Infectious myonecrosis
- = White tail disease
- = Infection with hepatopancreatic parvovirus

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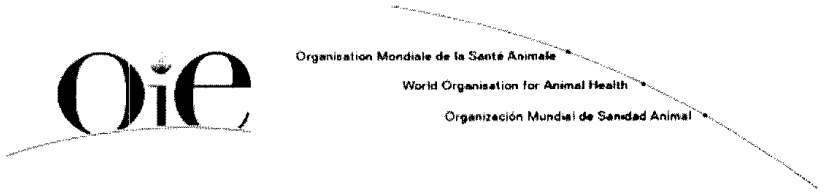
Appendix VI



Original: English
September 2004

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON NEW CHAPTERS FOR MOLLUSC DISEASES

Paris, 22-24 September 2004

The OIE *ad hoc* Group on New Chapters for Mollusc Diseases met at the OIE Headquarters in Paris from 22-24 September 2004.

The members of the OIE *ad hoc* Group and other participants are listed at Appendix A.

The adopted Agenda is given at Appendix B.

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr David Wilson, Head of the International Trade Department, welcomed the members of the *ad hoc* Group to the OIE Headquarters and wished them well in their important work.

Under Agenda item 2, the Interim Report (June 2004) on the OIE List of Aquatic Animal Diseases regarding mollusc diseases was addressed. The Members of the *ad hoc* Group considered the changes that occurred in the OIE *Aquatic Animals Health Code* (hereafter referred to as the *Aquatic Code*) under Chapter 1.1.2. "Disease Listing and Notification Criteria", and changed the Interim Report accordingly (Appendix C).

A revised chapter on infection with *Marteilia refringens* was drafted using the new template for disease chapters for the *Aquatic Code*. Comments from OIE Member Countries on the previous draft chapter on infection with *Marteilia refringens* were addressed. The proposed new chapter is attached at Appendix D.

Addressing the disease chapters and with particular emphasis on the "safe *commodity*" list, the *ad hoc* Group updated the "International Aquatic Animal Health Certificate for Live Molluscs and Gametes". The changes are shown in Appendix E.

A new Model Certificate, the "International Aquatic Animal Health Certificate for Dead Molluscs", was also drafted (Appendix F).

Compartmentalisation/Zoning

The *ad hoc* Group recommended that the Aquatic Animal Health Standards Commission (hereafter referred to as the 'Aquatic Animals Commission') prepare a revised chapter on "Compartmentalisation/Zoning" to include examples of compartments/zones in order to improve the Competent Authorities' understanding of these concepts. Discussing the issue, the *ad hoc* Group could identify three different sorts of compartments in the field of mollusc production.

The *ad hoc* Group considered the current definition of "Zone" insufficient and suggested reconsidering it so to cover the aspects related to the production and trade of molluscs, to make it compatible with the one present in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*). The *ad hoc* Group drafted a new definition for the concept of "Zone" (Appendix G) for consideration by the Aquatic Animals Commission.

In relation to the revised chapter on infection with *Marteilia refringens*, the *ad hoc* Group sought clarification from the Aquatic Animals Commission on Article X.X.X.5. at comma 3)b). The problem lies in the fact that the "compartment", as defined in the General Definitions of the *Aquatic Code*, has to include "aquaculture establishments". Some perplexities were expressed on how a "compartment", without an "aquaculture establishment", can exist.
On Articles X.X.X.4. and X.X.X.5., the *ad hoc* Group would like to know from the Aquatic Animals Commission if the paragraphs 3)b) of both articles imply the following point:

> "If in a country or zone there is a single aquaculture establishment, its monitoring is sufficient for evaluating the sanitary status of the entire country or zone, regardless of the sanitary status of the wild population. The *ad hoc* Group suggested such a case to be re-considered by the Aquatic Animals Commission."

Under Agenda item 4 a revised chapter on infection with *Marteilia refringens* was drafted using the new template for disease chapters for the *Manual of Diagnostic Tests for Aquatic Animals*. This chapter will be sent to Member Countries separately.

Next meeting

The *ad hoc* Group suggested to the Aquatic Animals Commission that the next meeting of the OIE *ad hoc* Group on New Chapters for Mollusc Diseases should be scheduled for July 2005. At that time the work could proceed by taking on board the comments and decisions arisen from the OIE General Session of May 2005.
For a better coordination, the Chair offered to allocate time for telephone conferencing with the Aquatic Animals Commission during the next meeting of the Bureau on 11-15 October 2004.

.../Appendices

Appendix VI (contd)

Appendix A

MEETING OF THE OIE AD HOC GROUP ON NEW CHAPTERS FOR MOLLUSC DISEASES
Paris, 22-24 September 2004

List of participants

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Appendix VI (contd)

Appendix B

MEETING OF THE OIE AD HOC GROUP ON NEW CHAPTERS FOR MOLLUSC DISEASES Paris, 22-24 September 2004

Agenda

1. **Adoption of the Agenda**

2. **OIE List of Aquatic Animal Diseases**

   Finalisation of the Interim Report on the OIE List of Aquatic Animal Diseases regarding mollusc diseases.

3. ***Aquatic Animal Health Code***

   Draft a new chapter on infection with *Marteilia refringens* for the *Aquatic Animal Health Code* using the template supplied.
   a) Considering Member Countries comments
   b) Addressing the points of:
      i) Surveillance and freedom requirements
      ii) Safe commodities
      iii) Compartmentalisation/zoning

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

   Start drafting a new chapter on Infection with *Marteilia refringens* for the *Manual of Diagnostic Tests for Aquatic Animals*.
   a) Taking into account changes applied to the *Aquatic Animal Health Code*.

5. **Agree on methods for continuing the work started**

   Set a timeline for completing the work.

Appendix C

OIE LISTED DISEASES – MOLLUSC DISEASES

[FULL VERSION OF THIS APPENDIX IS AT APPENDIX III]

Appendix VI (contd)

Appendix D

CHAPTER X.X.X.

INFECTION WITH *MARTEILIA REFRINGENS*

Article X.X.X.1.

For the purposes of this *Aquatic Code*, infection with *Marteilia refringens* means infection only with *Marteilia refringens.*

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual.*

Article X.X.X.2.

Susceptible species

For the purpose of this *Aquatic Code*, *susceptible species* for infection with *Marteilia refringens* are: *Ostrea* species, in particular the European Flat Oyster (*Ostrea edulis*), Australian Mud Oyster (*Ostrea angasi*), Argentinean Oyster (*Ostrea puelchana*) and Chilean Flat Oyster (*Ostrea chilensis*), Blue Mussel, *Mytilus edulis* and Mediterranean Mussel (*M. galloprovincialis*).

Infection with *Marteilia refringens* can also cause *subclinical* infection in these species.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Marteilia refringens* should be referred immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article X.X.X.3.

Commodities

1) When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Marteilia refringens* related conditions, regardless of the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*:

   a) gametes, eggs and larvae;

   b) processed non-viable molluscs (cooked, canned, smoked);

   c) fresh non-viable half-shell oysters.

2) When authorising import or transit of the following *commodities* of a species listed in Article X.X.X.2., *Competent Authorities* should require the conditions prescribed in Articles X.X.X.7. to X.X.X.11. of this Chapter, relevant to the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment:*

   a) *aquatic animals*;

   b) *aquatic animal products.*

Appendix VI (contd)

Appendix D (contd)

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of *Marteilia refringens*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Marteilia refringens*, and the potential consequences, associated with importation of the *commodity*, prior to a decision. This assessment should be made available to the *exporting country*.

Article X.X.X.4.

***Marteilia refringens* free country**

A country may *declare* itself *free* from *Marteilia refringens* if it meets the conditions in point 1) or 2) or 3) below.

If a country shares a water resource with one or more other countries, it can only *declare* itself a *Marteilia refringens* free country if all the areas covered by the shared water resource are declared *Marteilia refringens* free *zones* (see Article X.X.X.5.).

1) A country where none of the species listed in Article X.X.X.2. is present may *declare* itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the country for at least the past3 years and infection is not known to be established in wild populations.

OR

2) A country where the species listed in Article X.X.X.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 X.X.X. of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the country for at least the past 3 years and infection 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, for example because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when:

   a) it meets *basic biosecurity conditions* for at least the past 3 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 past 3 years in *aquaculture establishments* holding any of the species listed in Article X.X.X.2. and wild population of those species, without detection of *Marteilia refringens*.

Article X.X.X.5.

***Marteilia refringens* free zone or free compartment**

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Marteilia refringens* 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 *Marteilia refringens*, a *zone* or *compartment* where none of the species listed in Article X.X.X.2. is present may *declare* itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 3 years and infection is not known to be established in wild populations.

OR

2) In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where the species listed in Article X.X.X.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 X.X.X. of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 3 years and infection 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, for example because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may *declare* itself free from *Marteilia refringens* when:

   a) it meets *basic biosecurity conditions* for at least the past 3 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 past 3 years in *zones* and *compartments* holding any of the species listed in Article X.X.X.2., without detection of infection with *Marteilia refringens.*

These provisions also apply if the *zone* or *compartment* to be declared free lies in a *Marteilia refringens* - infected country or countries.

Article X.X.X.6.

Maintenance of free status

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

A country or *zone* or *compartment* that is declared free from *Marteilia refringens* following the provisions of point 3) of Articles X.X.X.4. or X.X.X.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Marteilia refringens* free provided that conditions that are conducive to clinical expression of infection with *Marteilia refringens*, 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 infection with *Marteilia refringens*, *targeted surveillance* will need to be continued, but at a level commensurate with the degree of risk assessed by the *Competent Authority.*

Appendix D (cont'd)

Article X.X.X.7.

Importation of live animals from a country, zone or compartment declared free from *Marteilia refringens*

When importing live *aquatic animals* of the species listed in Article X.X.X.2., other than *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* free from *Marteilia refringens*, 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 X.X.X.4. or X.X.X.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. [X] given in Part 6 of this *Aquatic Code*.

Article X.X.X.8.

Importation of live animals for aquaculture activities from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animals* of the species listed in Article X.X.X.2. for *aquaculture activities*, other than those *commodities* listed in point 1) of Article X.X.X.3., from a country, zone or compartment not declared *free*, the *Competent Authority* of the *importing country* should require that the consignment be delivered directly into approved secure rearing facilities that at all times, through to slaughter and processing, ensure isolation from the local environment and prevent the potential release of *Marteilia refringens* through treatment of all effluent and waste.

Article X.X.X.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animals* of the species listed in Article X.X.X.2. for processing and/or human consumption, other than those live *commodities* listed in point 1) of Article X.X.X.3., from a country, zone or compartment not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure holding facilities for a short period before processing and/or consumption, and

2) all effluent and waste material be treated in a manner that ensures inactivation of *Marteilia refringens*.

Article X.X.X.10.

Importation of products from a country, zone or compartment free from *Marteilia refringens*

When importing *aquatic animal products* of the *species* listed in Article X.X.X.2., other than *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* free from *Marteilia refringens*, 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 X.X.X.4. or X.X.X.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. [X] given in Part 6 of this *Aquatic Code*.

Article X.X.X.11.

Importation of products from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animal products* of the species listed in Article X.X.X.2., other than those *commodities* listed in point 1) of Article X.X.X.3., from a country, zone or compartment not declared free, the *Competent Authority* of the *importing country* should require that they be processed only in approved mollusc processing plants with facilities to effectively treat effluent and waste in a manner that ensures complete inactivation of *Marteilia refringens*.

Appendix E

Model Certificate No. 3.

INTERNATIONAL AQUATIC ANIMAL HEALTH CERTIFICATE FOR LIVE MOLLUSCS AND GAMETES

Appendix VI (contd)

LIVE MOLLUSCS AND GAMETES

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

❑ Cultured stocks ❑ Wild stocks

1) Species:

Scientific name:.....

Common name:.....

2) Age: ❑ Gametes ❑ Larvae ❑ 0–11 months ❑ 12–24 months

❑ >24 months ❑ Unknown

3) Total weight (kg):.....

OR

Number (×1000):.....

II. Place of production

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

III. Origin of consignment (if different from II)

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

IV. Destination

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

4) Nature and identification of means of transport:.....

.....

Appendix VI (contd)

Appendix E (contd)

V. Declaration

I, the undersigned, certify that the live molluscs and/or gametes in the present consignment have as their place of production a: ☐ Country, ☐ Zone, ☐ Aquaculture establishment that is subjected to an official mollusc 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 have been declared free from the pathogens causing the *diseases* listed in this *Aquatic Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Infection with *Bonamia exitiosa*						
Infection with *Bonamia ostreae*						
~~Infection with *Haplosporidium nelsoni*~~						
Infection with *Marteilia refringens*						
~~Infection with *Marteilia sydneyi*~~						
~~Infection with *Mikrocytos mackini*~~						
~~Infection with *Mikrocytos roughleyi*~~						
Infection with *Perkinsus marinus*						
Infection with *Perkinsus olseni/ atlanticus*						
Infection with *Xenohaliotis californiensis*						
~~Infection with *Haplosporidium costale*~~						

Exporting country:.. .....

Competent Authority:.....

Stamp:

Date:.....

Issued at:.....

Name and address of Certifying Official:

.....

.....

.....

Signature:.....

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

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Appendix F

Model Certificate No. 4.

INTERNATIONAL AQUATIC ANIMAL

HEALTH CERTIFICATE FOR

DEAD MOLLUSCS

Appendix VI (contd)

Appendix F (contd)

DEAD MOLLUSCS

NOTE: Mark all the relevant items with a cross in the appropriate space.

I. Identification

❑ Cultured stocks ❑ Wild stocks

1) Species:

Scientific name: .....

Common name: .....

2) Age: ❑ 0–12 months ❑ 12–24 months ❑ >24 months ❑ Unknown

3) Commodity ❑ Fresh off shell ❑ Fresh half shell ❑ Frozen

4) Total weight (kg):.....

OR

Number :.....

II. Place of production

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

III. Origin of consignment (if different from II)

1) Country:.....

2) Zone:.....

3) Aquaculture establishment/Zone:

Name:.....

Location:.....

IV. Destination

1) Country:.....

2) Zone:.....

3) Company:

Name:.....

Location:.....

4) Nature and identification of means of transport:.....

.....

Appendix VI (contd)

Appendix F (contd)

V. Declaration

I, the undersigned, certify that the dead molluscs in the present consignment have as their place of production a: ☐ Country, ☐ Zone, ☐ Aquaculture establishment that is subjected to an official mollusc 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 have been declared free from the pathogens causing the diseases listed in this *Aquatic Code*, as identified in the table below.

	Country		Zone		Aquaculture establishment	
	Yes	No	Yes	No	Yes	No
Infection with *Bonamia exitiosa*						
Infection with *Bonamia ostreae*						
Infection with *Marteilia refringens*						
Infection with *Perkinsus marinus*						
Infection with *Perkinsus olseni/ atlanticus*						
Infection with *Xenohaliotis californiensis*						

Exporting country:.....

Competent Authority:.....

Stamp:

Date:.....

Issued at:.....

Name and address of Certifying Official:

.....

.....

.....

Signature:.....

IMPORTANT NOTE: This certificate must be completed no more than three days prior to shipment.

Appendix VI (contd)

Appendix G

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1

Zone

means a portion of one or more countries comprising an entire, or part of, catchment area from the source of a waterway to the estuary, more than one catchment area, ~~part of a catchment area from the source of a waterway to a barrier,~~ or a part of the coastal area, ~~or an estuary with a precise geographical delimitation,~~ that consists of a homogeneous hydrological system with a distinct health status with respect to a specific disease for which required surveillance, control and biosecurity measures have been applied. Such *zones* must be clearly delineated on a map of the *territory* of the country(ies) concerned by the *Competent Authority*.

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Appendix VII

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

Original: English
October 2004

REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON NEW CHAPTERS FOR CRUSTACEAN DISEASES

Paris, 11-13 October 2004

The OIE *ad hoc* Group on new chapters for crustacean diseases met at the OIE Headquarters in Paris from 11 to 13 October 2004.

The members of the OIE *ad hoc* Group and other participants are listed at Appendix A.

The adopted Agenda is given at Appendix B.

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr David Wilson, Head of the International Trade Department welcomed the members of the *ad hoc* Group to the OIE Headquarters and wished them well in their important work.

1. OIE listed diseases

The Members of the *ad hoc* Group (as members of the team revising the list of crustaceans diseases) discussed relevant issues with the Bureau of the Aquatic Animal Health Standards Commission, and consequently prepared a report to justify the maintenance, the removal or the addition of crustacean diseases to/from the OIE list of diseases (Appendix C).

2. *Aquatic Animal Health Code* Chapter

A revised chapter on infection with white spot disease was drafted using the new template for disease chapters for the *Aquatic Animal Health Code* (hereafter referred to as the "*Aquatic Code*"). Comments from OIE Member Countries on the previous draft chapter were taken into account in preparing this revised chapter. The proposed revised chapter is attached at Appendix D; due to the significant changes proposed, the proposal is circulated as new text.

The *ad hoc* Group recommended that the Aquatic Animal Health Standards Commission (hereafter referred to as the "Aquatic Animals Commission") develop definitions for "mechanical vector" and "catchments" for addition to the *Aquatic Code.*

In Articles 4.1.2.4. and 4.1.2.5., the *ad hoc* Group recommended changing the length of time required for declaration of freedom from 25 to 10 years. This 10-year period without the occurrence of the disease in a country or zone/compartment was considered to be more appropriate as a basis for freedom from white spot disease because:

a) white spot disease was unknown 10 years ago;

b) the life cycle of the most important host species is 2 years or less;

c) much of the crustacean aquaculture industry is less than 25 years old.

The time for the *basic biosecurity conditions* to be in place has been proposed as 2 years, because the life cycle of the principal host species is 2 years or less.

3. ***Manual of Diagnostic Tests for Aquatic Animals* Chapter**
The *ad hoc* Group started revising the chapter on white spot disease. In due course a draft will be circulated to Member Countries for comment.

4. **Next meeting**
The *ad hoc* Group suggested to the Bureau of the Aquatic Animals Commission that the next meeting of the OIE *ad hoc* Group on new chapters for crustacean diseases should be scheduled for mid 2005, to address the comments and decisions arising from the OIE General Session of May 2005.

.../Appendices

Appendix VII (contd)

Appendix A

MEETING OF THE OIE AD HOC GROUP ON NEW CHAPTERS FOR CRUSTACEAN DISEASES
Paris, 11-13 October 2004

List of participants

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Appendix VII (contd)

Appendix B

MEETING OF THE OIE AD HOC GROUP ON NEW CHAPTERS FOR CRUSTACEAN DISEASES Paris, 11-13 October 2004

Adopted Agenda

1. **Adoption of the Agenda**

2. **OIE List of Aquatic Animal Diseases**

   Report on the OIE List of Aquatic Animal Diseases regarding crustacean diseases.

3. ***Aquatic Animal Health Code***

   Draft a new chapter on white spot disease for the *Aquatic Animal Health Code* using the template supplied.

   a) Considering Member Countries comments

   b) Addressing the points of:

      i) Surveillance and freedom requirements

      ii) Safe commodities

      iii) Compartmentalisation/zoning

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

   Start drafting a new chapter on white spot disease for the *Manual of Diagnostic Tests for Aquatic Animals*, taking into account changes applied to the *Aquatic Animal Health Code*.

5. **Agree on methods for continuing the work started**

   Set a timeline for completing the work.

6. **Other business**

Appendix VII (contd)

Appendix C

OIE LISTED DISEASES – CRUSTACEAN DISEASES

[FULL VERSION OF THIS APPENDIX IS AT APPENDIX III]

Appendix VII (contd)

Appendix D

PROPOSED REVISED CHAPTER

CHAPTER 4.1.2.

WHITE SPOT DISEASE

Article 4.1.2.1.

For the purposes of this *Aquatic Code*, white spot disease (WSD) means infection with the viral species *White spot syndrome virus* (WSSV) in the genus *Whispovirus* of the family Nimaviridae. Common synonyms are listed in Chapter 4.1.2. of the *Aquatic Manual*.

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

Article 4.1.2.2.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for WSD are all decapod (order *Decapoda*) crustaceans from marine and brackish or freshwater sources. In addition, bivalves, rotifers, the non-decapodal crustacean *Artemia salina*, krill, copepods, and aquatic arthropods, sea slaters (*Isopoda*) and *Euphydradae* insect larvae, can accumulate high concentrations of viable WSSV although there is no evidence of replication in these species.

Suspect cases of natural infection with WSSV in species other than those listed in this Article should be referred immediately to the OIE Reference Laboratory for WSD, whether or not clinical signs are associated with the findings.

Article 4.1.2.3.

Commodities

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

   a) cooked, canned or dried crustaceans (or molluscs as mechanical vectors) for direct human consumption;

   b) chitin prepared from crustaceans shell by chemical extraction;

   c) heat dried or sun dried crustacean by-products intended for use in animal feeds or dry pelleted animal feeds containing crustacean by-products;

   d) *Artemia* cysts;

   e) chemically preserved (and rendered non-infectious) specimens of the species listed in Article 4.1.2.2.

Appendix D (contd)

2) When authorising import or transit of the following *commodities* of a species listed in Article 4.1.2.2., *Competent Authorities* should require the conditions prescribed in Articles 4.1.2.7. to 4.1.2.11. of this Chapter, relevant to the WSD status of the *exporting country*, *zone* or *compartment*:

   a) *aquatic animals*;

   b) *aquatic animal products*.

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of WSD, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of WSSV, and the potential consequences, associated with importation of the *commodity*, prior to a decision. This assessment should be made available to the *exporting country*.

Article 4.1.2.4.

WSD free country

A country may declare itself free from WSD if it meets the conditions in point 1), 2) or 3) below.

If a country shares a water resource with one or more other countries, it can only declare itself a WSD free country if all the areas covered by the shared water resource are declared WSD free countries or zones (see Article 4.1.2.5.).

1) A country where none of the species listed in Article 4.1.2.2. is present may declare itself free from WSD when *basic biosecurity conditions* have been in place continuously in the country for at least the past 2 years.

OR

2) A country where the species listed in Article 4.1.2.2. are present but there has never 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 declare itself free from WSD when *basic biosecurity conditions* have been in place continuously 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 clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from WSD when:

   a) it has met *basic biosecurity conditions* 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 past 2 years

Article 4.1.2.5.

WSD free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from WSD 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 point 1), 2) or 3) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a WSD 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 species listed in Article 4.1.2.2. is present may be declared free from WSD when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2) A *zone* or *compartment* where the species listed in Article 4.1.2.2. 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 WSD when *basic biosecurity conditions* have been in place continuously 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 clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from WSD when:

   a) it has met *basic biosecurity conditions* 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, throughout the *zone* or *compartment*, for at least the past 2 years.

Article 4.1.2.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from WSD following the provisions of points 1) or 2) of Articles 4.1.2.4. or 4.1.2.5., respectively, may maintain its status as WSD free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from WSD following the provisions of point 3) of Articles 4.1.2.4. or 4.1.2.5., may discontinue *targeted surveillance* and maintain its status as WSD free provided that conditions that are conducive to clinical expression of WSD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are maintained.

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

Article 4.1.2.7.

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

When importing *aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., 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*, certifying that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WSD.

The certificate shall be in accordance with Model Certificate No. [X] in Part 6 of this *Aquatic Code.*

Article 4.1.2.8

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

When importing for *aquaculture activities aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country*, should require that:

1) the consignment be delivered directly into and held in approved secure rearing facilities,

2) the imported *aquatic animals* and their first generation progeny be continuously isolated from the local environment, and

3) all effluent and waste material be treated in a manner that ensures inactivation of WSSV.

If the intention of the introduction is the establishment of new genetic lines, international standards, such as the Guidelines of the International Council for the Exploration of the Seas (ICES) should be followed.

For the purposes of this *Aquatic Code*, the ICES Guidelines for Aquatic Species Introduction may be summarised to the following main points:
1) identify stock of interest (cultured or wild) in its current location;
2) evaluate stock's health/disease history;
3) take and test samples for WSD, pests and general health/disease status;
4) import and *quarantine* in a secure facility a founder (F-0) population;
5) produce F-1 generation from the F-0 stock in *quarantine*;

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

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

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

Article 4.1.2.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from WSD

When importing for processing and/or human consumption *aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in approved secure holding facilities for a short period before processing and/or consumption, and

2. all effluent and waste material be treated in a manner that ensures inactivation of WSSV.

Article 4.1.2.10.

Importation of products from a country, zone or compartment free from WSD

When importing *aquatic animal products* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* free from WSD, 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*, certifying that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WSD.

The certificate shall be in accordance with Model Certificate No. [X] in Part 6 of this *Aquatic Code*.

Article 4.1.2.11

Importation of products from a country, zone or compartment not declared free from WSD

When importing *aquatic animal products* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure storage facilities, and be processed only in approved processing plants, and

2) all effluent and waste material be treated in a manner that ensures inactivation of WSSV.

Appendix VIII

REVISED CHAPTER PROPOSED BY THE BUREAU OF THE AQUATIC ANIMALS COMMISSION

CHAPTER 2.1.1.

EPIZOOTIC HAEMATOPOIETIC NECROSIS

Community comment

The Community supports this proposal but provided the comments below are taken on board.

Article 2.1.1.1.

For the purposes of this *Aquatic Code*, epizootic haematopoietic necrosis (EHN) means infection with the viral species EHN virus (EHNV) in the genus *Ranavirus* of the family Iridoviridae.

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

Article 2.1.1.2.

Community comment

The Community would ask the OIE to consider a formal "fast track" procedure for inclusion of new susceptible species.

Justification: Article 2.1.1.2 define the susceptible species, and all other articles in the chapter related to free country, zone or compartment and importation of aquatic animals and aquatic animal products refer to article 2.1.1.2. If there is new scientific evidence of infection with the disease in other species, the free countries, zones or compartments have no possibility to introduce sanitary measures against the disease before the aquatic code can be changed at the next general session (unless it perform import risk analysis, which usually is very time consuming). On the other hand countries free from the disease based on the absence of susceptible species, can loose the free status if the list of susceptible species is changed. These countries therefore need some sort of validation/evaluation of new scientific evidence of infection with the disease in other species than those listed.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for EHN are: redfin perch (*Perca fluviatilis*), rainbow trout (*Oncorhynchus mykiss*), Macquarie perch (*Macquaria australasica)*, silver perch (*Bidyanus bidyanus*), mountain galaxias (*Galaxias olidus*), mosquito fish (*Gambusa affinis*) and other species belonging to the family Poeciliidae.

Suspect cases of natural infection with EHNV in species other than those listed in this Article should be referred immediately to the OIE Reference Laboratory for EHN, whether or not clinical signs are associated with the findings.

Article 2.1.1.3.

Community comment

The Community would ask the OIE to make the scientific data on which the decision to consider ensilage a proper inactivation of ENHV was based, available. To the Community's knowledge there are no publications on the inactivation of EHNV.

The Community acknowledge the fact that this draft chapter is a model, but will urge the OIE to carefully assess, in each individual disease chapter, what can be considered a safe commodity based upon scientific data.

Commodities

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

   a) leather made from fish skin via a full curing process;

   b) fish by-products, such as flame-dried or sun-dried meals, and ensilaged fish;

   c) dead eviscerated fish of a species listed in Article 2.1.1.2. (chilled, sun-dried, smoked or frozen) not intended for further processing prior to retail sale;

   d) dead fish of non-susceptible species, eviscerated or non-eviscerated;

   e) canned fish;

   f) chemically preserved (and rendered non-infectious) specimens of the species listed in Article 2.1.1.2.

2) When authorising import or transit of the following *commodities* of a species listed in Article 2.1.1.2., *Competent Authorities* should require the conditions prescribed in Articles 2.1.1.7. to 2.1.1.11. of this Chapter, relevant to the EHN status of the *exporting country*, *zone* or *compartment*:

   a) *aquatic animals*;

   b) *aquatic animal products*.

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of EHN, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of EHNV, and the potential consequences, associated with importation of the *commodity*, prior to a decision. This assessment should be made available to the *exporting country*.

Article 2.1.1.4.

Community comment

1) Comments to Article 2.1.1.4:

The present text is unclear and needs to be re-written for the sake of clarity. The Community questions the justification for requirement of 10 years of basic biosecurity conditions in 2.1.1.4 point 2 (and 2.1.1.5

point 2). The Community support the idea that countries, zones or compartment should be able to get the free status sooner if they have a surveillance program, but the difference between 2 and 10 year is not justified.

Furthermore, the Community do not agree with the proposed text, as it would be impossible for a Member Country sharing coastal waters with another Country not declared free, to declare freedom.

Until the OIE has finalised the development of the concept of compartmentalisation, the Community requests that the Member Countries may apply the principle of establishing a buffer zone towards non-declared free Countries.

Consequently Community propose that Article 2.1.1.4 should read

<u>EHN disease free country, zone or compartment</u>

A country may declare itself free from EHN if it meets the conditions in point 1), 2) or 3) below. A zone or compartment within the territory of one or more countries not declared free from EHN 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 point 1), 2) or 3) below

1) A country, zone or compartment where none of the species listed in Article 2.1.1.2. is present may declare itself free from EHN when basic biosecurity conditions have been in place continuously in the country for at least the past 2 years.

OR

2) A country, zone or compartment where the species listed in Article 2.1.1.2. and conditions that are conducive to clinical expression of the disease (described in Chapter X.X.X. of the Aquatic Manual) are present, but there has not been any observed occurrence of the disease for at least the past 25 years may declare itself free from EHN when basic biosecurity conditions have been in place continuously in the country for at least the past 10 years.

OR

3) A country, zone or compartment where there has not been any observed occurrence of the disease for at least the past 2 years may declare itself free from EHN when:

> **a) basic biosecurity conditions have been in place continuously in the country 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 past 2 years.**

If a country shares a water resource with one or more other countries, or if a zone or compartment extends over more than one country, it can only declare itself an EHN free country if :
a) all the areas covered by the shared water resource, zone or compartment are declared EHN free; or
b) the Member Country establishes the necessary buffer zones in its territory as appropriate. The delimitations of the buffer zones must be such that it protects the disease free Member Country from passive introduction of the disease

<u>2) Comments which come as a consequence of comment 1):</u>

a) here is also a need to define "Buffer zone" (See Community comment to Appendix XI)

b) this proposal makes Article 2.1.1.5 superfluous.

EHN free country

A country may declare itself free from EHN if it meets the conditions in point 1), 2) or 3) below.

If a country shares a water resource with one or more other countries, it can only declare itself an EHN free country if all the areas covered by the shared water resource are declared EHN free countries or zones (see Article 2.1.1.5.).

1) A country where none of the species listed in Article 2.1.1.2. is present may declare itself free from EHN when *basic biosecurity conditions* have been in place continuously in the country for at least the past 2 years.

OR

2) A country where the species listed in Article 2.1.1.2. 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 declare itself free from EHN when *basic biosecurity conditions* have been in place continuously in the country for at least the past 10 years.

OR

3) A country where the last observed occurrence of the *disease* was within the past 25 years or where the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from EHN when:

   a) it has met *basic biosecurity conditions* 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 past 2 years.

Article 2.1.1.5.

EHN free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from EHN 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 point 1), 2) or 3) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared an EHN 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 species listed in Article 2.1.1.2. is present may be declared free from EHN when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2) A *zone* or *compartment* where the species listed in Article 2.1.1.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from EHN when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 10 years.

OR

3) A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 25 years or where the infection status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from EHN when:

   a) it has met *basic biosecurity conditions* 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 past 2 years.

Article 2.1.1.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from EHN following the provisions of points 1) or 2) of Articles 2.1.1.4. or 2.1.1.5., respectively, may maintain its status as EHN free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from EHN following the provisions of point 3) of Articles 2.1.1.4. or 2.1.1.5., respectively, may discontinue *targeted surveillance* and maintain its status as EHN free provided that conditions that are conducive to clinical expression of EHN, as described in Chapter X.X.X. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are maintained.

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

Community comment

The Community believes it is important that when the different disease chapters, has articles on how to achieve disease free status, and to maintain disease free status, there should also be an articles on how to restore the status if the status may have been lost.

The Community propose that the text referred to in Article 1.2.1.4, point 2 and 3 (see Appendix XIV of this report) are introduced in the disease chapters. The Community also propose that it should be possible to regain disease free status faster than getting the disease free status if full prophylactic and appropriate sanitary measures have been applied to prevent possible reappearance or spread of the disease.

Article 2.1.1.7.

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

When importing *aquatic animals* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., 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*, certifying that, on the basis of the procedures described in Articles 2.1.1.4. or 2.1.1.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from EHN.

The certificate shall be in accordance with Model Certificate No. [X] in Part 6 of this *Aquatic Code*.

Article 2.1.1.8.

Community comment

The Community believes that the existing wording could make the Article inconsistent with 2.1.1.3 (3). The proposed measures *may* be an acceptable way of handling the risk identified under 2.1.1.3 (3).

The Community therefore propose that the first paragraph should read

When importing for *aquaculture activities aquatic animals* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* assess the risk and apply the necessary risk mitigation measures. Such measures may be:

This principle comment is also valid for Articles 2.1.1.9. and 2.1.1.11

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

When importing for *aquaculture activities aquatic animals* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly into and held in approved secure rearing facilities;

2) the imported *aquatic animals* and their first generation progeny be continuously isolated from the local environment; and

3) all effluent and waste material be treated in a manner that ensures inactivation of EHNV.

Article 2.1.1.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from EHN

When importing for processing and/or human consumption *aquatic animals* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure holding facilities for a short period before processing and/or consumption; and

2) all effluent and waste material be treated in a manner that ensures inactivation of EHNV.

Article 2.1.1.10.

Importation of products from a country, zone or compartment free from EHN

When importing *aquatic animal products* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* free from EHN, 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*, certifying that, on the basis of the procedures described in Articles 2.1.1.4. or 2.1.1.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from EHN.

The certificate shall be in accordance with Model Certificate No. [X] in Part 6 of this *Aquatic Code*.

Article 2.1.1.11.

Importation of products from a country, zone or compartment not declared free from EHN

When importing *aquatic animal products* of the species listed in Article 2.1.1.2., other than those *commodities* listed in point 1) of Article 2.1.1.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure storage facilities, and be processed only in approved processing plants, and

2) all effluent and waste material be treated in a manner that ensures inactivation of EHNV.

Appendix IX

REVISED CHAPTER PROPOSED BY
THE BUREAU OF THE AQUATIC ANIMALS COMMISSION

CHAPTER 4.1.2.

WHITE SPOT DISEASE

Community comment

The Community can only support this proposal provided the comments below are taken on board.

Article 4.1.2.1.

For the purposes of this *Aquatic Code*, white spot disease (WSD) means infection with the viral species *White spot syndrome virus* (WSSV) in the genus *Whispovirus* of the family Nimaviridae. Common synonyms are listed in Chapter 4.1.2. of the *Aquatic Manual*.

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

Article 4.1.2.2.

Community comment

The Community questions the list of carrier species indicated under Article 4.1.2.2.

In the definition, aquatic animals comprise all life stages (including eggs and gametes) of fish, molluscs and crustaceans .....

Although the species capable of accumulating high concentrations of WSSV in this Article is not defined as susceptible species, it may be a contradiction to the scope of the Code that Article 4.1.2.2 and subsequently Articles 4.1.2.7-4.1.2.11 should apply to animals not covered by the Code. "Aquatic arthropods" covers more than crustaceans (as in the definition) . Consequently these species are beyond the scope of the Code.

This problem should rather be dealt with under Article 4.1.2.3 point 3)

The Community therefore propose top delete the second sentence of the first paragraph, making that paragraph read: For the purposes of this *Aquatic Code*, *susceptible species* for WSD are all decapod (order *Decapoda*) crustaceans from marine and brackish or freshwater sources.

The Community would also ask the OIE to consider a formal "fast track" procedure for inclusion of new susceptible species.

Justification: Article 4.1.2.2 define the susceptible species, and all other articles in the chapter related to free country, zone or compartment and importation of aquatic animals and aquatic animal products refer to article 4.1.2.2. If there is new scientific evidence of infection with the disease in other species, the free countries, zones or compartments have no possibility to introduce sanitary measures against the disease before the aquatic code can be changed at the next general session (unless they performs import risk

analysis, which usually is very time consuming). On the other hand countries free from the disease based on the absence of susceptible species, can loose the free status if the list of susceptible species is changed. These countries therefore need some sort of validation/evaluation of new scientific evidence of infection with the disease in other species than those listed.

Susceptible species

For the purposes of this *Aquatic Code*, *susceptible species* for WSD are all decapod (order *Decapoda*) crustaceans from marine and brackish or freshwater sources. In addition, bivalves, rotifers, the non-decapodal crustacean *Artemia salina*, krill, copepods, and aquatic arthropods, sea slaters (*Isopoda*) and *Euphydradae* insect larvae, can accumulate high concentrations of viable WSSV although there is no evidence of replication in these species.

Suspect cases of natural infection with WSSV in species other than those listed in this Article should be referred immediately to the OIE Reference Laboratory for WSD, whether or not clinical signs are associated with the findings.

Article 4.1.2.3.

Commodities

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

   a) cooked, canned or dried crustaceans (or molluscs as mechanical vectors) for direct human consumption;

   b) chitin prepared from crustaceans shell by chemical extraction;

   c) heat dried or sun dried crustacean by-products intended for use in animal feeds or dry pelleted nimal feeds containing crustacean by-products;

   d) *Artemia* cysts;

   e) chemically preserved (and rendered non-infectious) specimens of the species listed in Article 4.1.2.2.

2) When authorising import or transit of the following *commodities* of a species listed in Article 4.1.2.2., *Competent Authorities* should require the conditions prescribed in Articles 4.1.2.7. to 4.1.2.11. of this Chapter, relevant to the WSD status of the *exporting country*, *zone* or *compartment*:

   a) *aquatic animals*;

   b) *aquatic animal products.*

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of WSD, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of WSSV, and the potential consequences, associated with importation of the *commodity*, prior to a decision. This assessment should be made available to the *exporting country*.

Article 4.1.2.4.

Community comment

1) Comments to Article 4.1.2.4:

The present text is unclear and needs to be re-written for the sake of clarity. The Community questions the justification for requirement of 2 years of basic biosecurity conditions in 4.1.2.4 point 2 (and 4.1.2.5 point 2). The Community suggests the idea that countries, zones or compartment should be able to get the free status sooner if they have a surveillance program.

Furthermore, the Community do not agree with the proposed text, as it would be impossible for a Member Country sharing coastal waters with another Country not declared free, to declare freedom.

Until the OIE has finalised the development of the concept of compartmentalisation, the Community requests that the Member Countries may apply the principle of establishing a buffer zone towards non-declared free Countries.

Consequently Community propose that Article 4.1.2.4 should read

WSD disease free country, zone or compartment

A country may declare itself free from WSD if it meets the conditions in point 1), 2) or 3) below. A zone or compartment within the territory of one or more countries not declared free from WSD 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 point 1), 2) or 3) below

1) A country, zone or compartment where none of the species listed in Article 4.1.2.2. is present may declare itself free from WSD when basic biosecurity conditions have been in place continuously in the country for at least the past 2 years.

OR

2) A country, zone or compartment where the species listed in Article 4.1.2.2. and conditions that are conducive to clinical expression of the disease (described in Chapter X.X.X. of the Aquatic Manual) are present, but there has not been any observed occurrence of the disease for at least the past 25 years may declare itself free from EHN when basic biosecurity conditions have been in place continuously in the country for at least the past 10 years.

OR

3) A country, zone or compartment where there has not been any observed occurrence of the disease for at least the past 2 years may declare itself free from WSD when:

a) basic biosecurity conditions have been in place continuously in the country 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 past 2 years.

If a country shares a water resource with one or more other countries, or if a zone or compartment extends over more than one country, it can only declare itself an WSD free country if :
a) all the areas covered by the shared water resource, zone or compartment are declared WSD free; or
b) the Member Country establishes the necessary buffer zones in its territory as appropriate. The delimitations of the buffer zones must be such that it protects the disease free Member Country from passive introduction of the disease

2) Comments which come as a consequence of comment 1):

a) here is also a need to define "Buffer zone" (See Community comment to Appendix XI)

b) this proposal makes Article 4.1.2.5 superfluous.

WSD free country

A country may declare itself free from WSD if it meets the conditions in point 1), 2) or 3) below.

If a country shares a water resource with one or more other countries, it can only declare itself a WSD free country if all the areas covered by the shared water resource are declared WSD free countries or zones (see Article 4.1.2.5.).

1) A country where none of the species listed in Article 4.1.2.2. is present may declare itself free from WSD when *basic biosecurity conditions* have been in place continuously in the country for at least the past 2 years.

OR

2) A country where the species listed in Article 4.1.2.2. are present but there has never 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 declare itself free from WSD when *basic biosecurity conditions* have been in place continuously 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 clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from WSD when:

   a) it has met *basic biosecurity conditions* 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 past 2 years.

Article 4.1.2.5.

WSD free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from WSD 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 point 1), 2) or 3) below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a WSD 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 species listed in Article 4.1.2.2. is present may be declared free from WSD when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 2 years.

OR

2) A *zone* or *compartment* where the species listed in Article 4.1.2.2. 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 WSD when *basic biosecurity conditions* have been in place continuously 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 clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from WSD when:

   a) it has met *basic biosecurity conditions* 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, throughout the *zone* or *compartment*, for at least the past 2 years.

Article 4.1.2.6.

Maintenance of free status

A country or *zone* or *compartment* that is declared free from WSD following the provisions of points 1) or 2) of Articles 4.1.2.4. or 4.1.2.5., respectively, may maintain its status as WSD free provided that *basic biosecurity conditions* are continuously maintained.

A country or *zone* or *compartment* that is declared free from WSD following the provisions of point 3) of Articles 4.1.2.4. or 4.1.2.5., may discontinue *targeted surveillance* and maintain its status as WSD free provided that conditions that are conducive to clinical expression of WSD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are maintained.

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

Community comment

The Community believes it is important that when the different disease chapters, has articles on how to achieve disease free status, and to maintain disease free status, there should also be an articles on how to restore the status if the status may have been lost.

The Community propose that the text referred to in Article 1.2.1.4, point 2 and 3 (see Appendix XIV of this report) are introduced in the disease chapters. The Community also propose that it should be possible to regain disease free status faster than getting the disease free status if full prophylactic and appropriate sanitary measures have been applied to prevent possible reappearance or spread of the disease.

Article 4.1.2.7.

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

When importing *aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., 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*, certifying that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WSD.

The certificate shall be in accordance with Model Certificate No. [X] in Part 6 of this *Aquatic Code*.

Article 4.1.2.8

Community comment

The Community believes that the existing wording could make the Article inconsistent with 4.1.2.3 (3). The proposed measures *may* be an acceptable way of handling the risk identified under 4.1.2.3 (3).

The Community therefore propose that the first paragraph should read

When importing for *aquaculture activities aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* assess the risk and apply the necessary risk mitigation measures. Such measures may be:

This principle comment is also valid for Articles 4.1.2.9. and 4.1.2.11

Furthermore, the Community questions the justification for the different approach taken in this Appendix and the corresponding Article in Appendixes VIII and X. The Community invites the OIE AAC to harmonise the lay-out of the different Chapters of the Code.

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

When importing for *aquaculture activities aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country*, should require that:

1) the consignment be delivered directly into and held in approved secure rearing facilities;

2) the imported *aquatic animals* and their first generation progeny be continuously isolated from the local environment; and

3) all effluent and waste material be treated in a manner that ensures inactivation of WSSV.

If the intention of the introduction is the establishment of new genetic lines, international standards, such as the the Guidelines of the International Council for the Exploration of the Seas (ICES) should be followed.

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

1. identify stock of interest (cultured or wild) in its current location;
2. evaluate stock's health/disease history;
3. take and test samples for WSD, pests and general health/disease status;
4. import and *quarantine* in a secure facility a founder (F-0) population;
5. produce F-1 generation from the F-0 stock in *quarantine*;
6. culture F-1 stock and at critical times in its development (life cycle) sample and test for WSD and perform general examinations for pests and general health/disease status;
7. if WSD is not detected, pests are not present, and the general health/disease status of the stock is considered to meet *basic biosecurity conditions* of the importing *compartment*, *zone*, or country the F-1 stock maybe defined as WSD free or specific pathogen free (SPF) for WSSV;

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

Article 4.1.2.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from WSD

When importing for processing and/or human consumption *aquatic animals* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure holding facilities for a short period before processing and/or consumption, and

2) all effluent and waste material be treated in a manner that ensures inactivation of WSSV.

Article 4.1.2.10.

Importation of products from a country, zone or compartment free from WSD

When importing *aquatic animal products* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* free from WSD, 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*, certifying that, on the basis of the procedures described in Articles 4.1.2.4. or 4.1.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WSD.

The certificate shall be in accordance with Model Certificate No. [X] in Part 6 of this *Aquatic Code*.

Article 4.1.2.11

Importation of products from a country, zone or compartment not declared free from WSD

When importing *aquatic animal products* of the species listed in Article 4.1.2.2., other than those *commodities* listed in point 1) of Article 4.1.2.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure storage facilities, and be processed only in approved processing plants, and

2) all effluent and waste material be treated in a manner that ensures inactivation of WSSV.

Appendix X

REVISED CHAPTER PROPOSED BY
THE BUREAU OF THE AQUATIC ANIMALS COMMISSION

CHAPTER X.X.X.

INFECTION WITH MARTEILIA REFRINGENS

Community comment

The Community supports this proposal provided the comments below taken on board.

Article X.X.X.1.

For the purposes of this *Aquatic Code*, infection with *Marteilia refringens* means infection only with *Marteilia refringens*.

Methods for surveillance, diagnosis and confirmatory identification are provided in the *Aquatic Manual*.

Article X.X.X.2.

Community comment

The Community would ask for the justification for claiming *Mytilus edulis* and *M galloprovencialis* as susceptible species to *Marteilia refringens*, as this is an amendment compared to the 2004 Code, without any supporting evidence.

The Community would also ask the OIE to consider a formal procedure for "fast track" inclusion of new susceptible species.

Justification: Article X.X.X.2 define the susceptible species, and all other articles in the chapter related to free country, zone or compartment and importation of aquatic animals and aquatic animal products refer to article X.X.X.2. If there is new scientific evidence of infection with the disease in other species, the free countries, zones or compartments have no possibility to introduce sanitary measures against the disease before the aquatic code can be changed at the next general session (unless they performs import risk analysis, which usually is very time consuming). On the other hand countries free from the disease based on the absence of susceptible species, can loose the free status if the list of susceptible species is changed. These countries therefore need some sort of validation/evaluation of new scientific evidence of infection with the disease in other species than those listed.

Susceptible species

For the purpose of this *Aquatic Code*, *susceptible species* for infection with *Marteilia refringens* are: *Ostrea* species, in particular the European Flat Oyster (*Ostrea edulis*), Australian Mud Oyster (*Ostrea angasi*),

Argentinean Oyster (*Ostrea puelchana*) and Chilean Flat Oyster (*Ostrea chilensis*), Blue Mussel, *Mytilus edulis* and Mediterranean Mussel (*M. galloprovincialis*).

Infection with *Marteilia refringens* can also cause *subclinical* infection in these species.

Suspect cases, as defined in the *Aquatic Manual*, of infection with *Marteilia refringens* should be referred immediately to the appropriate OIE Reference Laboratory, whether or not clinical signs are associated with the findings.

Article X.X.X.3.

Commodities

1) When authorising import or transit of the following *commodities*, *Competent Authorities* should not require any *Marteilia refringens* related conditions, regardless of the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*:

   a) gametes, eggs and larvae of molluscs;

   b) processed non-viable molluscs (cooked, canned, smoked);

   c) fresh non-viable half-shell oysters.

2) When authorising import or transit of the following *commodities* of a species listed in Article X.X.X.2., *Competent Authorities* should require the conditions prescribed in Articles X.X.X.7. to X.X.X.11. of this Chapter, relevant to the *Marteilia refringens* status of the *exporting country*, zone or *compartment:*

   a) *aquatic animals*;

   b) aquatic animal products.

3) When considering the import or transit of a *commodity* not listed above from an *exporting country*, *zone* or *compartment* not declared free of *Marteilia refringens*, *Competent Authorities* of the *importing country* should conduct an analysis of the risk of introduction, establishment and spread of *Marteilia refringens*, and the potential consequences, associated with importation of the *commodity*, prior to a decision. The outcome of this assessment should be made available to the *exporting country*.

Article X.X.X.4.

Community comment

If new susceptible species a formal "fast track" procedure is needed

1) Comments to Article x.x.x.4:

The present text is unclear and needs to be re-written for the sake of clarity. The Community questions the justification for requirement of 3 years of basic biosecurity conditions in x.x.x.4 point 2 (and x.x.x.5 point 2). The Community suggests that countries, zones or compartment should be able to get the free status sooner if they have a surveillance program.

Furthermore, the Community do not agree with the proposed text, as it would be impossible for a Member Country sharing coastal waters with another Country not declared free, to declare freedom.

Until the OIE has finalised the development of the concept of compartmentalisation, the Community requests that the Member Countries may apply the principle of establishing a buffer zone towards non-

declared free Countries.

Finally, there must be a typing error in x.x.x.4 point 3) where 3 years should be 2. There are no supporting evidence that the surveillance period for molluscs must be 3 year compared with the 2 years for fish and crustacean diseases.

Consequently Community propose that Article x.x.x.4 should read

Marteilia refringens disease free country, zone or compartment

A country may declare itself free from Marteilia refringens if it meets the conditions in point 1), 2) or 3) below. A zone or compartment within the territory of one or more countries not declared free from Marteilia refringens 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 point 1), 2) or 3) below

1) A country, zone or compartment where none of the species listed in Article x.x.x.2. is present may declare itself free from Marteilia refringens when basic biosecurity conditions have been in place continuously in the country for at least the past 2 years.

OR

2) A country, zone or compartment where the species listed in Article x.x.x.2. and conditions that are conducive to clinical expression of the disease (described in Chapter X.X.X. of the Aquatic Manual) are present, but there has not been any observed occurrence of the disease for at least the past 25 years may declare itself free from EHN when basic biosecurity conditions have been in place continuously in the country for at least the past 10 years.

OR

3) A country, zone or compartment where there has not been any observed occurrence of the disease for at least the past 2 years may declare itself free from Marteilia refringens when:

a) basic biosecurity conditions have been in place continuously in the country 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 past 2 years.

If a country shares a water resource with one or more other countries, or if a zone or compartment extends over more than one country, it can only declare itself an Marteilia refringens free country if :
a) all the areas covered by the shared water resource, zone or compartment are declared EHN free; or
b) the Member Country establishes the necessary buffer zones in its territory as appropriate. The delimitations of the buffer zones must be such that it protects the disease free Member Country from passive introduction of the disease

2) Comments which come as a consequence of comment 1):

a) here is also a need to define "Buffer zone" (See Community comment to Appendix XI)

b) this proposal makes Article x.x.x.5 superfluous.

Marteilia refringens free country

A country may declare itself free from *Marteilia refringens* if it meets the conditions in point 1) or 2) or 3) below.

If a country shares a water resource with one or more other countries, it can only declare itself a *Marteilia refringens* free country if all the areas covered by the shared water resource are declared *Marteilia refringens* free zones (see Article X.X.X.5.).

1) A country where none of the species listed in Article X.X.X.2. is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the country for at least the past 3 years and infection is not known to be established in wild populations.

OR

2) A country where the species listed in Article X.X.X.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 X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the country for at least the past 3 years and infection 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, for example because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when:

   a) it meets *basic biosecurity conditions* for at least the past 3 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 past 3 years.

Article X.X.X.5.

***Marteilia refringens* free zone or free compartment**

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

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Marteilia refringens* 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 *Marteilia refringens*, a *zone* or *compartment* where none of the species listed in Article X.X.X.2. is present may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 3 years and infection is not known to be established in wild populations.

OR

2) In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where the species listed in Article X.X.X.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 X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when *basic biosecurity conditions* have been in place continuously in the *zone* or *compartment* for at least the past 3 years and infection 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, for example because of the absence of conditions conducive to clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may declare itself free from *Marteilia refringens* when:

   a) it meets *basic biosecurity conditions* for at least the past 3 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 past 3 years.

Article X.X.X.6.

Maintenance of free status

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

A country or *zone* or *compartment* that is declared free from *Marteilia refringens* following the provisions of point 3) of Articles X.X.X.4. or X.X.X.5., respectively, may discontinue *targeted surveillance* and maintain its status as *Marteilia refringens* free provided that conditions that are conducive to clinical expression of infection with *Marteilia refringens*, 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 *compartment* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Marteilia refringens*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of reinfection.

Community comment

The Community believes it is important that when the different disease chapters, has articles on how to achieve disease free status, and to maintain disease free status, there should also be an articles on how to restore the status if the status may have been lost.

The Community propose that the text referred to in Article 1.2.1.4, point 2 and 3 (see Appendix XIV of this report) are introduced in the disease chapters. The Community also propose that it should be possible to regain disease free status faster than getting the disease free status if full prophylactic and appropriate sanitary measures have been applied to prevent possible reappearance or spread of the disease.

Article X.X.X.7.

Importation of live animals from a country, zone or compartment declared free from *Marteilia refringens*

When importing live *aquatic animals* of the species listed in Article X.X.X.2., other than *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* free from *Marteilia refringens*, 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 X.X.X.4. or X.X.X.5. (as applicable), whether the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. [X] given in Part 6 of this *Aquatic Code*.

Article X.X.X.8.

Community comment

The Community believes that the existing wording could make the Article inconsistent with x.x.x.3 (3). The proposed measures *may* be an acceptable way of handling the risk identified under x.x.x.3 (3).

The Community therefore propose that the first paragraph should read

When importing for *aquaculture activities aquatic animals* of the species listed in Article x.x.x.2., other than those *commodities* listed in point 1) of Article x.x.x.3., from a country, *zone* or *compartment* not declared free, the *Competent Authority* of the *importing country* assess the risk and apply the necessary risk mitigation measures. Such measures may be:

This principle comment is also valid for Articles x.x.x.9. and x.x..11

Importation of live animals for aquaculture activities from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animals* of the species listed in Article X.X.X.2. for *aquaculture activities*, other than those *commodities* listed in point 1) of Article X.X.X.3., from a country, zone or compartment not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly into and held in approved secure rearing facilities;

2) the imported *aquatic animals* and their first generation progeny be continuously isolated from the local environment; and

3) all effluent and waste material be treated in a manner that ensures inactivation of *Marteilia refringens*.

Article X.X.X.9.

Importation of live animals for processing and/or human consumption from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animals* of the species listed in Article X.X.X.2. for processing and/or human consumption, other than those live *commodities* listed in point 1) of Article X.X.X.3., from a country, zone or compartment not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure holding facilities for a short period before processing and/or consumption, and

2) all effluent and waste material be treated in a manner that ensures inactivation of *Marteilia refringens*.

Article X.X.X.10.

Importation of products from a country, zone or compartment free from *Marteilia refringens*

When importing *aquatic animal products* of the *species* listed in Article X.X.X.2., other than *commodities* listed in point 1) of Article X.X.X.3., from a country, *zone* or *compartment* free from *Marteilia refringens*, 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 X.X.X.4. or X.X.X.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The certificate shall be in accordance with Model Certificate No. [X] given in Part 6 of this *Aquatic Code*.

Article X.X.X.11.

Importation of products from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animal products* of the species listed in Article X.X.X.2., other than those *commodities* listed in point 1) of Article X.X.X.3., from a country, zone or compartment not declared free, the *Competent Authority* of the *importing country* should require that:

1) the consignment be delivered directly to and held in approved secure storage facilities, and be processed only in approved processing plants, and

2) all effluent and waste material be treated in a manner that ensures inactivation of *Marteilia refringens*.

Appendix XI

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1

Community comment

1. The Community invites the OIE to harmonise its definition of Aquaculture with the most current definition as laid down by the FAO. Slightly modified to meet the purpose of the OIE Aquatic Code it would read:

"Aquaculture means the keeping, rearing or cultivation of aquatic animals using techniques designed to increase the production of the animals in question beyond the natural capacity of the environment; the animals remain the property of a natural or legal person throughout the rearing or culture stage, up to and including harvesting"

2. The Community do not agree with the proposed amendment of the definition of zone, as it includes requirements for surveillance, control and biosecurity which are only applicable to disease free zones, and not to zones in general. The Community therefore propose to have the proposed addition in the definitions of Free country, in Free zone and in Free compartment.

3. The Community propose to include a definition of "Buffer zone" to read:
"Buffer zone, means a zone established in relation to a free country, zone or compartment, in which surveillance must be maintained without achieving status as free. The delimitations of the buffer zones must be such that it protects the disease free country, zone or compartment from passive introduction of the disease"

4. The definition of "self declaration of freedom of disease" in the 2004 Code must be rewritten to be consistent with Article 1.2.1.4 paragraph 4 of Appendix XIV.

Finally the Community would like to point out that there are some inconsistencies in the definition on zone used in Appendix VI (Appendix G) and Appendix XI.

5. The Community will reiterate its previous comments with respect the definitions of aquatic animals and aquaculture animals. With the existing definitions, a wild fish is not an aquatic animal since it is not connected with aquaculture activities. Therefore it is necessary to have both a definition for aquatic animals and a definition of aquaculture animals. This is the only way that wild aquatic animals may be sufficiently covered by the Code.

The Community therefore propose the following definitions;

"Aquaculture animal means all life stages (including eggs and sperm/gametes) of any aquatic animal coming from a farm, including those from the wild intended for a farm"

Aquatic animal means fish (classes Agnatha, Chondrichytes and Osteichtyes), molluscs (entire group Mollusca) and crustaceans (entire class Crustacea)

Aquaculture ~~***Aquacultural***~~ ***activities***
any activity concerning farming, *marketing*, ~~*processing*~~, etc, of *aquatic animals*.

Compartment
one or more *aquaculture establishments* under a common biosecurity management system containing an aquatic animal population with a distinct health status with respect to a specific *disease* or *diseases* for

which required surveillance, control and biosecurity measures are applied for the purpose of international trade. Such compartments must be clearly documented by the *Competent Authority(ies).*

Diseases listed by the OIE

diseases that ~~fulfil the criteria outlined~~ are listed in Chapter 1.1.~~2~~3. of this *Aquatic Code.*

Notification

the procedure by which:

a) the *Veterinary Administration* informs the *Central Bureau*,

b) the *Central Bureau* informs the *Veterinary Administrations* of Member Countries

of the ~~suspicion or~~ confirmation of a *disease outbreak*, according to the provisions of Section 1.2. of this *Aquatic Code.*

Water catchment

an area or basin of land bounded by natural features such as hills or mountains, from which all run-off water flows.

Zone

a portion of one or more countries comprising an entire catchment area from the source of a waterway to the estuary, more than one catchment area, part of a catchment area from the source of a waterway to a barrier, or a part of the coastal area, or an estuary with a precise geographical delimitation, that consists of a homogeneous hydrological system with a distinct health status with respect to a specific *disease* or *diseases* for which required surveillance, control and biosecurity measures are applied for the purpose of *international trade*. Such zones must be clearly delineated ~~on a map of the territory of the country concerned~~ by the *Competent Authority(ies).*

— text deleted

Appendix XII

APPENDIX 5.2.1.

GENERAL RECOMMENDATIONS ON DISINFECTION

Community comment

The Community agrees with the proposed amendments.

Article 5.2.1.1.

~~Specific *disinfection* methods are provided in Chapter 1.1.5 of the *Aquatic Manual*.~~

~~Article 5.2.1.2.~~

Disinfection is employed as a common disease management tool in aquaculture. ~~It may be used for disease prevention, control or eradication and to prevent the spread of infectious agents into and from an *aquaculture establishment*.~~ *Disinfection* procedures should be part of a *disinfection* programme designed for a specific purpose. *Disinfection* may ~~consequently~~ be used ~~as a routine practice~~ in biosecurity programmes ~~designed~~ to eradicate or exclude specific diseases from *aquaculture establishments*, as well as a routine sanitary measure ~~employed~~ to reduce disease incidence within *aquaculture establishments*.
Disinfection of installations and equipment (including *vehicles* and boats) should be carried out ~~in areas where and~~ according to procedures ~~and methods~~ such that the ~~risk of contaminating~~ contamination of other water and other aquatic animal populations with infectious material is avoided. ~~For example, organic material generated/removed during the cleaning process, such as pond sludge, etc., should be disposed of in an appropriate manner that prevents spread of disease by such material and is environmentally safe.~~
There is a great variety of products and ~~processes~~ procedures for washing and disinfecting installations or equipment, ~~including vehicles and boats~~, ~~that can be~~ used in *aquaculture establishments*. The decision on which product to use should take into account ~~correct choice of such products will depend on~~ their efficacy, their safety for ~~potential effect on~~ *aquatic animals* and the environmental ~~impact~~, and costs ~~induced by their use~~. ~~*Disinfection* procedures should be part of a *disinfection* programme that establishes the best and appropriate available methods to prevent the entry or decrease the load of targeted pathogens in an *aquaculture establishment*.~~
~~Following *disinfection* or *stamping out*, the *aquaculture establishment* should be restocked from a disease-free source.~~

Article 5.2.1.~~2~~3.

~~Disinfectants are chemical substances acting on micro-organisms and their vital cellular processes, either by controlling their multiplication or by killing the agent. There are two main groups:~~

~~1) Oxidative *disinfectants* (chlorides, iodides, iodophores) of high germicide power and action scope. These have a corrosive and irritant effect on surfaces and mucosa. The iodine present in iodophores is associated with other elements that improve their action by giving them the humectant properties of detergents.~~

~~2) *Disinfectants* of with selective actions (quaternary ammonia, phenols, formaldehyde and alcohol) that act on the cell membrane of the micro-organisms. Their germicide action depends on the dose. The higher the resistance of the micro-organisms to be controlled, the higher the *disinfectant* concentrations required.~~

The efficacy of *disinfection* is affected by various factors, including temperature, pH, and the presence of organic matter, and the manufacturer's instructions for effective use should be followed. ~~Temperature is a~~

~~determinant factor in the action of disinfectants~~. At high temperatures, the disinfecting action is faster as long as the decomposition limit of the product is not reached. Similarly, pH also affects the action of *disinfectants*. For example, quaternary ammonia is more efficient at alkaline pH while iodine and iodophores are more efficient at neutral or acid pH.

Special attention ~~ought to~~ should be paid to organic ~~matters~~ material and greasy substances that can significantly reduce the efficacy of the *disinfectant*. Therefore, surfaces should be ~~It is recommended to~~ cleaned thoroughly ~~the surfaces to be disinfected~~ before applying *disinfectants*~~, as their actions can drastically decrease due to the presence of these elements~~.

The safe use of *disinfectants* may require ~~entails the implementation of~~ measures to protect personnel, ~~and cultured~~ *aquatic animals* and ~~to mitigate~~ the environment,~~al effects~~ and the manufacturer's instructions for safe use should be followed~~. It is first necessary to protect the skin and eyes from contact with dangerous substances by using impermeable clothing, rubber boots, glasses and a hat. The respiratory tract must be protected by wearing a mask and the operator must not touch any food or smoke without having thoroughly washed his/her hands. Finally, the *disinfectants* must be stored in a way that presents no direct or indirect danger to animal or human life and the environment.~~

Approved procedures for the use of *disinfectants* in aquaculture should be established. ~~An approval scheme should consider the *disinfection* effectiveness against target pathogens, toxicological and ecotoxicological properties of the *disinfectants*.~~

~~Article 5.2.1.4. (move to the Manual)~~

~~The choice of *disinfection* procedures depends on the size, type and nature of the materials and facilities to be disinfected. The range of surfaces to be disinfected consists of fabric or woven material (clothes, nets), hard surfaces (plastic, cement) or permeable materials (earth, gravel). *Disinfection* is more difficult on permeable surfaces and requires more time.~~

~~*Disinfection* procedures must be established and used according to the objectives of *disinfection* and identified risks. Diseased *aquatic animals*, mortality fluids and tissues (viscera, blood, mucus, faeces, and effluent waters) and their association to equipment and workers are risk factors in the transmission of pathogens that could eventually infect healthy aquatic animal populations.~~

~~Basic *disinfection* protocols include the removal of all *aquatic animals*, dead and alive from the facility, a cleaning programme that is designed to eliminate all the remaining organic matter adhering to the surfaces, the use of *disinfectants* on equipment and installations and a final neutralisation step of chemical products.~~

~~When removing animals from the facilities prior to *disinfection*, the direct disposal of diseased populations of *aquatic animals* of any life stage or age into receiving waters is a dangerous practice that facilitates the spread of *disease* from farmed to wild populations or to neighbouring farms that use the same water supply. Such disposal should not be permitted. When the decision is made to discard a population due to the presence of *disease*, the stock in the tank or pond should be harvested and/or humanely killed in the tank or pond. The water in the tank or pond should be disinfected (see specific sections in Chapter 1.1.5 of the *Aquatic Manual*) prior to discharge. The emptied tank or pond should be disinfected prior to restocking.~~

Article 5.2.1.3

Specific *disinfection* procedures are provided in Chapter 1.1.5. of the *Aquatic Manual.*

~~text deleted~~ — text deleted

Appendix XIII

COMPARTMENTALISATION

Community comment
The Community supports the general approach. However, it might still need some further considerations.

The concept of a compartment is based on the application of strict biosecurity management procedures and relies on cooperation between the industry and the national Competent Authority. Its aim is to show the existence of a distinct animal health status based on common management of biosecurity issues. To be credible, this system needs an appropriate surveillance programme supported by a strong veterinary infrastructure.

1. Compartments and zones for aquatic animals

a) Examples of the concept of 'compartment'

i) A group or cluster of coastal farms that can be considered as one epidemiological unit due to their geographical localisation and distance from other groups or clusters of farms, and because they are under a common biosecurity management system; or

ii) one individual continental farm which can be considered as one epidemiological unit, as it is not influenced by the animal health status in the water catchment area to which its effluents drains; or

iii) more than one farm if each farm in the compartment complies with the criteria as described under point a)ii), but due to extensive movement of animals among farms must be considered as one epidemiological unit, and where all farms are under a common biosecurity management system.

b) Examples of the concept of 'zone'

i) An entire water catchment area from its source to its estuary, a part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area, or without common biosecurity management systems.

ii) More than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary.

c) Practical application of compartments

i) A group or cluster of coastal farms that can be considered as one epidemiological unit due to their geographical localisation and distance from other groups or clusters of farms, and because they are under a common biosecurity management system, typical examples here are:

- Mollusc farming in a bay, where there may be numerous farms (under more than one ownership). There might be (extensive) movement of animals inside the compartment/between the farms. However, the farmers have a joint management practice regarding biosecurity, so from a management point of view they can be seen as a unit. There are no hydrological barriers between the farms. There are hydrological barriers between this compartment and nearby compartments (situated in another bay area, another fjord, etc).

- Fish farms in a bay/basin/fjord. There are no hydrological barriers between the farms. However, the farmers have a joint management practice regarding biosecurity, so from a management point of view they can be seen as a unit. There are hydrological barriers between these farms and nearby compartments (situated in another bay area/basin, another jord, etc).

ii) One individual continental farm which can be considered as one epidemiological unit, as it is not influenced by the animal health status in the water catchment area to which its effluents drains.

- The typical example here is where one single continental farm is supplied with water directly from a well, a borehole or a spring. Where such water supply is situated outside the premises of the farm, the water should be supplied directly to the farm, and be channelled through a pipe. There should be natural or artificial barriers that prevent aquatic animals or their pathogens from entering the farm from the surrounding watercourses. The farm should, where appropriate, be protected against flooding and infiltration of water from the surrounding watercourses.

- This example corresponds to the "free aquaculture establishment" in the *Aquatic Code*.

iii) More than one farm if each farm in the compartment complies with the criteria as described under point a)ii) but due to extensive movement of animals between farms must be considered as one epidemiological unit, and where all farms are under a common management system regarding biosecurity.

- The typical example here is where one (or more) companie(s) have more than one farm and are independent throughout the production cycle. A compartment for salmonid production may for example consist of a hatchery which delivers fertilised eggs to one or more "smolt" farms which again delivers fish to several ongrowing farms. Each of the different units complies with the requirements under a)ii). No live animals or their pathogens enter into the compartment from farms which are not a part of the compartment. All farms are under a common management system regarding biosecurity.

d) Practical application of zones

i) An entire water catchment area from its source to its estuary, a part of a water catchment area from the source(s) to a natural or artificial barrier that prevents the upward migration of aquatic animals from lower stretches of the water catchment area, while the farms located inside the zone are NOT under a common management system regarding biosecurity.

- The typical example here is a river system, where there are numerous farms using the water from the river as their water source. The farms are NOT under a common management system regarding biosecurity. A challenge here might be the possibility of wild fish migrating into the zone from coastal/estuarial areas outside the zone, which may have a different disease status than the farms inside the zone.

- This example corresponds to the "free zone" in the *Aquatic Code*.

ii) More than one water catchment area, including their estuaries, due to the epidemiological link between the catchment areas through the estuary, while the farms located inside the zone are NOT under a common management system regarding biosecurity.

- The typical example is where more than one river drains into an estuary. One of the rivers is infected with *Gyrodactylus salaris*. Wild fish from one river can migrate through the estuary and up a previously *G. salaris* free river, provided the salinity in the estuary is below 25 ppt. Consequently, the zone in such case comprises all rivers draining into an estuary, including the estuary. The delimitations of the zone is sea water at a salinity of 25 ppt or higher (which is considered to kill the parasite within minutes).

2. Compartmentalisation for terrestrial animals

Compartmentalisation could be an appropriate approach for a commercial poultry industry when dealing with avian influenza. In most countries or zones, one can recognize at least three types of poultry sub-populations: the commercial poultry industry, the traditional back yard poultry and wild birds (including migratory waterfowl). In most countries, differentiating domestic poultry from migratory birds is nearly impossible using the concept of zoning/regionalization. While the separation of back yard birds and wild birds from individual commercial poultry operations can be achieved, it would be very difficult to demonstrate a different health status over widely separated parts of vertically integrated conventional poultry enterprises using these concepts. Therefore, compartmentalisation of the industrial poultry sector, based on strict and auditable biosecurity management protocols operated by individual enterprises, may be able to provide for safe trade in poultry and poultry products from this compartment even if other sectors cannot be declared free of avian influenza.

Compartmentalisation can also be applied to the differentiation of industrial swine production from traditional free-range pigs and wild pig populations, for example in cases where there is a risk from classical swine fever from feral and/or wild pigs. Industrial swine production in most countries is vertically integrated, including all steps in the chain, from feed production, breeding, fattening and slaughter to primary processing. Appropriate steps may be taken to isolate this industry from various disease threats. A systematic approach to managing the biosecurity at all steps of the production chain, with an identification of the critical control points and the accompanying auditing procedures may be able to provide for safe trade of pigs and pig products through compartmentalisation, even if the other pig sub-populations are affected by classical swine fever.

Appendix XIV

CHAPTER 1.2.1.

NOTIFICATIONS AND EPIDEMIOLOGICAL INFORMATION

Community comment

The Community supports this proposal provided the comments below are taken on board.

Article 1.2.1.1.

For the purposes of this *Aquatic Code* and in terms of Articles 5, 9 and 10 of the Statutes, every Member Country of the OIE shall recognise the right of the *Central Bureau* to communicate directly with the *Veterinary Administration* of its *territory* or *territories*.

All *notifications* and all information sent by the OIE to the *Veterinary Administration* shall be regarded as having been sent to the country concerned and all *notifications* and all information sent to the OIE by the *Veterinary Administration* shall be regarded as having been sent by the country concerned.

Article 1.2.1.2.

1. Countries shall make available to other countries, through the OIE, whatever information is necessary to minimise the spread of important aquatic animal *diseases* and their aetiological agents and to assist in achieving better world-wide control of these *diseases*.

2. To achieve this, countries shall comply with the reporting requirements specified in Article 1.2.1.3.

3. To assist in the clear and concise exchange of information, reports shall conform as closely as possible to the current OIE disease reporting format.

4. Recognising that scientific knowledge concerning the relationship between *disease agents* and *diseases* is constantly evolving and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, countries shall ensure through their reports that they comply with the spirit and intention of paragraph 1 above. This means that the presence of an infectious agent, even in the absence of clinical *disease*, should be reported.

5. In addition to *notifying* ~~new~~ findings in accordance with Article 1.2.1.3., countries shall also provide information on the measures taken to prevent the spread of *diseases*, including possible quarantine measures and restrictions on the movement of *aquatic animals*, *aquatic animal products*, *biological products* and other miscellaneous objects that could by their nature be responsible for transmission of *disease*. In the case of *diseases* transmitted by vectors, the measures taken against such vectors shall also be reported.

Article 1.2.1.3.

Veterinary Administrations shall send to the OIE:

1. *Notification* by fax, telegram or electronically ~~mail~~, within 24 hours, of any of the following events:

a) for *diseases listed by the OIE*, the first occurrence or re-occurrence of a *disease* in a country or *zone/compartment* of the country, if the country or *zone/compartment* of the country was previously considered to be free of that particular *disease*; or

b) for *diseases listed by the OIE*, if the *disease* has occurred in a new host species; or

c) for *diseases listed by the OIE*, if the *disease* has occurred with a new pathogen strain or in a new *disease* manifestation; or

d) for *diseases listed by* the OIE, if there is potential for international spread of the *disease*; or

e) for *diseases listed by the OIE*, if the *disease* has newly recognised zoonotic potential; or

f) for diseases not listed by the OIE, if there is a case of an *emerging disease* or pathogenic agent should there be findings that are of epidemiological significance to other countries.

In deciding whether findings justify immediate *notification*, countries must ensure that they comply with the obligations of Section 1.3. of this *Aquatic Code* (especially Article 1.3.1.1.), to report developments that may have implications for *international trade.*

2. ~~Monthly~~ Weekly reports by fax, telegram or electronically ~~mail~~ subsequent to a *notification* under paragraph 1 above, to provide further information on the evolution of an incident that justified ~~urgent~~ immediate *notification*. These reports should continue until the *disease* has been eradicated or the situation has become sufficiently stable that ~~annual~~ six-monthly reporting under paragraph 3 will satisfy the obligation of the country to the OIE; in each case, a final report on the incident should be submitted.

3. ~~Annual~~ Six-monthly reports on the absence or presence and evolution of *diseases listed by the OIE*, and findings of epidemiological ~~importance~~ significance to other countries with respect to *diseases* that are not listed.

4. An annual questionnaire concerning any other information of significance to other countries.

Article 1.2.1.4.

Community comment

The Community proposes that the OIE AAC consider including the notification of finding/occurrence of listed diseases in wild stocks in the yearly OIE questionnaire for wildlife diseases, and applying the notification criteria under this Code the presence in aquaculture animals.

The Community also propose that point 2 and 3 are moved into the specific disease chapters as they have nothing to do with notification, but rather to the regaining of the disease free status.

Furthermore, the notification under point 1 is only relevant if the country wish to regain freedom. In such case, the notification under point 4 would be applicable again. Consequently paragraph 4 covers all situations and this Article may therefore be simplified to read:

1. The *Veterinary Administration* or other *Competent Authority* of a country that sets up one or several *free zones/compartments* shall inform the OIE, giving necessary particulars and indicating clearly the location of the *zones/compartments* on a map of the country.

1. The *Veterinary Administration* or other *Competent Authority* of a *territory* in which an *infected zone/compartment* was located shall inform the *Central Bureau* when this *zone/compartment* is free from the *disease*.

2. An *infected zone/compartment* of a determined *disease* shall be considered as such until a period exceeding the known *infective period* for the *disease* in question has elapsed after the last reported *outbreak* and when full prophylactic and appropriate sanitary measures have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in the various chapters of Parts 2, 3 or 4 of this *Aquatic Code*.

3. A country may be considered to be again free from a specific *disease* when all the conditions given in the corresponding chapters of Parts 2, 3 or 4 of this *Aquatic Code* have been fulfilled.

4. The *Veterinary Administration* or other *Competent Authority* of a country that sets up one or several *free zones/compartments* shall inform the OIE, giving necessary particulars and indicating clearly the location of the *zones/compartments* on a map of the country.

~~Article 1.2.1.5.~~

~~*Veterinary Administrations* shall communicate to the OIE the provisions of their importation and exportation aquatic animal health regulations.~~

~~They shall also communicate any amendments to their regulations as soon as they are made and, at the latest, before the annual General Session of the OIE International Committee.~~

Article 1.2.1.5~~6~~.

1. The *Central Bureau* shall send by fax, telegram or electronically ~~mail~~ to the *Veterinary Administration* concerned, all *notifications* received as provided in Articles 1.2.1.2–1.2.1.4.

2. The *Central Bureau* shall notify Member Countries through *Disease Information* of any event of exceptional epidemiological significance reported by a Member Country.

~~3. The *Central Bureau*, on the basis of information received and of any official communication, shall prepare an annual report concerning the application of this *Aquatic Code* and its effects on *international trade*.~~

— text deleted

Appendix XV

23rd Conference

of the

OIE Regional Commission for Asia, the Far East and Oceania

Noumea (New Caledonia), 25-28 November 2003

Recommendation No. 2

Update on developments in aquatic animal diseases

CONSIDERING THAT

Aquaculture has been growing rapidly in many countries in the region and is predicted to continue to grow in all Member Countries,

There has not been a matching expansion of a supporting aquatic animal health infrastructure, and the aquatic animal sector in the region is currently not as well provided with diagnostic and professional health services as the livestock sector. Member Countries see an increasing role for health professionals (veterinarians and others) in their country,

In some Member Countries, fisheries authorities have either the sole responsibility for aquatic animal health or share it with the Veterinary Services. In these countries, fisheries authorities would take the lead in mounting an emergency response to an aquatic animal disease outbreak, and the Veterinary Services are usually well experienced in managing terrestrial animal emergency disease outbreaks, but there is infrequent contact between the two,

In many Member Countries, draft texts for the *Aquatic Code* and the *Aquatic Manual* reach aquatic animal health experts either too late or not at all, resulting in few official comments. This means that Member Countries do not sufficiently use the opportunity to influence the setting of international standards that underpin international trade,

Fundamental changes to the *Aquatic Code* and *Aquatic Manual* have been adopted in 2003. These include the listing of aquatic animal diseases and the requirements for reporting on the status of listed diseases. It is important that Member Countries fully understand these new arrangements and accept and fulfil their obligations on disease reporting,

Most Member Countries provide annual and quarterly aquatic animal disease reports, but there are numerous reporting errors such as the use of inappropriate symbols; the provision of conflicting information to the OIE's Tokyo Office and to the Central Bureau; and not reporting new disease occurrences that would be of major epidemiological significance to other countries in the region,

The OIE continues to engage in regional aquatic animal health initiatives, together with the FAO and NACA, but enhanced involvement of both veterinary and fisheries authorities within Member Countries is required to achieve the desired outcomes in areas such as improving Member Countries' knowledge of OIE standard-setting activities in the field of aquatic animal health and the transparency of epidemiological reporting,

THE REGIONAL COMMISSION FOR ASIA, THE FAR EAST AND OCEANIA

RECOMMENDS

A) THAT THE OIE:

1. Reinforce to Delegates their responsibility to the OIE for terrestrial as well as aquatic animals.

2. Encourage Member Countries to strengthen veterinary and other tertiary education in aquatic animal health.

3. Request Member Countries to clarify the roles and responsibilities for aquatic animal health assigned to veterinary and other authorities in their country.

4. Provide opportunities to assist cooperation between veterinary and other authorities responsible for aquatic animal health in Member Countries, for example, by inviting other authorities to attend OIE-sponsored conferences/workshops that have an aquatic theme.

5. Direct efforts at increasing general awareness with national Delegates world-wide about, for example, the provisions of the *Aquatic Code* and *Aquatic Manual*.

6. Request the Aquatic Animal Commission to provide regular updates of the *Aquatic Code* and *Aquatic Manual* at Regional Commission Conferences or other suitable venues.

7. Direct efforts at obtaining more comments on draft texts for the *Aquatic Code* and *Aquatic Manual* from a larger number of national Delegates, for example, consider from the Delegates of Member Countries the nomination of an 'aquatic national focal point' as a parallel recipient of Aquatic Animal Commission reports on behalf of national Delegates.

8. Provide Member Countries with the necessary assistance and guidance on accurate, timely and effective aquatic animal disease reporting.

9. Continue to cooperate with relevant international and regional organisations to increase awareness about aquatic animal health in the region, to improve disease reporting and to foster cooperation between veterinary and fisheries authorities within countries.

B) THAT THE MEMBER COUNTRIES:

1. Direct efforts at improving the coverage of the aquatic sectors with health services and strengthen veterinary and other tertiary education in aquatic animal health.

2. Clarify the roles and responsibilities for aquatic animal health assigned to veterinary and other authorities in their country.

3. Request their Veterinary Services to improve the communication and cooperation with fishery authorities, especially regarding disease reporting and disease emergency responses.

4. Where primary responsibility for aquatic animal health rests with an authority other than the Veterinary Services, nominate an 'aquatic national focal point' from the other authority, so that the OIE may circulate Aquatic Animal Commission reports to the 'aquatic national focal point' at the same time as when circulating to national Delegates (providing comments back to the OIE must take place through, and with the endorsement of, the national Delegate to the OIE).

5. Significantly enhance circulation of draft texts for the *Aquatic Code* and *Aquatic Manual* amongst experts, and provide comments through the national Delegate to the OIE.

6. Significantly improve the quality of aquatic animal disease reports, and request the OIE's assistance where clarification is needed.

Appendix XVI

WORK PLAN OF THE AQUATIC ANIMALS COMMISSION FOR 2005

Aquatic Animal Health Code

- Ongoing review of the list of diseases and listing criteria
- Revise all disease chapters in the *Aquatic Code*, with the assistance of *ad hoc* groups and other experts in line with requirements for surveillance for recognition of freedom from infection and identification of "safe commodities"
- Revise the current *Aquatic Code* Chapter on zoning to include compartmentalisation
- Revise definitions for "infection", "disease", and "diseases listed by the OIE"
- Revise Appendix on General Recommendations on Disinfection
- Revision of Chapter 1.2.1. on Notification and Epidemiological Information
- Harmonise horizontal chapters with those in the *Terrestrial Code*
- Develop guiding principles for the listing of closely related disease agents
- Incorporate principles of biosecurity into existing chapters
- Draft new *Aquatic Code* Chapter on Disposal of Aquatic Animal Waste
- Revision of model health certificates
- Harmonise *Aquatic Manual* Chapter 1.1.4. in line with corresponding work for the *Terrestrial Code*

Manual of Diagnostic Tests for Aquatic Animals

- Ask authors for preparation of updates of disease chapters for the fifth edition of the *Aquatic Manual*, using the new template
- Revise the specific *Aquatic Manual* Chapters on disinfection of fish and of mollusc *aquaculture establishments*

Meetings

- OIE Global Conference on Aquatic Animal Health
- Give presentations on the activities of the Aquatic Animals Commission at the Conference of OIE Regional Commissions
- Assist in the implementation of recommendations adopted by the OIE Regional Commission for Asia, the Far East and Oceania in 2003, and endorsed by the International Committee of the OIE in 2004

- Consider holding, if possible regarding budget, a Commission meeting back-to-back with the ISVEE XI symposium in Cairns (Australia) in August 2006

Other issues

- Evaluate Member Countries' comments on proposed changes to the *Aquatic Code* and *Aquatic Manual* and make appropriate changes in time for submission to the OIE International Committee for adoption
- Update the Aquatic Animals Commission's web pages
- Develop criteria for identification of appropriate OIE-sponsored publications in the field of aquatic animal health
- Consider new candidates for OIE Reference Laboratories for listed diseases
- Develop a new template for annual reports of Reference Laboratory activities
- Evaluate annual reports (2004) of OIE Reference Laboratories and Collaborating Centres for aquatic animal diseases
- Ask diagnostic chapter authors to update disease cards for listed diseases at the same time as they update the *Aquatic Manual* chapter
- Redesign and distribute to Member Countries the questionnaire on diseases of amphibians.

ANNEX IPN

Referenses to OIE/OIE ad hoc group below are made in relation to the meeting report of the Bureau of the OIE Aquatic Animal Health Standards Commission, Paris, 11-15 October 2004 (if not otherwise indicated)

OIE criteria for listing an aquatic animal disease

Diseases proposed for listing must meet all of the relevant parameters set for each of the criteria, namely A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a *disease* must have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8.

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
		A. Consequences	
9.		The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in *susceptible*[1] *species*, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.
10.	Or	The disease has been shown to or scientific evidence indicates that it is likely to negatively affect wild aquatic animal populations that are an asset worth protecting for economic or ecological reasons.	Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, the asset could be ecological or environmental in nature, for example, if the population consists of an endangered species of aquatic animal or an aquatic animal potentially endangered by the disease.
11.	Or	The agent is of public health concern.	
		And	
		B. Spread	
12.		Infectious aetiology of the disease is proven.	
13.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
14.	And	Potential for international spread, including via live animals, their products ~~and~~ or inanimate objects.	International trade in aquatic animal species *susceptible* to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is a likely risk.
15.	And	Several countries or countries with *zones* may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 as well as the relevant disease chapter of the *Aquatic Manual*.	*Free countries/zones* could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible, however, individual countries that run a control programme on such a disease can demand its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of *broodstock* from widespread diseases, or the protection of the last remaining *free zones* from a widespread disease.

1 'Susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
		And **C. Diagnosis**	
16.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see OIE *Manual of Diagnostic Tests for Aquatic Animals*) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

Evaluation of Infectious pancreatic necrosis (IPN) by the EU ad hoc group *(including the OIE ad hoc group evaluation)*

+	criterion applies
(+)	criterion applies but to limited circumstances
-	criterion does not apply
(-)	criterion does not apply sufficiently
?	insufficient information available
NA	not applicable.

D. Consequences

9. Significant losses due to morbidity, mortality or product quality

OIE ad hoc group: Infectious pancreatic necrosis (IPN) is a highly contagious viral disease principally of young fish of salmonid species held under intensive hatchery conditions (Wolf et al., 1960; Hill, 1982; Wolf, 1988). The disease most characteristically occurs in young fry of trout, char and salmon species. Although high mortalities can occur in first-feeding fry, susceptibility generally decreases with age, with resistance to clinical disease usually being reached at about 3 months post-hatch. The economic impact of such outbreaks in such young fish is not high and, where it is endemic, the salmonid farming industry has largely learned to live with the disease, often simply discarding affected fry batches. Control methods include the implementation of hygiene practices in salmonid husbandry, through the avoidance of the introduction of fertilised eggs originating from IPNV-carrier brood stock, and the use of a protected water supply (e.g., spring or borehole) where the ingress of fish, particularly possible virus carriers, is prevented. In outbreaks, a reduction in the population density ('thinning out') can reduce the overall mortality. However, it also causes significant losses in Atlantic salmon smolts after transfer from fresh water to seawater (Smail et al., 1989) but whether this is due to expression of infection acquired in freshwater or from a marine fish reservoir in the vicinity of the salmon cages is not clear.
Commercial vaccines are now available to ameliorate the losses in Atlantic salmon marine farms but there are mixed reports about their efficiency.

Conclusion by the OIE ad hoc group: (+) (criterion applies but to limited circumstances)

EU *ad hoc* group: IPN is considered the most serious viral disease in salmon production (Ariel *et al.*, 2002). It affects, as described by the OIE *ad hoc* group, mainly salmonid fry and atlantic salmon (*Salmo salar*) smolt shortly after transfer from freshwater to seawater. IPN is also associated with loss of appetite and therefore production (Damsgård, 1998). Losses in fry because of IPN vary from less than 10 % to more than 90 % (OIE Aquatic Manual, 2003, fourth edition). IPN infected salmon smolts are estimated to have a mortality rate five times higher than non-infected smolts (Jarp, 1999). In spite of control and management measures the economic impact of IPN is serious. Data from Shetland for 2001 showed an average loss of 20–30 % (losses as high as 80 % were observed) in affected farms and an overall loss of 10% of the total smolt input to seawater sites (Report of the Aquaculture Health Joint Working Group on Infectious Pancreatic Necrosis in Scotland, 2003). Norway reports an average mortality during IPN outbreaks of 10% - 20% post smolts, with mortalities reaching more than 90% in some cases (Brun, 2003). IPN cause significant losses due to morbidity, mortality and product quality in the Norwegian fish farming industry. The disease is today recognized to be one of the largest fish health problems in Norwegian aquaculture (Martin Binde, personal

communication). Pathogeneticy of the virus seems to increase over the years. No treatment or entirely effective vaccine is available at present (OIE Aquatic, 2003, fourth edition)

Conclusion by the EU *ad hoc* group: + (criterion applies)

10. Affects wild fish populations

OIE ad hoc group: *Although there have been many isolations of IPN virus from a wide range of wild fish species, there is no published scientific evidence that demonstrates such infections have any adverse effect at the population level, or even on the individual host.*

Conclusion by the OIE ad hoc group: - (criterion does not apply)

EU *ad hoc* group: The EU *ad hoc* group challenges the OIE *ad hoc* groups opinion that IPN fails to comply with criterion 2.
Within the European Community Council Directive 92/43/EEC on the conservation of natural habitats and wild fauna specifies the species and habitats worth protecting in the Community. The Directive specifies that e.g. *Salmo salar* in fresh water area require special protection. Furthermore, the Directive lays down that e.g. *Salmo salar* stocks in fresh water may need management measures.
While statistically 90 percent of all salmon (*Salmo salar*) recruitment in the Baltic Sea consists of compensatory reared salmon only 50 percent of the catches belong to this category, indicating lower post smolt survival of compensatory reared salmon.
Considering the effects of IPN on post smolt survival as described under criterion 1, it is likely that an accelerated decrease in post-smolt survival will be the result if zones with hatcheries and smolt-farms conducting restocking programmes cannot be protected from IPN any longer. Existing broodfish farms, hatcheries and smolt farms in Sweden and Finland are based on river water and are thus influenced by the fish health status of the water catchment area. Because of prohibitive costs the water supplies cannot be protected. Mortalities of the magnitudes described under criterion 1 for Scotland and Norway could not be compensated for and therefore endanger the programmes. Thus, freedom of brood fish stocks, hatcheries and smolt farms from IPN has to be considered as a prerequisite for successful restocking programmes.
Salmon fishery in the Baltic Sea is heavily dependent on stocked salmon (*Salmo salar*).
As already mentioned about 50 percent of all salmon catch origin from restocking. The value of the commercial catches on stocked salmon in the Baltic (all Baltic Sea countries involved) can be estimated to 3,3 – 3,8 million EURO (1200 tonnes). Non-commercial catch (non-licensed fishermen and recreational fisheries) on salmon and trout can be estimated to 11-16 million EURO only in Sweden (those figures include all returns including profits in tourist industry, fishing supply etc.).

Conclusion by the EU *ad hoc* group: + (criterion applies)

11. Public health concern

OIE ad hoc group: *None*

Conclusion by the OIE ad hoc group: - (criterion does not apply)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: - (criterion does not apply)

E. Spread

12. Infectious aetiology proven

No doubts about the aetiology being an infectious birnavirus.

Conclusion by the OIE ad hoc group: + (criterion applies)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: + (criterion applies)

13. Infectious agent associated but aetiology not proven

OIE ad hoc group: Not applicable.

EU *ad hoc* group: Not applicable.

14. Potential for international spread via live animals, their products and inanimate objects

OIE ad hoc group: The biggest risk of international spread of IPN is via live fish. However, the international trade is traditionally mostly in eyed-eggs that have been subjected to a disinfection procedure. It is widely accepted that vertical transmission of IPN is a typical characteristic of the disease in trout. The published evidence for vertical transmission of IPNV via the fertilised egg of trout species is quite comprehensive and, in the main, conclusive, but the evidence for salmon species is much less convincing. For Atlantic salmon in Europe, there is a potential international trade in live salmon smolts to on-growing marine cage farms, delivery being by wellboat or, more rarely, by helicopter. This would introduce the potential for transfer of the virus in carrier fish but, as stated above, it is not certain that such fish are the cause of outbreaks of IPN in salmon farms rather than the source being infected local wild marine fish.

Conclusion by the OIE ad hoc group: (+) (criterion applies but to limited circumstances)

EU *ad hoc* group: The EU *ad hoc* group agrees with the OIE *ad hoc* group that horizontal transmission of IPN poses the biggest risk. However vertical transmission has been reported for brook trout (Bootland *et al.*, 1991; Bullock, *et al.*,1976) and rainbow trout (Dorson *et al.*, 1985), as well as for Arctic char (Ahne *et al*, 1985). Vertical transmission

intra-ovum is demonstrated for brook trout and rainbow trout (Dorson *et al.*, 1997). While vertical transmission has not been conclusively demonstrated in salmon, it is thought likely to occur. As international trade is traditionally mostly in eyed-eggs and disinfection procedures do not affect intra-ovum transmission, the EU *ad hoc* group challenges the view that criteria 6 only applies to limited circumstances.

Furthermore, while the OIE *ad hoc* group questions, whether infected salmon smolt rather than infected local wild marine fish is the source of outbreaks of IPN in salmon farms, the EU *ad hoc* group feels that infected smolt is the most likely source of infection (see criterion 1). We are not aware of any reports of feral fish transmitting IPN to farmed stocks rather than vice versa.
A study on the distribution and prevalence of IPN virus in wild fish, principally mature brown trout, in Loch Awe/Scotland after an IPN outbreak in a rainbow trout farm showed that IPN virus was not self-sustaining as a natural infection in the wild fishery in the absence of the source of virus, e.g. farmed fish (Munro *et al.*, 1976).

Conclusion by the EU *ad hoc* group: + (criterion applies)

15. Several countries/zones may be declared free

OIE ad hoc group: The disease already has a wide geographical distribution, occurring in most major freshwater salmonid-farming countries of North and South America, Europe and Asia. However, there have been no reports of the clinical disease from countries in Oceania and it is possible that these countries could provide the evidence to justify being declared free either on historical grounds or through targeted surveillance as described in the OIE Aquatic Manual.

It is widespread and well-established in the marine Atlantic salmon industries of the major producer countries – only Tasmania, Australia is still believed to be free.

Conclusion by the OIE ad hoc group: (-) (criterion does not apply sufficiently)

EU *ad hoc* group: Recently, Sweden, as well as the continental part of Finland and a zone in the United Kingdom (Isle of Man) have been declared free by Commission Decision 2004/453/EC. Oceania is free of the disease (OIE Aquatic Manual 2003, fourth edition), and according to our information even Australia and Iceland may be declared free of the disease.

According to experiences in Sweden and Finland, IPN-infected farms can under certain conditions be cleared from infection – yet thorough sanitation protocols are required. As indicated in the explanatory notes of criterion 7, it is important to protect broodstocks and remaining free zones from a widespread disease. In addition, restocking programs – as applied in countries as Sweden and Finland – aiming at the protection of species worth protecting (*as Salmo salar*) should be encouraged and not endangered.

~~Furthermore, as not all countries/zones with potential for establishing salmon farming have utilized these oportunities, it is possible that these countries/zones could provide evidence to justify being declared free either on historical grounds or through targeted surveillance as described in the OIE Aquatic Manual.~~

Conclusion by the EU *ad hoc* group: + (criterion applies)

F. Diagnosis

16. A repeatable and robust means of detection/diagnosis exists

OIE ad hoc groups: Diagnostic tests for IPN virus, as described in the OIE Aquatic Manual, are widely available.

Although the tests have not undergone formal standardization and validation, their routine nature and the fact that they have been in use for many years without dubious results make them acceptable.

Conclusion by the OIE ad hoc groups: + (criterion applies)

EU *ad hoc* group: EU agrees with the OIE conclusion

Conclusion by the EU *ad hoc* group: + (criterion applies)

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BKD ANNEX

Final version, 22nd December 2004

Assessment compiled by the EU *ad hoc* group of fish diseases experts and fish health authorities, based on discussions during the EU working group meeting on 13 Dec 2004 in Brussels, for the consideration of the OIE Aquatic Animal Health Standards Commission.

OIE criteria for listing an aquatic animal disease

Diseases proposed for listing must meet all of the relevant parameters set for each of the criteria, namely A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a disease must have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8.

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
		A. Consequences	
17.		The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in *susceptible*[1] *species*, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.
18.	Or	The disease has been shown to or scientific evidence indicates that it is likely to negatively affect wild aquatic animal populations that are an asset worth protecting for economic or ecological reasons.	Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, the asset could be ecological or environmental in nature, for example, if the population consists of an endangered species of aquatic animal or an aquatic animal potentially endangered by the disease.
19.	Or	The agent is of public health concern.	
		And **B. Spread**	
20.		Infectious aetiology of the disease is proven.	
21.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
22.	And	Potential for international spread, including via live animals, their products ~~and~~ or inanimate objects.	International trade in aquatic animal species *susceptible* to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is a likely risk.

1 'Susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'

No.	Criteria (A–C)	Parameters that support a listing	Explanatory notes
23.	And	Several countries or countries with *zones* may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 as well as the relevant disease chapter of the *Aquatic Manual*.	*Free countries/zones* could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible, however, individual countries that run a control programme on such a disease can demand its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of *broodstock* from widespread diseases, or the protection of the last remaining *free zones* from a widespread disease.
And **C. Diagnosis**			
24.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see OIE *Manual of Diagnostic Tests for Aquatic Animals*) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

Assessment of Bacterial Kidney Disease (Renibacterium salmoninarum) by the EU ad hoc group (including the OIE ad hoc group evaluation)

\+ criterion applies
(+) criterion applies but to limited circumstances
\- criterion does not apply
(-) criterion does not apply sufficiently
? insufficient information available
NA not applicable.

G. Consequences

17. Significant losses due to morbidity, mortality or product quality

OIE *ad hoc* group: The association of *Renibacterium salmoninarum* with disease in farmed and wild salmonid fish is well established (Evelyn, 1993). The presence of the bacterium, in the absence of disease is also commonly encountered (Fryer and Lannan, 1993). Salmon with advanced cases of the bacterial kidney disease (BKD) can suffer significant mortality both in freshwater or during transition to seawater or during seawater residence (Banner *et al.*, 1986).

Conclusion by the OIE *ad hoc* group: - (criterion does not apply)

EU *ad hoc* group: The EU *ad hoc* group challenges the opinion of the OIE *ad hoc* group that BKD fails to comply with criterion 1. EU *ad hoc* group agrees with the OIE *ad hoc* group text concerning criterion 1 but disagrees with the conclusion drawn up by the OIE *ad hoc* group. According to the OIE *ad hoc* group, "*the impact of the disease on cultured populations of salmonids is clear*" (see OIE-text in criteria 2). Several authors have

published work underlining the effect of BKD on farmed populations (see e.g. OIE Aquatic Manual, 2003, fourth edition). Losses as high as 80 % in stocks of Pacific salmon and 40 % in stocks of Atlantic salmon have been reported (Evenden *et al.* 1993). Moreover, it is estimated e.g. that, in British Columbia coastal waters, 20-60 % of farmed salmon may succumb to BKD prior to commercial harvest (Albright *et al*, 1988).

BKD can cause significant production losses in Atlantic salmon also in Europe. Losses may occur in freshwater and in broodstock units but the biggest losses seem to occur in marine cages late in the production cycle. The latter observation is particularly significant as these are large fish with heavy investment in labour and feed costs. There is evidence that a light infection is significant as salmon entering saltwater continue to develop BKD with later mortality (Bullock and Herman, 1980).The following examples illustrate the scale of this potential loss:

- In Scotland BKD occurs rarely, due to the strict control programme, but again losses are generally associated with the later stages of production in fish from 1-2 Kg in weight. Industry are currently reporting stock losses to be roughly 2% per month on infected sites with sub-optimal marketing due to early harvest at affected sites. Exceptionally losses of up to 40% have been recorded.
- Previous Scottish experience (Bruno, 1986) has shown that losses in Atlantic salmon pre-smolts from BKD have also been severe with one case documented with 20% losses over a 6 month period. At transfer to seawater 69% of the fish where found to be infected with the causative agent of BKD and 56% showed evidence of gross pathology resulting in a further 15% loss in the stock (Bruno, 1986).
- Faeroe Islands losses up to 15-20% of production on individual farms have been reported, with up to 60-70% of farms affected. In addition to direct losses from mortality reduced growth and susceptibility to other diseases is also reported

It is also apparent that losses can occur in rainbow trout culture especially in marine cage rearing sites:

- In the UK there are historical reports of losses in cage sites up to 10% of production in the late 1980's. The mortalities were in all sizes of fish up to market size. Bruno (1986) reported that losses at four trout farms were 15-20% per annum and in extreme cases mortalities reached 5% per day over short periods.
- According to experiences in Finland in 2001 (Finnish National Veterinary and Food Research Institute, unpublished data), BKD was diagnosed in 0-1 year old rainbow trout soon after their transfer from fresh water farm to seawater farms. The source of infection was the infected brood fish farm. The diseased fish had also severe peritonitis partly due to vaccination. It seemed that the stress caused by vaccination and transport to sea triggered the diseases and also the secondary effects of ip. vaccination. Acute mortality was estimated to reach 10 %. However, mortality continued over a long period time and losses due to reduced growth in infected fish was also observed.
- In Poland BKD has shown to cause considerable mortality at fresh water farms; up to 60% in 1989-1992 and 30 % at two farms in 2000.

When occurring, BKD is difficult to control as the use of antibacterials is not sufficiently effective although prolonged treatment may stop the progression of the disease to some

extent. There are some promising results on the effect of live vaccines. However, it is not known now whether vaccination will be a relevant control system of BKD in future.

Thus, prevention is the only valid method of control which means that health control, surveillance and certification as well as movement restrictions on live fish, eggs and gametes have to be in force (for imports as well as in trade). If BKD cannot be controlled by preventive measures, it may give large socio-economic impacts on the aquaculture industry.

Conclusion by the EU *ad hoc* group: + (criterion applies)

18. Affects wild fish populations

OIE *ad hoc* group: The impact of the disease on cultured populations of salmonids is clear but the potential effects on wild salmonids is much less clear. The presence of the bacterium in populations with no contact with hatchery-reared salmonids, indicates a potential concern for the health of wild populations of fish (Souter *et al.*, 1987) but studies to demonstrate such population impacts are not available. All salmonids, recently to include whitefish, are known hosts for the bacterium which may be present throughout the natural geographic distribution of wild and cultured salmonid fishes.

Conclusion by the OIE *ad hoc* group: - (criterion does not apply)

EU *ad hoc* group: The EU *ad hoc* group challenges the opinion of the OIE *ad hoc* group that BKD fails to comply with criterion 2, as several authors have published work underlining the effect of BKD in wild populations (see e.g. OIE Aquatic Manual, 2003, fourth edition). In addition, the EU *ad hoc* group wish to point out that information on the effects of pathogens on the wild fish populations are usually missing before they actually happen. We refer to the situation concerning *Gyrodactylus salaris* and Atlantic salmon in Norway in the 1970's. EU *ad hoc* group is not suggesting as dramatic effects in the BKD free zones, but calls attention to our lack of knowledge on these kinds of effects due to limited scientific interests and the long-lasting and difficult nature of the research.

Several references provide clear evidence of affect of BKD on wild salmonid stocks. BKD has been shown to affect the physiological adjustment needed when salmonids migrate from fresh water to salt water. There are many experimental studies demonstrating losses in BKD infected chinook salmon experimentally transferred from freshwater to seawater (Elliott *et al.*, 1997) and also implicating BKD as a major cause of mortality in wild chinook and coho smolts on entry into seawater (Ellis *et al.*, 1978; Fryer and Sanders, 1981; Banner *et al.*, 1983; Banner and Rohovec, 1985; Fryer and Lannan, 1993; Elliot *et al.* 1995; Holey *et al.*, 1998; Mesa *et al.* 1999; Moles 1997; Williams *et. al* 2001). For example, Fryer and Sanders (1981) reported that losses in sea water coho smolts was considerably higher than a fresh water group with the majority of deaths occurring between 2-4 months after sea water transfer. BKD was first reported in Atlantic salmon from the River Dee in Scotland. Epizootics of BKD from Scottish rivers between 1930 and 1960 were associated with significant mortality and high prevalence of BKD infected fish in returning broodstock (Smith, 1964). Moreover, there is a report suggesting that chronic BKD could be in association with the mortality of wild freshwater fish (Arctic char and brown trout) in waters in which there has never been fish farming or stocking activity (Jónsdóttir *et al.* 1998).

Another consideration in assessing BKD against criteria 2 is whether wild salmonid stocks are "*an asset worth protecting for economic or ecological reasons*". Within the European Community Council Directive 92/43/EEC on the conservation of natural habitats and wild fauna specifies the species and habitats worth protecting in the Community. The Directive specifies that e.g. *Coregonus oxyrhhynchus* in North Sea area and *Salmo salar* in fresh water area require special protection. Furthermore, the Directive lay down that e.g. *Salmo salar* stocks in fresh water, *Thymallus thymallus* and *Coregonus* spp. stocks may need management measures. It is notable that all these species are susceptible to BKD (Smith, 1964; Kettler *et al.*, 1986; Kettler, 1987; Nagai, 2002; Rimaila-Pärnänen, 2002).

Wild salmonid populations, especially the Atlantic salmon and the sea trout, are in severe decline in many sea areas and this has principally been associated with a reduced marine survival. For example, in the Baltic Sea statistically 90 percent of all salmon (*Salmo salar*) recruitment consists of compensatory reared salmon and only 50 percent of the catch belong to this category, indicating lower post smolt survival of stocked salmon. Considering the effects of BKD on post smolt survival as described above, it is likely that an accelerated decrease in post-smolt survival will be the result if zones with broodstock farms, hatcheries and smolt farms conducting restocking programmes cannot be protected from BKD any longer. The existing broodfish farms, hatcheries and smolt farms e.g. in Sweden and Finland are based on river water and are thus influenced by the fish health status of the water catchment area. Because of prohibitive costs the water supply cannot be protected. Thus, freedom of brood fish stocks, hatcheries and smolt farms from BKD has to be considered as a prerequisite for successful restocking programmes.

Conclusion by the EU *ad hoc* group: + (criterion applies)

19. Public health concern

OIE *ad hoc* group: There is no evidence to suggest that the bacterium possesses any capabilities to infect homiotherms. In fact, the bacterium may be quite host specific for members of the family Salmonidae.

Conclusion by the OIE *ad hoc* group: - (criterion does not apply)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: - (criterion does not apply)

H. Spread

20. Infectious aetiology proven

OIE *ad hoc* group: *Renibacterium salmoninarum* is the proven aetiological agent of BKD and a firm association between the bacterium and disease outbreaks is established (Evelyn, 1993). What remains difficult to assess are all factors that contribute to disease as detection of the bacterium by sensitive diagnostic methods indicates a rather broad

distribution of the agent in salmonid populations. A majority of these detections occur in the absence of disease.

Conclusion by the OIE *ad hoc* group: + (criterion applies)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: + (criterion applies)

21. Infectious agent associated but aetiology not proven

OIE *ad hoc* group: Not applicable.
EU *ad hoc* group: Not applicable.

22. Potential for international spread via live animals, their products and inanimate objects

OIE *ad hoc* group: The bacterium is capable of spreading via both horizontal and vertical modes with perhaps the greatest concern being transport over large distances with salmonid eggs originating from moderate to heavily infected female salmon (Evelyn, 1993; Fryer and Sanders, 1981). That the bacterium can be present within the egg and therefore not subject to surface disinfection was established by Evelyn (reviewed in Evelyn, 1993). Transport of live fish also represent a mode by which the agent may be spread over shorter distances.

Conclusion by the OIE *ad hoc* group: + (criterion applies)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: + (criterion applies)

23. Several countries/zones may be declared free

OIE *ad hoc* group: No countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the OIE *Aquatic Manual*.

Conclusion by the OIE *ad hoc* group: (-) (criterion does not apply sufficiently)

EU *ad hoc* group: EU *ad hoc* group agree that BKD is widespread. However, there are few countries and also many zones in European countries that are free or *may be declared free*. These countries are valuable source of uninfected material which could be used as a Community-wide resource. This resource should remain fully protected in the future. According to the Commission Decision 2004/453/EY the whole territory of Ireland and in the United Kingdom the territories of Northern Ireland, the Isle of Man and Jersey are free of BKD. In addition, in other parts of Great Britain and continental parts of Finland and Sweden BKD have a limited occurrence and the eradication programmes have been approved by the Commission Decision 2004/453/EY. Norway is preparing an application for additional guarantees for BKD according to article 13 of Council Directive 91/67/EC

on the grounds that the whole continental parts of the country are considered free from the disease. Also Island has conducted BKD-eradication programme since 1985 and is planning to apply for BKD-freedom in future. Thus, several countries/zones may be declared BKD-free and there are experiences of successful eradication programmes in many countries.

Conclusion by the EU *ad hoc* group: + (criterion applies)

I. Diagnosis

24. A repeatable and robust means of detection/diagnosis exists

OIE *ad hoc* groups: Suitable screening methods as well as standardized procedures exist. A series of robust tests including antigen and DNA-based systems are available for detection of the agent or its respective antigens or nucleic acids. These tests are widely available and in some cases fully commercialized.

Conclusion by the OIE *ad hoc* groups: + (criterion applies)

EU *ad hoc* group: EU agrees with the OIE conclusion.

Conclusion by the EU *ad hoc* group: + (criterion applies)

Table: Summary compiled by the EU *ad hoc* group of the evaluation of BKD related to the listing criteria

A 1	A 2	A 3	B 4	B 5	B 6	B 7	C 8	Retain on OIE list?
+	+	-	+	NA	+	+	+	Yes

Overall conclusion: BKD fulfils the OIE criteria for listing an aquatic animal disease (A1 + A2, B4+B6+B7 and C8). Thus, BKD should remain on the OIE list.

Listing was supported by the following States in the meeting in Brussels on 13th December 2004: United Kingdom, Sweden, Finland, Hungary, Luxembourg, Austria, France, Spain, Greece, The Netherlands, Germany, Denmark, Czech Republic and Norway. Additional support was received from Ireland, Poland and Island. Many experts from these countries have provided their experience and expertise particularly in relation to criteria 1, 2 and 7. None of the EU Member States have informed the *ad hoc* group to be against the listing, although some critical comments were received from German expert.

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ANNEX KHV

(Final version, 21st Dec 2004)

Invitation to the OIE Aquatic Animal Health Standards Commission, to assess this assessment for OIE listing of KHV, made by EU fish diseases experts after discussion by the EU working group of Member States, which met 13 Dec 2004 in Brussels

OIE criteria for listing an aquatic animal disease

Diseases proposed for listing must meet all of the relevant parameters set for each of the criteria, namely A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a *disease* must have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8.

No.	Criteria (ĀC)	Parameters that support a listing	Explanatory notes
		A. Consequences	
25.		The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the disease will lead to losses in *susceptible*[1] *species*, and that morbidity or mortality are related primarily to the agent and not management or environmental factors. (Morbidity includes, for example, loss of production due to spawning failure.) The direct economic impact of the disease is linked to its morbidity, mortality and effect on product quality.
26.	Or	The disease has been shown to or scientific evidence indicates that it is likely to negatively affect wild aquatic animal populations that are an asset worth protecting for economic or ecological reasons.	Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, the asset could be ecological or environmental in nature, for example, if the population consists of an endangered species of aquatic animal or an aquatic animal potentially endangered by the disease.
27.	Or	The agent is of public health concern.	

1 'Susceptible' is not restricted to 'susceptible to clinical disease' but includes 'susceptible to covert infections'

No.	Criteria (ÃC)	Parameters that support a listing	Explanatory notes
		And **B. Spread**	
28.		Infectious aetiology of the disease is proven.	
29.	Or	An infectious agent is strongly associated with the disease, but the aetiology is not yet known.	Infectious diseases of unknown aetiology can have equally high-risk implications as those diseases where the infectious aetiology is proven. Whilst disease occurrence data are gathered, research should be conducted to elucidate the aetiology of the disease and the results be made available within a reasonable period of time.
30.	And	Potential for international spread, including via live animals, their products ~~and~~ or inanimate objects.	International trade in aquatic animal species *susceptible* to the disease exists or is likely to develop and, under international trading practices, the entry and establishment of the disease is a likely risk.
31.	And	Several countries or countries with *zones* may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.1.4 as well as the relevant disease chapter of the *Aquatic Manual*.	*Free countries/zones* could still be protected. Listing of diseases that are ubiquitous or extremely widespread would render notification unfeasible, however, individual countries that run a control programme on such a disease can demand its listing provided they have undertaken a scientific evaluation to support their request. Examples may be the protection of *broodstock* from widespread diseases, or the protection of the last remaining *free zones* from a widespread disease.
		And **C. Diagnosis**	

No.	Criteria (ÃC)	Parameters that support a listing	Explanatory notes
32.		A repeatable, robust means of detection/diagnosis exists.	A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (see OIE *Manual of Diagnostic Tests for Aquatic Animals*) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

Evaluation of Koi Herpesvirus (KHV) disease and proposal for future listing by the OIE, after discussion with the working group of the EU, which met at Brussels, 13 Dec 2004, and discussed SANCO/10670/2004 (Report of the meeting of the Bureau of the OIE Aquatic Animal Health Standards Commission, Paris, 11-15 Oct 2004). A group of international KHV experts from the EU participated in the formation of this proposal.

\+ criterion applies
(+) criterion applies but to limited circumstances
\- criterion does not apply
(-) criterion does not apply sufficiently
? insufficient information available
NA not applicable.

J. Consequences

25. Significant production losses at a national or multinational (zonal or regional) level due to morbidity, mortality or product quality

KHV causes severe disease and high mortalities (80-100%) in all ages of farmed common carp and koi carp (*Cyprinus carpio)* and is spreading around the globe with the international trade in ornamental carp (Gilad et al., 2003).

The first outbreaks of disease in cultured carp occurred near the northwest coast of Israel in spring 1998 and in the following three years regular outbreaks were seen in spring and autumn. By the end of 2000 the disease had spread to 90% of the carp farms in Israel at an estimated cost to Israeli aquaculture of 3 million US$ every year (Perelberg et al., 2003).

In mid-April 2002, a serious disease outbreak, later confirmed as KHV, causing high mortality in koi and common carp was reported affecting the East of Java Island in Indonesia (Rukyani, 2002). By November 2002 the disease had spread to Sumatra, with mortalities averaging 80%, and then further to Bali, East Kalimantan and Central Sulawesi. During the epizootic, very high mortalities (80-95%) were seen in both koi and common carp, with estimated losses of over 15 million US$ up to December 2003. Also in 2002 the first outbreak of KHV disease in Taiwan was reported and many further outbreaks were seen in 2003 and 2004 (Tu et al.2004).

In October 2003, an outbreak of KHV disease was reported affecting food carp cultured in two lakes in Ibaraki prefecture in Japan (Sano, 2004). Over the next two months an estimated 1200 tonnes of carp died in the two lakes and the disease epidemic then spread to Japan's other prefectures. The disease threatened the 75 million US$ ornamental carp (nishikigoi) industry, and all nishikigoi shows were cancelled for November 2003. By the middle of June 2004 the number of prefectures reporting detection of KHV had risen to 38, of 47 prefectures. The 2004 outbreaks had been mostly in wild populations of carp and aquaculture facilities on river water supply (Sano pers.comm.).

In 1997 and 1998 Germany had already outbreaks of KHV disease with mass mortality in koi ponds and koi dealerships (Bretzinger et al., 1999, Hoffmann, 2000). The koi branche in The Netherlands had similar KHV outbreaks from 2001 (Haenen et al, 2004). Germany has seen severe KHV outbreaks in carp farms in Saxony in 2003 and in Thuringia in 2004 (Schlotfeldt 2004). In the UK, KHV has been isolated from carp mortalities in angling waters in 2003 (Denham 2003) and again in 2004 (Haenen et al. 2004). In 2004, Poland has had its first and severe outbreaks of KHV in 3 carp farms of 12 suspicious farms, from a total of 300 big carp farms and many small farms, where carps for consumption are cultured (Antychowicz, pers.comm.).

Conclusion by the EU *ad hoc* group: + (criterion applies)

26. Affects wild fish populations

During 2003 the CEFAS Weymouth laboratory isolated KHV from common carp during investigations into large mortalities of carp in managed fishery lakes. There is more and more evidence that the spread of KHV is linked to the rearing or holding of common carp, destined for restocking fisheries, with ornamental varieties of carp. Also, in some cases, fishery owners have stocked their waters with ornamental carp such as ghost koi carp (common x koi carp) (Denham, 2003) and thereby spread the virus. Mass carp mortalities occurred in rivers and lakes in Okayama prefecture in Japan from May to July 2003, prior to the outbreaks in Ibaraki prefecture later in 2003 (Sano et al.2004). The 2004 outbreaks in Japan had been mostly in wild populations of carp and aquaculture facilities on river water supply (Sano pers.comm.). If KHV would spread to wild and cultured carps in developmental countries, where water temperatures are in the ideal range for the disease, it could destroy an important food protein source, being carp.

The overall risk of introducing the disease in wild carp populations is high.

Conclusion by the EU *ad hoc* group: + (criterion does apply)

27. Public health concern

There is no evidence to suggest that the virus possesses any capabilities to infect homeothermic animals. In fact, the virus is very host specific, so far for *Cyprinus carpio* only.

Conclusion by the EU *ad hoc* group: - (criterion does not apply)

K. Spread

28. Infectious aetiology proven

Koi Herpesvirus, a herpesvirus, is the proven aetiological agent of Koi Herpesvirus disease and a firm association between the herpesvirus and disease outbreaks is established (Bretzinger et al., 1999, Hedrick et al., 2000, Perelberg et al., 2003, Gilad et al. 2004).

Conclusion by the EU *ad hoc* group: + (criterion applies)

29. Infectious agent associated but aetiology not proven

EU *ad hoc* group: Not applicable.

30. Potential for international spread via live animals, their products and inanimate objects

The big concern is the large international trade in koi carp. The virus has been shown to be able to spread via live koi carp movements (Gilad et al. 2003, Haenen et al., 2004) . There is good evidence that the spread of KHV to common carp is linked to the rearing or holding of common carp, destined for restocking fisheries, with ornamental varieties of carp (Denham 2003). There is no reported direct risk for carp products or inanimate objects. Japan has started a national prevention strategy (Miwa, 2004; Yamada, 2004).

Conclusion by the EU *ad hoc* group: + (criterion applies)

31. Several countries/zones may be declared free

KHV is a relatively-new emerging disease. The diagnostic tests, especially the PCR assays, are practised at more laboratories every year. So far, officially no countries or zones have been declared free based on the general surveillance principles outlined in Chapter 1.1.4. of the OIE *Aquatic Manual*. However, Scandinavian countries like Sweden have a strict import control of live fish, a clinical negative history concerning the disease, and check their imported carps and koi carp in quarantine for KHV, so they are likely to be declared free. Because the impact of KHV disease, Japan immediately introduced new (inter)national legislation in June 2003, to protect their koi carp and carp stocks, and to be able to effectively control the disease (Kimiya, 2004). Some newly accessed EU member states, which had no suspicions of KHV disease in the past face the problem of starting up the KHV diagnosis only now, and at the same time considering national legislation. These processes take time, and might be too late to stay KHV free.

Conclusion by the EU *ad hoc* group: (+) criterion applies but to limited circumstances

L. Diagnosis

32. A repeatable and robust means of detection/diagnosis exists

KHV is still a young disease, and new tests have only recently been described. During the EU National Reference Lab workshop on carp diseases at CEFAS, Weymouth, in June 2003, it was advised to use at least two of the available diagnostic methods in parallel to improve the accuracy of KHV diagnosis (Haenen et al. 2004):

- **Light microscopy & Transmission Electron microscopy (TEM)**
- **Virus isolation in cell culture:** KF-1 and CCB cell lines are used to isolate KHV (Hedrick et al. 2000, Neukirch & Kunz 2001), but virus isolations are relatively low in sensitivity.
- **Detection of KHV DNA**: robust PCR assays, described by Gilad et al. (2002) and Gray et al. (2002) are used most often, and are more sensitive than virus isolations.

- **Detection of antibodies to KHV:** antibody detection by ELISA (Ronen et al., 2003; Hedrick, pers.comm.)

In practice, at laboratories, where KHV PCR techniques have been more or less validated, the PCR assay (Gilad et al., 2002, Gray et al., 2002) is used for diagnosis of KHV infections. Development of more sensitive PCR assays is underway at several laboratories, (Gilad et al., 2004; from other labs: to be published).

8b : A robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies

The disease occurs naturally at temperatures between 17°C and 26°C with an incubation period of 7-21 days depending on water temperature. Morbidity is often 100% with mortality up to 90% at higher temperatures. Behavioural signs of disease include lethargy, fatigue, disorientation, erratic swimming and frequent ventilation (gasping). The most consistent gross clinical sign of disease is an irregular discolouration of the gills consistent with moderate to severe gill necrosis. Other commonly reported clinical signs include anorexia, enophthalmia (sunken eyes), pale, irregular patches on the skin associated with excess mucus secretion and also decreased production of mucus in patches, leaving the epidermis with a sandpaper-like texture.

Conclusion by the EU *ad hoc* group: + (criterion applies)

Table: summary of this evaluation of Koi Herpes Virus related to the OIE criteria

1	2	3	4	5	6	7	8	Put at OIE list?
+	+	-	+	**NA**	+	**(+)**	+	**YES**

Overall conclusion:: Having fulfilled the criteria as outlined in the OIE guidelines (A1 + A2, B4, B6, B7 and C8) the experts (mentioned under D.) recommend listing of Koi Herpes Virus by the O.I.E., and ask the Aquatic Animals Health Standards Commission to assess this claim.

D. Source of expertise

This assessment is supported by experts from the following Member States

- Austria
- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Italy

- Luxembourg
- Norway
- Poland
- Republic of Ireland
- Slovenia
- Spain
- Sweden
- The Netherlands
- United Kingdom

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ANNEX *Perkinsus olseni/atlanticus*

OIE listed aquatic diseases

EU evaluation of the infection with *Perkinsus olseni/atlanticus*

A. CONSEQUENCES

33. Significant losses due to morbidity, mortality or product quality

Perkinsus olseni was originally reported as the cause of mass mortality among abalone in Australia (Lester and Davis 1981), which initially supported its listing. Since then, very few report of the disease has been made. While *Perkinsus olseni* infects a wide range of hosts, it is noted usually without apparent disease.

Conclusion by the EU *ad hoc* group: (+) (criterion applies but to limited circumstances)

34. Affects wild fish populations

The threat posed by *P. olseni/atlanticus* seems to vary between regions and infected host species. Moreover the currently known geographical distribution indicates it is widespread.

Conclusion by the EU *ad hoc* group: + (criterion does apply)

35. Public health concern

There is no evidence to suggest that Perkinsus may create public health concern.

Conclusion by the EU *ad hoc* group: - (criterion does not apply)

B. SPREAD

36. Infectious aetiology proven

Conclusion by the EU *ad hoc* group: + (criterion applies)

37. Infectious agent associated but aetiology not proven

EU *ad hoc* group: Not applicable.

38. Potential for international spread via live animals, their products and inanimate objects

Conclusion by the EU *ad hoc* group: + (criterion applies)

39. Several countries/zones may be declared free

The parasite is largely widespread. In addition to Europe, it has been reported in the Southern hemisphere in the Cook Islands, New Zealand and Australia (Hine and Thorn 2000), and in the Eastern hemisphere, in Korea (Park et al. 1999) and in Japan (Hamaguchi et al. 1998). The parasite should also be reported soon in Uruguay (Cremonte and al, forthcoming publication).

Conclusion by the EU *ad hoc* group: - criterion does not applies

C. DIAGNOSIS

40. A repeatable and robust means of detection/diagnosis exists

Conclusion by the EU *ad hoc* group: + (criterion applies)

Table: summary of this evaluation of the infection with Perkinsus olseni/atlanticus related to the OIE criteria

Agent	1	2	3	4	5	6	7	8	Conclusion
P. olseni/atlanticus	(+)	+	-	+	N/A	+	-	+	De-list

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