



EUROPEAN UNION

Brussels  
SANCO G2/MMK/kh (2013)15594

Dear Director General,



**Subject: EU comments on the Aquatic Code and on the Terrestrial Manual**

Please find here attached:

- the comments of the EU on the report of the September 2012 meeting of the OIE Aquatic Animal Health Standards Commission, for consideration at its next meeting of March 2013; and
- the comments of the EU on the draft chapters of the OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, submitted for Member comments in November 2012.

We trust you will find this useful and we thank you for your continued cooperation.

Yours sincerely,

<p>Dr. Martin Blake Chief Veterinary Officer and OIE Delegate Ireland</p>	<p>Bernard Van Goethem Director Veterinary and International affairs DG Health and Consumers European Commission</p>
	

Annexes: 2

Copy: All Directors / Chief Veterinary Officers of the EU 27 and Croatia, Iceland, Liechtenstein, Norway, Switzerland and Turkey.

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## ANNEX 1

Original: English  
September 2012

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

Paris, 24–28 September 2012

#### EU comments

**The EU would like to thank the Aquatic Animal Health Commission for its work and for having taken into consideration EU comments on the Aquatic Code and Aquatic Manual submitted previously.**

**EU comments on this report of the September 2012 meeting of the Aquatics Animal Commission are inserted in the text below.**

**The EU would like to stress its continued commitment to participate in the work of the OIE and to offer all technical support needed by the Aquatics Animal Commission and its *ad hoc* groups for future work on the Aquatic Code and Manual.**

The OIE Aquatic Animal Health Standards Commission (hereinafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 24 to 28 September 2012.

Details of participants and the adopted agenda are given at [Annexes 1 and 2](#).

The Commission reviewed the documents identified in the agenda, addressing comments that Member Countries had submitted by 27 August 2012 and amended texts in the OIE *Aquatic Animal Health Code* (the *Aquatic Code*) where appropriate. The amendments are shown in the usual manner by double underline and strikethrough and may be found in the Annexes to the report.

Member Countries should note that, unless stated otherwise, texts submitted for comment may be proposed for adoption at the 81st OIE General Session in May 2013. Depending on the comments received on each text, the Commission will identify the texts proposed for adoption in May 2013 in the report of its March 2013 meeting.

The Aquatic Animals Commission strongly encourages Member Countries to participate in the development of the OIE's international standards by submitting comments on this report. It would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Proposed deletions should be indicated in 'strikethrough' and proposed additions with 'double underline'. Member Countries should not

use the automatic ‘track-change’ function provided by word processing software as such changes are lost in the process of collating Member Countries’ submissions into the Commission’s working documents.

The table below summarises the texts presented in the Annexes. Annexes 3 to 7 are presented for Member Country comment; Annexes 8 to 9 are presented for Members’ information.

Comments on this report must reach OIE Headquarters **prior to 8 February 2013** to be considered at the March 2013 meeting of the Commission. All comments should be sent to the OIE International Trade Department at: [trade.dept@oie.int](mailto:trade.dept@oie.int).

<b>Texts for Members’ comment</b>	<b>Annex number</b>
Glossary	Annex 3
Notification of diseases and epidemiological information (Chapter 1.1.)	Annex 4
Criteria for listing aquatic animal diseases (Chapter 1.2.)	Annex 5
Diseases listed by the OIE (Chapter 1.3.)	Annex 6
Infectious salmon anaemia (Chapter 10.5.)	Annex 7
<b>Annexes for Members’ information</b>	
Aquatic Animal Health Standards Commission Work Plan for 2012/2014	Annex 8
Report of the <i>ad hoc</i> Group on the OIE Evaluation of Aquatic Animal Health Services	Annex 9
Report of the <i>ad hoc</i> Group on the OIE List of Aquatic Animals Diseases (Finfish Team)	Annex 10

### **Meeting with the OIE Director General**

Dr Bernard Vallat, OIE Director General, congratulated newly elected and re-elected members of the Aquatic Animals Commission and thanked them for their commitment to the work of the OIE. He also thanked Dr Melba Reantaso, Aquaculture Officer, for FAO’s on-going participation as an Observer at this meeting. Dr Vallat informed the Aquatic Animals Commission on the outcomes of a recent meeting with the Director General of the FAO, Dr Jose Graziano da Silva, where it was agreed that the OIE/FAO chart and Vademecum (a chart and a text that describes FAO and OIE competencies and complementarities in the field of animal health) be amended to include aquatic animals. Dr Graziano da Silva also agreed to attend the opening Session of the 2013 OIE General Session.

Dr Vallat noted that because aquaculture and aquatic animal health is a relatively new area of work for some Member Countries, it was important that the report of the Aquatic Animals Commission be didactic to ensure all Member Countries understand the work of the Aquatic Animals Commission. Dr Vallat encouraged the Aquatic Animals Commission to develop a work plan and to prioritise its tasks given the limited number of meetings each year. He also offered support for the convening, on request, of relevant *ad hoc* Group’s to support the work of the Aquatic Animals Commission.

Dr Franck Berthe, the President of the Aquatic Animals Commission, raised the possibility of the OIE hosting a third Global conference on aquatic animal health in 2014 or 2015 bearing in mind that much time is needed to plan such an event. The conference would provide a unique forum to continue to highlight the importance of aquatic animal health and the important contribution aquaculture plays in food security. Dr Vallat supported this suggestion and encouraged the Aquatic Animals Commission to continue to develop this proposal.

### **1. General discussion and work plan**

The Aquatic Animals Commission reviewed the current work plan and the status of the *Aquatic Code* and *Aquatic Manual* and established priorities and time lines for these activities. The Commission identified the following topics of work:

### *Aquatic Code*

- Amend Chapter 10.5. Infectious salmon anaemia (ISA) based on the guiding principles established by the *ad hoc* Group on pathogen differentiation and comments received from Member Countries;
- Propose OsHV-1  $\mu$ var as an emerging disease;
- Propose Infection with Salmon pancreas disease virus for listing; If adopted develop *Code* chapter;
- Review the scope, purpose and content of Chapter 6.1. Control of hazards in feed;
- Harmonise Chapter 2.2. Import Risk Analysis with the equivalent Terrestrial Code chapter;
- Develop a chapter on risk analysis for antimicrobial resistance in aquaculture to be included in Section 6 of the Code;
- Develop a new chapter on the Evaluation of Aquatic Animal Health Services;
- Review chapters in Section 4 of the Code in order to improve guidance on the control of disease;
- Develop a new Code chapter with the criteria for listing susceptible species;
- Explore the negligible risk concept for disease specific chapters (e.g. EUS).

### *Aquatic Manual*

- Revise Chapter 2.3.5. Infectious salmon anaemia to respond to Member Countries comments and align with the Code chapter;
- Revise Chapter 2.4.9. to focus information on OsHV-1  $\mu$ var;
- Develop a Disease card for Salmon pancreas disease virus; a Manual chapter will be developed if listing of SPD is adopted;
- Revise Chapter 2.3.1. Epizootic ulcerative syndrome based on the recommendations of the *ad hoc* Group.

The Aquatic Animals Commission wished to provide to Member Countries an overview of upcoming activities in order to provide them with the opportunity to plan and provide comments at the appropriate time. This work plan will be reviewed and updated at each Commission meeting.

The detailed Commission's Work Plan is presented in [Annex 8](#).

#### **EU comments**

**The EU thanks the Aquatic Animals Commission for providing this detailed work plan and in particular encourages the Aquatic Commission to work concurrently on relevant Aquatic Code and Manual chapters. Indeed, it is very important that for diseases that are accepted by the OIE World Assembly for listing, the development of a new Code chapter and the review of the existing Manual chapter (i.e. ISA and OsHV-1) or the development of a new Manual chapter (i.e. salmon pancreas disease) be made concurrently.**

**Furthermore, the EU would like to advise the OIE that the European Food Safety Authority (EFSA) has recently published an opinion on Infectious salmon anaemia (<http://www.efsa.europa.eu/en/efsajournal/pub/2971.htm>).**

**Finally, the EU would like to bring to the attention of the OIE Aquatic Animals Commission a short discussion paper prepared by experts from the UK on the annual return to OIE on animal population data (cf. Appendix at the end of this document, p 81-85). The EU would be grateful for an indication by the Aquatic Animals Commission whether the suggestions therein could lead to improving the data collection undertaken by the OIE in the area of aquatic animals.**

## **2. OIE Aquatic Animal Health Code**

The Aquatic Animals Commission welcomed comments provided by Australia, Canada, Chile, European Union, Japan, Mexico, New Zealand, Thailand, the United States of America, and the African Union-Interafrican Bureau for Animal Resources (AU-IBAR).

### **2.1. Glossary**

#### **Definition of ‘Aquatic Animal Health Professional’**

The Aquatic Animals Commission considered the recommendations of the *ad hoc* Group on the OIE Evaluation of Aquatic Animal Health Services (presented at [Annex 9](#)), which had reviewed the draft definition for ‘aquatic animal health professional’ (AAHP) to address Member Country comments.

The Aquatic Animals Commission agreed with the recommendations of the *ad hoc* Group that the definition for AAHP should describe what the person is given the authority to undertake and that the Competent Authority is responsible for, considering the appropriate level of qualification/expertise relative to the defined task. As the qualifications required are likely to vary widely with the needs and capacity of each Member Country.

The Commission made some amendments to the proposed definition to improve clarity:

#### ***Aquatic Animal Health Professional***

means a person who, for the purposes of the *Aquatic Animal Health Code*, is authorised by the *Competent Authority* to carry out certain designated tasks in a territory, is under the responsibility and direction of the *Competent Authority*, and has the appropriate qualifications and training to perform the designated tasks.

The Aquatic Animals Commission noted that should this definition be adopted, the following consequential changes should be made:

1. Delete the words ‘or veterinary paraprofessionals’ from the definition for *Aquatic Animal Health Services* because paraprofessionals are included in the proposed definition for AAHP:

#### ***Aquatic Animal Health Services***

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

2. Delete the words ‘other’ from the phrase ‘*veterinarian* or ~~other~~ aquatic animal health professional’ in Chapters 6.3. and 6.4.

The revised Glossary is presented at Annex 3 for Member comments.

**EU comment**

**The EU thanks the OIE and in general supports the proposed changes to the glossary. Specific comments are inserted in the text of Annex 3.**

## **2.2. Chapter 1.1. Notification of Diseases and Epidemiological Information**

OIE Headquarters presented a proposal to modify the text in Chapter 1.1. with the goal of improving consistency between the *Aquatic Code* and the *Terrestrial Code*.

The Aquatic Animals Commission accepted several proposed modifications. Some modifications were not accepted, because the Commission considered that the existing text in the *Aquatic Code* was correct, even if the text was slightly different from that in the *Terrestrial Code*.

The revised Chapter 1.1. is presented at [Annex 4](#) for Member comments.

### **EU comments**

**The EU in general supports the proposed changes to this chapter but has a comment that is inserted in the text of Annex 4.**

## **2.3. Chapter 1.2. Criteria for listing aquatic animal diseases**

The Aquatic Animals Commission noted that Chapter 1.2. Criteria for listing aquatic animal diseases, describes the criteria for listing diseases in Chapter 1.3. of the *Aquatic Code*. The objective of listing is to support Member Countries efforts to prevent the transboundary spread of important diseases of aquatic animals through transparent and consistent reporting.

It is however important to differentiate between diseases listed in accordance with Article 1.2.1. and those listed as an ‘emerging disease’ in accordance with Article 1.2.2. For diseases listed in accordance with Article 1.2.1., there are corresponding disease-specific chapters in the *Aquatic Code* which provide standards for safe international trade in aquatic animals and their products. Diseases listed in accordance with Article 1.2.2. (emerging diseases) do not have a corresponding disease-specific chapter in the *Aquatic Code*. The purpose of listing diseases in accordance with Article 1.2.2. is to collect epidemiological information to improve understanding of an emerging disease. This information is collected to enable later consideration of listing of the disease in accordance with Article 1.2.1. The requirements for notification of listed diseases are detailed in Chapter 1.1. and apply equally to all diseases listed, including emerging diseases.

The Aquatic Animals Commission reemphasised the need for fast track listing of diseases for information purposes while ensuring this does not create unjustified trade barriers. The Commission recognised that the purpose of listing diseases to prevent transboundary spread and listing them as emerging diseases is not very clear in Chapter 1.2. and proposed to include a new introductory article to Chapter 1.2. to clarify the distinction between listing diseases to prevent transboundary spread and listing to recognise emerging diseases.

The revised Chapter 1.2. is presented at [Annex 5](#) for Member comments.

### **EU comments**

**The EU cannot support the proposed changes to this chapter, i.e. the newly drafted Article 1.2.1., as it does not agree with the rationale for the differentiation between diseases listed in accordance with Article 1.2.1 and those listed as emerging diseases in accordance with Article 1.2.2.**

**While recognising the importance of collecting epidemiological data on emerging diseases to advance scientific knowledge and to envisage future management options, the EU is of the opinion that listing of diseases for mere information purposes is not an option as it would represent a disproportionate and burdensome notification obligation for Members and, most importantly, may give rise to unjustified barriers to trade.**

Furthermore, this distinction could eventually give rise to de facto two separate lists and corresponding confusion.

Indeed, the reason for listing diseases and pathogenic agents is assist in the prevention of their transboundary spread and to allow for safe international trade of animals and animal products, by establishing a notification obligation of outbreaks of the given disease, which is a legally binding requirement for OIE Members that enables transparent and risk based management decisions.

Therefore, listing of emerging diseases that have a significant impact or zoonotic potential should be decided after a careful evaluation of the criteria, and not only to collect epidemiological information to improve understanding of the disease but primarily to prevent their transboundary spread via international trade by enabling Members to take precautionary measures.

Gathering of epidemiological data can be achieved by other means than official notification, including by surveillance and scientific studies. Such data on non-listed diseases can then be sent as voluntary information to the OIE.

Furthermore, the EU would like to invite the OIE to consider whether it is necessary to keep a separate article for emerging diseases or whether Articles 1.2.1 and 1.2.2 could be merged into one single article, similar to the corresponding Article in the Terrestrial Code. This would also seem sensible since there is only one list of aquatic diseases in Chapter 1.3 which does not distinguish between "regular" and emerging diseases.

Further comments are inserted in the text of Annex 5.

#### 2.4. Diseases listed by the OIE (Chapter 1.3.)

##### 2.4.1. Infection with ostreid herpesvirus-1 $\mu$ var (OsHV-1 $\mu$ var) as an emerging disease

The Aquatic Animals Commission acknowledged Member Countries opposition to the proposal to list OsHV-1 and OsHV-1  $\mu$ var. However, it noted that many Member Countries supported the listing of OsHV-1  $\mu$ var. After an extensive review of previous comments, the Aquatic Animals Commission concluded that OsHV-1  $\mu$ var meets criteria 2 and 4 of Article 1.2.2.: OsHV-1  $\mu$ var has been recognised as the infectious agent associated with the disease in oysters; and there is published evidence of significant spread of OsHV-1  $\mu$ var between oyster populations [EFSA Panel on Animal Health and Welfare (AHAW); Scientific Opinion on the increased mortality events in Pacific oyster (*Crassostrea gigas*). EFSA Journal 2010, 8 (11),1894].

The Aquatic Animals Commission requested that the *Aquatic Manual* chapter be revised to add more information focusing on OsHV-1  $\mu$ var (refer to Item 3.1.).

The Aquatic Animals Commission proposed ostreid herpesvirus-1  $\mu$ var (OsHV-1  $\mu$ var) be listed.

#### EU comment

**The EU thanks the OIE and supports the listing of OsHV-1  $\mu$ var. The concurrent adoption of an Aquatic Code chapter and of the Manual Chapter 2.4.9., reviewed accordingly, should be ensured. Therefore, it may be preferable to list OsHV-1  $\mu$ var only once these chapters are ready for adoption.**

##### 2.4.2. Infectious salmon anaemia

The Aquatic Animals Commission reviewed Member Countries comments and proposed to maintain the name of the disease for listing as proposed in the Commission's March 2012 Report, as:

‘Infectious salmon anaemia (infection with HPR-deleted or HPR0 infectious salmon anaemia virus)’.

This maintains consistency with the Aquatic Animals Commission proposed amendments to Chapter 10.5. on ISA (refer to Item 2.7.).

#### **EU comment**

**The EU supports the listing of Infectious Salmon Anaemia as proposed by the OIE and stresses the importance of making the distinction between infection with HPR-deleted or HPR0 ISAV also for notification purposes (cf. EU comments on Chapter 10.5).**

#### **2.4.3. Epizootic ulcerative syndrome**

The Aquatic Animals Commission considered the report of the *ad hoc* Group on the OIE List of Aquatic Animals Diseases (Finfish Team) (11–13 September 2012) which was convened to undertake an assessment of epizootic ulcerative syndrome (EUS) against the Criteria for Listing Aquatic Animal Diseases provided in Chapter 1.2. of the *Aquatic Code*, taking into consideration an assessment provided by Canada, proposing that EUS be delisted.

The Aquatic Animals Commission reviewed the assessment undertaken by the *ad hoc* Group and agreed with their conclusion that EUS should remain an OIE listed disease because it met the criteria for listing. The Commission considered the assessment to be very thorough and that data was provided that substantiated their conclusion.

The Aquatic Animals Commission noted that the purpose of listing diseases in the *Aquatic Code* is to assist Member Countries to prevent the transboundary spread of important diseases of aquatic animals through consistent and transparent reporting. The application of the listing criteria should be considered in this context. Criterion 7 should not be interpreted as a requirement for countries to make a self-declaration of freedom for a disease as a prerequisite to a disease being listed. Rather, there should be evidence to indicate that “several countries may be declared free” of the disease if the surveillance principles outlined in Chapter 1.4. of the *Aquatic Code* were to be applied. The Commission supported the *ad hoc* Group’s conclusion that this criterion was met. The Aquatic Animals Commission discussed comments regarding the role of environmental and host risk factors in the expression of EUS. The Commission noted that it is well established that *Aphanomyces invadans* is the primary causative agent of EUS. While host and environmental factors play an important role in the expression of disease (as for other aquatic animal diseases), it is clear that *Aphanomyces invadans* is a necessary cause.

In addition, the Aquatic Animals Commission considered the recommendations made by the *ad hoc* Group and agreed that Epizootic ulcerative syndrome be renamed ‘Infection with *Aphanomyces invadans*’ to ensure consistency with the approach taken in other chapters in the *Aquatic Code*.

#### **EU comments**

**The EU agrees with the OIE as regards the listing of this disease.**

**However, the name "epizootic ulcerative syndrome" should be retained in parenthesis as part of the title of Chapter 10.2., at least for an interim time, as follows:**

**"Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)".**

**Indeed, this would avoid confusion as EUS is the well-known name of the disease which is also used in the disease list of Chapter 1.3.**

**Furthermore, for reasons of consistency, the EU suggests renaming also the other diseases following the same principle ("Infection with [name of pathogen]"), either in one go or following a step by step approach whenever amending the relevant Code chapter.**



The report of the *ad hoc* Group on the OIE List of Aquatic Animals Diseases (Finfish Team) is presented at Annex 10 for Member Country information.

#### 2.4.4. Salmon pancreas disease

At the March 2012 meeting of the Aquatic Animals Commission, the Commission had requested Chile to provide additional information regarding criterion 7 for listing Salmon pancreas disease. Chile had advised that this additional information was not available at this time.

The Aquatic Animals Commission recognised that there had been an inconsistency in the way criterion 7 had been applied for Salmon pancreas disease and epizootic ulcerative syndrome (EUS). In light of its recent interpretation of criterion 7 for EUS (refer to Item 2.4.3), the Aquatic Animals Commission decided to reconsider Pancreas Disease for listing.

The Aquatic Animals Commission concluded that Salmon pancreas disease meets all the criteria for listing. The Commission recognised the need for guidance on the diagnosis of Salmon pancreas disease and requested that a Disease card be developed to provide information for Member Countries until a *Manual* chapter is developed.

The Aquatic Animals Commission proposed the listing of 'Infection with salmon pancreas disease virus' in Article 1.3.1.

#### EU comment

**The EU agrees with the OIE as regards the listing of this disease. However, the EU suggests using the term "Infection with salmonid alphavirus" as this would also include Sleeping Disease which causes significant mortality in rainbow trout.**

**Furthermore, the EU encourages the OIE to consider defining safe commodities when drafting the future Code chapter for this disease.**

The revised Chapter 1.3. is presented at [Annex 6](#) for Member comments.

#### 2.5. Import risk analysis (Chapter 2.2.)

In light of Member Country comments at the 2012 General Session to harmonise the import risk analysis chapters between the *Aquatic Code* and *Terrestrial Codes* the Aquatic Animals Commission reviewed the two chapters. The Commission requested that the International Trade Department review the relevant chapters in the *Aquatic* and *Terrestrial Codes* and provide an amended text to the Commission for consideration at their March 2013 meeting.

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

Extensive comments were received from Member Countries on many of the articles in this chapter. After consideration of these comments, the Aquatic Animals Commission agreed that the chapter required a fundamental review. This item has been included in the Aquatic Animals Commission work plan and at its March 2013 meeting the Commission will develop a Concept Note on how to review the purpose, scope and content of Chapter 6.1. This review will take into account all comments received from Member Countries.

#### 2.7. Infectious salmon anaemia (Chapter 10.5.)

The Aquatic Animals Commission considered comments provided by Member Countries on the drafts provided in the September 2011 and March 2012 Commission meeting reports and on the reports of the *ad hoc* Group on Pathogen Differentiation.

The Commission noted that several approaches to address the different levels of risk presented by HPR0 and HPR-deleted infectious salmon anaemia virus have been provided to Member Countries for comments in previous reports of the Aquatic Animals Commission (September 2011 and February 2012). These approaches present different levels of risk management to facilitate the safe international trade in aquatic animals and their products with respect to ISAV.

These approaches are summarised in the table below:

**Table 1. Approaches for the management of different levels of risk posed by ISAV**

Approaches	Level of risk management	Implications / comments
1.	Highest: <ul style="list-style-type: none"> <li>- trade measures include both HPR0 ISAV and HPR-deleted ISAV without differentiation;</li> <li>- reporting for both HPR0 ISAV and HPR-deleted ISAV without differentiation.</li> </ul>	<ul style="list-style-type: none"> <li>- maintains the status quo for the current <i>Aquatic Code</i> chapter;</li> <li>- no differentiation of risk between HPR0 ISAV and HPR-deleted ISAV;</li> <li>- concern of requiring trade measures for a non-pathogenic form (HPR0 ISAV) of a pathogen (even though it has been substantiated to be putatively pathogenic after mutation (deletion) in the HPR region);</li> <li>- declaration of freedom from ISA requires freedom from both HPR0 ISAV and HPR-deleted ISAV. It does not enable countries with HPR0 only any advantage although they are a lower risk than countries infected with both HPR0 ISAV and HPR-deleted ISAV.</li> </ul>
2.	High: <ul style="list-style-type: none"> <li>- separate trade measures for HPR0 and HPR-deleted ISAV;</li> <li>- reporting for both HPR0 ISAV and HPR-deleted ISAV with differentiation.</li> </ul>	<ul style="list-style-type: none"> <li>- recommended approach by Aquatic Animals Commission;</li> <li>- differentiation of the risk between HPR0 ISAV and HPR-deleted ISAV;</li> <li>- less restrictive trade measures;</li> <li>- reporting will provide information on HPR0 ISAV and HPR-deleted ISAV.</li> </ul>
3.	Medium: <ul style="list-style-type: none"> <li>- trade measures for HPR-deleted ISAV only;</li> <li>- reporting for both HPR0 ISAV and HPR-deleted ISAV.</li> </ul>	<ul style="list-style-type: none"> <li>- trade measures apply to HPR-deleted ISAV but not HPR0;</li> <li>- the lower risk presented by HPR0 is not addressed by trade measures;</li> <li>- reporting will provide information on HPR0 and HPR-deleted ISAV.</li> </ul>
4.	Low: <ul style="list-style-type: none"> <li>- trade measures for HPR-deleted ISAV only;</li> <li>- reporting for HPR-deleted ISAV only.</li> </ul>	<ul style="list-style-type: none"> <li>- trade measures apply to HPR-deleted ISAV only;</li> <li>- the lower risk presented by HPR0 is not addressed by trade standards;</li> <li>- reporting will provide information on HPR-deleted ISAV only.</li> </ul>

The Aquatic Animals Commission wished to reiterate to Member Countries that the current *Aquatic Code* chapter for ISA (approach 1) clearly applies to the virus species ISAV, which includes both HPR0 ISAV and HPR-deleted ISAV. This is the correct interpretation of the current ISA *Aquatic Code* chapter that should be applied by Member Countries.

The Aquatic Animals Commission received comments from a Member questioning the link between non-pathogenic HPR0 ISAV and the emergence of pathogenic HPR deleted ISAV. The Commission noted that there is a growing body of scientific information that indicates that ISA outbreaks may occur as a result of the emergence of HPR-deleted ISAV from HPR0 ISAV. The Aquatic Animals Commission considered some specific examples of the scientific evidence for phylogeographic associations between HPR0 ISAV and HPR-deleted ISAV [e.g. Christiansen D.H. *et al.*, 2011. A

low-pathogenic variant of infectious salmon anemia virus (ISAV-HPR0) is highly prevalent and causes a non-clinical transient infection in farmed Atlantic salmon (*Salmo salar* L.) in the Faroe Islands. *J. Gen. Virol.*, **92**, 909–918; Lyngstad T.R., 2012. Tracing transmission pathway for infectious salmon anaemia virus. Thesis for the degree of Philosophiae Doctor Norwegian School of Veterinary Science]. The Aquatic Animals Commission agreed that HPR0 ISAV must be considered putatively pathogenic due to the possibility of emergence of pathogenic strains (Cunningham *et al.*, [2002]) A novel variant of the infectious salmon anaemia virus (ISAV) haemagglutinin gene suggests mechanisms for virus diversity. *Bull. Eur. Assoc. Fish Pathol.*, **22**, 366–374; McBeath *et al.*, 2011. Presence of a full-length highly polymorphic region (HPR) in the ISAV haemagglutinin-esterase does not affect the primary functions of receptor binding and esterase activity. *Arch. Virol.*, **156**, 2285–2289]. Current evidence indicates the risk is low but not negligible.

The Aquatic Animals Commission noted that there are three possible levels of disease status with respect to ISAV:

1. HPR-deleted ISAV and HPR0 ISAV endemic;
2. HPR0 ISAV endemic (but HPR-deleted ISAV free);
3. HPR-deleted ISAV and HPR0 ISAV free.

The Aquatic Animals Commission agreed that the different levels of risk presented by HPR-deleted ISAV and HPR0 ISAV, and the possibility of three levels of health status with respect to ISAV, warrant differentiation of HPR-deleted ISAV and HPR0 ISAV for trade measures and reporting requirements.

Approaches 2 and 3 (see Table 1 above) to risk management differentiate risk posed by HPR-deleted ISAV and HPR0 ISAV respectively.

The Aquatic Animals Commission considered that Approach 3 does not take into account residual risk posed by HPR0 ISAV to mutate to virulent forms of the virus.

The Aquatic Animals Commission agreed that Approach 2, as circulated to Members for comment in the September 2011 Commission meeting report, would best manage the different levels of risk presented HPR-deleted ISAV and HPR0 ISAV. This approach would allow recognition of three levels of health status and assist members with differing health status to trade safely. The current *Aquatic Code* chapter does not provide this level of flexibility because it treats HPR-deleted ISAV and HPR0 ISAV as equal risks.

The Aquatic Animals Commission requested that the *Aquatic Manual* chapter be revised (refer to Item 3.1).

The Aquatic Animals Commission reviewed and amended Chapter 10.5. to reflect Approach 2.

Due to the extensive modification and restructuring of the previous draft text, the Commission decided to present this text as a clean document (i.e. without track changes).

The revised Chapter 10.5. is presented at [Annex 7](#) for Member comment.

#### EU comment

**The EU supports option number 2 as described above, which is also the approach recommended by the OIE Aquatic Animal Commission and is consistent with the recent EFSA opinion (cf. <http://www.efsa.europa.eu/en/efsajournal/pub/2971.htm>). However, Chapter 10.5 should clearly distinguish between HPR-deleted or HPR0 ISAV, both in relation to the notification obligations (ISAV strain differentiation should be required when notifying cases of ISAV) and the recommendations for trade, taking into account the different level of risk posed by the virulent HPR-deleted or non-virulent HPR0**

**ISAV. Nevertheless, the trade recommendations should allow a country free from HPR0 ISAV (or with an eradication program regarding HPR0 ISAV) to prevent the importation of live fish infected or contaminated with HPR0 ISAV.**

**Further comments are inserted in the text of Annex 7.**

### **3. Manual of Diagnostic Tests for Aquatic Animals**

Ms Sara Linnane, Scientific Editor, from the Scientific and Technical Department, provided an update on this item.

#### **3.1. Update on the status of the seventh edition of the Aquatic Manual**

The seventh edition of the *Aquatic Manual* was adopted at the General Session in May 2012 with the exception of the chapter on infectious salmon anaemia. Publication has been delayed, but it is hoped that an updated online version will be available by the end of the year. At present, a new edition of the *Aquatic Manual* is published every three years. To avoid workload coinciding with publication of new editions of the *Terrestrial Manual*, the Aquatic Animals Commission agreed to extend the publication cycle by one year (i.e. publish a new edition every four years) beginning in 2014.

The Aquatic Animals Commission confirmed a previous agreement to identify annually a limited number of chapters that need to be updated, rather than to update all the chapters at one time. This approach was also followed by the Biological Standards Commission for the *Terrestrial Manual*. To assist the Aquatic Animals Commission to identify chapters, authors will be asked annually if their chapters need to be updated. The online version of the *Aquatic Manual* therefore will remain the most up-to-date version.

For the coming year, the Aquatic Animals Commission identified: epizootic ulcerative syndrome, infectious salmon anaemia and infection with ostreid herpesvirus for update; the latter two chapters received a large volume of Member Country comments in the previous review cycle and all three chapters need to be amended in line with their corresponding updated *Aquatic Code* chapter.

The following amendments were requested to the *Aquatic Manual* chapters for:

#### **ISA:**

- update the scientific information on the potential risk of transition of HPR0 to a deleted variant, taking into account the upcoming EFSA report;
- update information on diagnostic methods for differentiation (suspect and confirmed cases) between HPR0 ISAV and HPR-deleted ISAV, to reflect the definition of ISA in Chapter 10.5.

#### **EUS:**

- revise section 7 (Corroborative diagnostic criteria) to ensure that the definitions for 'suspect case' and 'confirmed case' take account of differences in geographical distribution of the pathogen. Such an approach has been taken in Chapter 2.4.3. Infection with *Bonamia ostreae* and could be applied in the EUS chapter.

#### **OsHV-1 $\mu$ var:**

- add more information focusing the chapter on OsHV-1  $\mu$  var;
- update information on diagnostic methods for differentiation (suspect and confirmed cases).

Apart from these chapters, the Aquatic Animals Commission noted that the experts on viral encephalopathy and retinopathy had collaborated to produce an updated consensus chapter. Should the Aquatic Animals Commission be satisfied with the updates, all four chapters will be circulated for Members' comment following the next meeting in March 2013.

### **EU comment**

**The EU would like to reiterate its previous comment on the importance of adopting the corresponding Aquatic Code and Manual chapters on ISA and OsHV-1 concurrently, as the case definitions in the Code and the definition of a confirmed case in the Manual go hand in hand.**

#### **3.2. Comments received on the chapters that were adopted at the General Session**

The Aquatic Animals Commission was grateful to those Member Countries that had sent comments on chapters that had been adopted at the General Session. These comments would be provided to the experts for consideration when they are invited to update their chapters.

#### **3.3. Report of the meeting of the OIE *ad hoc* Group on Aquatic Animal Health Surveillance**

The Aquatic Animals Commission considered the report of the *ad hoc* Group on Aquatic Animal Health Surveillance (3–4 July 2012) which included three stand-alone documents presented as worked examples on how to develop surveillance systems specific for a fish, a mollusc and a crustacean disease (Viral haemorrhagic septicaemia, *Bonamia ostreae*, White spot disease respectively).

The Aquatic Animals Commission agreed to review the documents provided. Once the review process is complete, the documents will be given an ISBN number and published on the Commission's web page.

#### **3.4. Criteria for Listing Aquatic Animal Species as Susceptible to Infection with a Specific Pathogen**

The Aquatic Animals Commission reconsidered the use of the criteria for listing aquatic animal species as susceptible and agreed that they should be included in the *Aquatic Code* to ensure consistency in the way susceptible species are listing in *Code* and *Manual* chapters.

The Aquatic Animals Commission considered this to be an important item. It is included in the work plan and will be discussed at the March 2013 meeting.

### **4. OIE Reference Centres**

#### **4.1. Report of an OIE mission to evaluate the performance of an OIE Reference Laboratory**

The Aquatic Animals Commission was informed that the OIE headquarters is keen to ensure the highest standard in the quality of services offered by the OIE Reference Centres in accordance with their terms of reference as provided for in the Basic Texts and that the OIE was willing to deploy expert missions, where appropriate, to visit selected OIE Reference Centres on an *ad hoc* basis.

In this connection the Commission noted the report of a recent OIE mission to visit one of the OIE Reference Laboratories. The Commission found the report to be a factual and fair account of the situation under which the laboratory operates and noted the recommendations contained in the report.

The Commission members expressed the view that it is essential that all OIE Reference Laboratories operate within a functional quality system. It recommended that the OIE conduct similar on-site visits to other Reference Laboratories.

#### **4.2. Presentation of the proposed new annual report template**

Dr Raffaella Nisi joined the meeting for this agenda item to present the proposed new annual report template. Dr Nisi explained that the new template would allow the automatic compilation of key quantitative information on OIE Reference Centres. It should facilitate networking between OIE Reference Laboratories through the easy online access to qualitative data, as well as allowing random surveys of laboratory performance, and fulfilment of the Terms of Reference of the growing number of OIE Reference Laboratories. The new template has been designed as a web-based format, linked to software that will allow data to be analysed and converted into maps and graphs. This should enable trends in activities to be determined. The reformatted template has been structured around each Term of Reference for OIE Reference Laboratories. Questions are closed (yes/no answers) to generate more accurate and comparable information from the laboratories. Tables to allow for the collection of detailed information related to the activities carried out by the laboratories have also been included.

The Aquatic Animals Commission welcomed the new annual report template. A non-interactive mock-up of the template is available on the web site at: <http://www.oie.int/eng/sst/quest.htm>.

A fully working version of the template should be available for the 2013 reports. For the 2012 reports, this template will be used but as a Microsoft Word document rather than a web-based tool.

## 5. Laboratory Twinning Projects

Dr Keith Hamilton updated the Commission on OIE Laboratory Twinning, providing the new members with background on the programme and its principles. The Commission agreed that to expedite the approval process for Aquatic Animal Health Twinning Projects they would be happy to review proposals and provide technical input electronically and outside the biannual Commission meetings. The Commission also acknowledged that, with only one Twinning project for an aquatic animal disease out of a total of 40 which have been initiated, aquatic animal diseases were considerably underrepresented in the programme. The Aquatic Animals Commission recommended that more should be done to promote twinning for aquatic animal diseases and to identify priorities at the OIE regional meetings.

Dr Hamilton presented the three latest Twinning proposal applications to the Aquatic Animals Commission (U.S.A – China for infectious haematopoietic necrosis (IHN); U.S.A – Indonesia for crustacean/shrimp diseases; Japan –Indonesia for Koi herpes virus). The Aquatic Animals Commission members welcomed all three proposals and agreed to submit more detailed technical feedback to Dr Hamilton, who will relay this to the applicants.

## 6. OIE Register of diagnostic tests

Dr François Diaz informed the Aquatic Animals Commission on the OIE Procedure for Registration of Diagnostic Kits.

He informed the Aquatic Animals Commission that the diagnostic kit (IQ 2000™ WSSV Detection and Prevention System), added to the OIE Register in 2008, had undergone a scheduled reassessment. The Aquatic Animals Commission was informed that OIE experts for the disease targeted by the kit had been consulted and asked their opinion on the need for a new evaluation of the certified kit. The outcome of the consultation was that there is no need for a new evaluation. The Aquatic Animals Commission was not aware of any reason to disagree with the experts. The Aquatic Animals Commission proposed renewal of the registration for this kit, according to the OIE procedure.

## 7. Other relevant activities

### 7.1. OIE *ad hoc* Group on Evaluation of AAHS

Dr Alicia Gallardo Lagno, Chair of the *ad hoc* Group on Evaluation of Aquatic Animal Health Services, informed the Aquatic Animals Commission that the Group held its first meeting in August 2012 to develop a stand-alone PVS Tool for the Evaluation of Performance of Aquatic Animal Health Services (AAHS). The *ad hoc* Group reviewed the draft sixth edition of the PVS Tool for the Evaluation of Performance of Veterinary Services and amended specific critical competencies (CC), Levels of Advancement and Indicators so that the Tool was appropriate for the evaluation of performance of AAHS. The *ad hoc* Group noted that the majority of CC were applicable to the

evaluation of AAHS. However, the following CC were amended because of differences when considering AAHS: CC I-1 Professional and technical staffing of the Veterinary Services or Aquatic Animal Health Services; CC I-2 Competencies of veterinarians or aquatic animal health professionals, and other technical personnel; CC II-8 Food safety; CC II-12 Traceability; CC III-5 Veterinary Statutory Body and other professional authorities. Dr Gillian Mylrea reported that the new OIE PVS Tool – Aquatic would be printed in a booklet form and made available on the OIE website in early 2013.

The Commission endorsed the development of a stand-alone PVS Tool – Aquatic and again encouraged Member Countries to request OIE PVS evaluations of AAHS with a view to obtaining needed investments on the parts of governments and donors to strengthen governance of AAHS.

## **8. Cooperation with FAO**

Dr Melba Reantaso gave a brief historical account of cooperation on aquatic animal health (AAH) between OIE and FAO, through the Department of Fisheries and Aquaculture (FAO/FI), which spanned 20 years including 18 years with as an Observer on the Aquatic Animals Commission. OIE had contributed to FAO's regional technical cooperation projects and activities in Asia, Africa, Western Balkan as well as normative work on prudent and responsible use of veterinary medicines and aquaculture certification guidelines. FAO had participated in a number of OIE *ad hoc* Groups, OIE Global conferences on aquatic animal health (Panama and Norway) and workshops for OIE focal points on aquatic animals. Under the FAO Crisis Management Center-Food Chain programme, the most recent cooperation was during the emergency investigation of a significant new shrimp disease in Vietnam and white spot disease of shrimp in Mozambique. Dr Reantaso noted the very positive outcomes resulting from recent meetings between Dr Vallat and the FAO Fisheries Assistant Director General Arni Mathiesen and the FAO Director General Dr Jose Graziano da Silva which renewed institutional commitments to jointly address issues on aquatic animal diseases and aquaculture. This will pave the way for a new agreement to be developed on between the OIE and FAO on aquaculture activities.

## **9. Next meeting**

The Aquatic Animals Commission proposed to hold their next meeting on 11–15 March 2013.

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.../ Annexes

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

**Paris, 24–28 September 2012**

**List of participants**

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Annex 1 (contd)

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

**Paris, 24–28 September 2012**

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**Adopted agenda**

**Welcome and meeting with the OIE Director General**

**1. General discussion and work plan**

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

- 2.1. Glossary
- 2.2. Chapter 1.1. Notification of Diseases and Epidemiological Information
- 2.3. Chapter 1.2. Criteria for listing aquatic animal diseases
- 2.4. Chapter 1.3. Diseases listed by the OIE
  - 2.4.1. Infection with ostreid herpesvirus-1 (OsHV-1  $\mu$ var) as an emerging disease
  - 2.4.2. Infectious salmon anaemia
  - 2.4.3. Epizootic ulcerative syndrome
  - 2.4.4. Pancreas disease
- 2.5. Import risk analysis (Chapter 2.2.)
- 2.6. Control of hazards in aquatic animal feed (Chapter 6.1.)
- 2.7. Infectious salmon anaemia (Chapter 10.5.)

**3. OIE *Manual of Diagnostic Tests for Aquatic Animals***

- 3.1. Update on the status of the seventh edition of the *Aquatic Manual*
- 3.2. Comments received on the chapters that were adopted at the General Session
- 3.3. Report of the meeting of the OIE *ad hoc* Group on Aquatic Animal Health Surveillance
- 3.4. Criteria for Listing Aquatic Animal Species as Susceptible to Infection with a Specific Pathogen

**4. OIE Reference Laboratories and Collaborating Centres**

- 4.1. Report of an OIE mission to evaluate the performance of an OIE Reference Laboratory
- 4.2. Presentation of the proposed new annual report template

**5. Laboratory Twinning Projects**

Annex 2 (contd)

**6. OIE Register of diagnostic tests**

**7. Other relevant activities**

7.1. OIE *ad hoc* Group on Evaluation of AAHS

**8. Cooperation with FAO**

**9. Other business**

9.1. Meeting dates for 2013

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## GLOSSARY

### EU comments

The EU thanks the OIE and in general supports the proposed changes to the glossary.

However, the EU questions whether it is necessary, for the purposes of the Aquatic Code, to limit the definition of Aquatic animal health professional (AAHP) to those persons carrying out tasks under the responsibility and direction of the Competent Authority (CA). This would exclude persons working e.g. in the private sector (comparable to private veterinarians), which would not be referred to as AAHP as they are not under the responsibility and direction of the CA, thus excluding them from obligations and responsibilities as foreseen in various parts of the Aquatic Code. Of note, this requirement is not foreseen in the definition of "official veterinarian" in the Terrestrial Code.

In the proposed new definition for aquatic animal health professional, as well as in the existing definition of Aquatic Animal Health Services, the word "territory" should be italicised to make reference to the glossary definition of that term.

Furthermore, to avoid confusion, in the proposed consequential change to the definition of Aquatic Animal Health Services, the EU would prefer keeping the term veterinary paraprofessionals, by replacing the word "or" by "including", as follows:

*"Aquatic Animal Health Services*

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

### *Aquatic animal health professional*

means a person who, for the purposes of the Aquatic Animal Health Code, is authorised by the Competent Authority to carry out certain designated tasks in a territory, is under the responsibility and direction of the Competent Authority, and has the appropriate qualifications and training to perform the designated tasks.



## CHAPTER 1.1.

NOTIFICATION OF DISEASES AND  
EPIDEMIOLOGICAL INFORMATION**EU comments**

**The EU in general supports the proposed changes to this chapter but has a comment that is inserted in the text below.**

## Article 1.1.1.

For the purposes of the *Aquatic Code* and in terms of Articles 1.1.5, 1.1.9 and 1.1.10 of the OIE Organic Statutes, every Member of the OIE shall recognise the right of the *Headquarters* to communicate directly with the *Veterinary Authority* of its *territory* or *territories*.

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

## Article 1.1.2.

1. ~~Countries~~ Members shall make available to other ~~countries~~ Members, through the OIE, whatever information is necessary to minimise the spread of important aquatic animal diseases of aquatic animals and their ~~aetiological~~ pathogenic agents and to assist in achieving better world-wide control of these *diseases*.
2. To achieve this, ~~countries~~ Members shall comply with the ~~reporting~~ notification requirements specified in Article 1.1.3.
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 *pathogenic agents* and *diseases* is constantly ~~evolving~~ developing and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, ~~countries~~ Members shall ensure through their reports that they comply with the spirit and intention of ~~paragraph point~~ 1 above. This means that the presence of an infectious agent, even in the absence of clinical ~~disease signs~~, should be reported.
5. In addition to notifying findings in accordance with Article 1.1.3., ~~countries~~ Members 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~~ which 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 ~~described~~ specified.

## Article 1.1.3.

The *Veterinary Authority* shall, under the responsibility of the Delegate, send to Headquarters:

1. in accordance with relevant provisions in the *disease* specific chapters, immediate *notification*, through the World Animal Health Information System (WAHIS) or by fax or e-mail within 24 hours of any of the following events:

**EU comment**

The use of the term *notification* throughout the chapter should be coherent with the definition in the glossary. Indeed, according to the definition, all information on the occurrence of an *outbreak of a disease or infection* sent to *Headquarters* by the *Veterinary Authority* and vice-versa according to the provisions of this chapter is considered as *notification*. This would include *notification* within 24 hours (which is referred to as "immediate notification" in this Chapter), weekly, 6-monthly and annual reports.

Therefore, the EU questions the added value of the word "immediate" in the above point or elsewhere in the Code, as it is confusing and does not improve the text. Indeed, the word "immediate" is less precise and contradicts the concept of "within 24 hours".

- a) ~~for diseases listed by the OIE, the first occurrence or re-occurrence of a disease in a country or zone or compartment of the country, if the country or zone or 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~~
- e) ~~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 the disease has a newly recognised zoonotic potential; or~~
- e) ~~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.~~
- a) first occurrence of a listed disease in a country, a zone or a compartment;
- b) re-occurrence of a listed disease in a country, a zone or a compartment following a report that declared an outbreak ended;
- c) first occurrence of a new strain of a pathogen of a listed disease new to a country, a zone or a compartment;
- d) a sudden and unexpected increase in the distribution, incidence, morbidity or mortality of a listed disease prevalent within a country, a zone or a compartment;
- e) evidence of change in the epidemiology of a listed disease (including host range, pathogenicity, strain) in particular if there is a zoonotic impact;
- f) an emerging disease or the pathogenic agent with significant morbidity or mortality, or zoonotic potential.

### EU comment

The EU is of the opinion that the notion of "pathogenic agent" in point f) above is too broad and unclear to be included in the concept of "emerging diseases". It is also to be noted that "pathogenic agents" are not included in the corresponding provision of the Terrestrial Code. Therefore, the words "or the pathogenic agent" should be deleted.

Furthermore, the EU invites the OIE to consider inverting points e) and f) above, to be in line with the corresponding provision of the Terrestrial Code.

In deciding whether findings justify immediate *notification* (within 24 hours), ~~countries~~ Members must ensure that they comply with the obligations of Chapters 5.1. and 5.2. of the *Aquatic Code* (especially Article 5.1.1.), to report developments that may have implications for *international trade*.

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

3. Six-monthly reports on the absence or presence and evolution of *diseases listed diseases by the OIE*, and information of epidemiological significance to other countries Members with respect to diseases that are not listed.
4. ~~An Annual questionnaire reports~~ concerning any other information of significance to other countries Members.

~~Article 1.1.4.~~

1. The *Veterinary Authority* of a country in which an *infected zone* or *compartment* was located shall inform the *Headquarters* when this *zone* or *compartment* is free from the *disease*.
2. An *infected zone* or *compartment* ~~of a~~ for a particular disease shall be considered as such until a period exceeding the ~~known infective period for the disease in question~~ specified in the Aquatic Code has elapsed after the last reported ~~case, outbreak~~ and when full prophylactic and appropriate ~~sanitary animal health~~ sanitary animal health 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 ~~Section 8 to 11 of the Aquatic Code~~.
3. A Member may ~~be considered to regain freedom~~ again declare itself free (i.e. self-declaration of freedom from disease) from a specific *disease* when it ~~complies with all the conditions given in the corresponding relevant chapters of Section 8 to 11 of the Aquatic Code~~ have been fulfilled.
4. ~~The Veterinary Authority of a Country in which one or more free zones or compartments have been established may wish to inform the Headquarters, giving necessary particulars, of the zones or compartments and describing their location (e.g. by a map or other precise locators such as GPS [Global Positioning System] co-ordinates). The Headquarters may publish this information. The Veterinary Authority of a Country Member in which sets up one or more several free zones or compartments have been established may wish to~~ shall inform the *Headquarters*, giving necessary particulars details, of the *zones* or *compartments* and describing their location (e.g. by a map or other precise locators such as GPS [Global Positioning System] co-ordinates). ~~The Headquarters may publish this information.~~ including the criteria on which the free status is based, the requirements for maintaining the status and indicating clearly the location of the zones or compartments on a map of the territory of the Member.

~~Article 1.1.5.~~

1. ~~The Headquarters shall send by fax or e-mail to the Veterinary Authority concerned, all notifications received as provided in Articles 1.1.2. 1.1.4.~~
2. ~~The Headquarters shall notify Members through Disease Information of any event of exceptional epidemiological significance reported by a Member.~~

**EU comment**

**As for the relevant article of the Terrestrial Code, the EU questions the necessity to delete Article 1.1.5. as it does not relate to mere internal procedures at Headquarters but specifies the notification obligations of the OIE towards its Member Countries (cf. definition of notification in the glossary), which should be kept in this chapter.**

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— Text deleted





## CHAPTER 1.2.

CRITERIA FOR LISTING  
AQUATIC ANIMAL DISEASES**EU comments**

**The EU cannot support the proposed changes to this chapter, i.e. the newly drafted Article 1.2.1., as it does not agree with the rationale for the differentiation between diseases listed in accordance with Article 1.2.1 and those listed as emerging diseases in accordance with Article 1.2.2. (cf. EU comments under point 2.3. of the report).**

**Furthermore, the EU would like to invite the OIE to consider whether it is necessary to keep a separate article for emerging diseases or whether Articles 1.2.1 and 1.2.2 could be merged into one single article, similar to the corresponding Article in the Terrestrial Code. This would also seem sensible since there is only one list of aquatic diseases in Chapter 1.3 which does not distinguish between "regular" and emerging diseases.**

**Further comments are inserted in the text below.**

Article 1.2.1.Introduction

This chapter describes the criteria for listing *diseases* in Chapter 1.3 of the *Aquatic Code*. The objective of listing is to support Members' efforts to prevent the transboundary spread of important *diseases of aquatic animals* through transparent and consistent reporting.

For the *diseases* listed in accordance with Article 1.2.2., the corresponding disease-specific chapters in the *Aquatic Code* provide standards for safe international trade in *aquatic animals* and their products.

The purpose of listing *diseases* in accordance with Article 1.2.3. is to collect epidemiological information to improve understanding of an *emerging disease*. This information is collected to enable later consideration of listing of the *disease* in accordance with Article 1.2.2. *Diseases* listed in accordance with Article 1.2.3. do not have a corresponding disease-specific chapter in the *Aquatic Code*.

The requirements for notification of *listed diseases* are detailed in Chapter 1.1.

Article 1.2.1-1.2.2.**Criteria for listing an aquatic animal disease**

*Diseases* proposed for listing should meet the relevant criteria as set out in A. Consequences, B. Spread and C. Diagnosis. Therefore, to be listed, a *disease* should have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8. Such proposals should be accompanied by a *case definition* for the *disease* under consideration.

No.	Criteria for listing	Explanatory notes
<b>A. Consequences</b>		
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 species, and that morbidity or mortality are related primarily to the infectious 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

No.		Criteria for listing	Explanatory notes
			quality.
2.	Or	The disease has been shown to or scientific evidence indicates that it is likely to cause significant morbidity or mortality in wild aquatic animal populations.	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.	

No.		Criteria for listing	Explanatory notes
<b>And B. Spread</b>			
4.		Infectious aetiology of the disease is proven.	
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	Likelihood of international spread, including via live animals, their products or fomites.	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 likely.
7.	And	Several countries or countries with zones may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.4. of the <i>Aquatic Code</i> .	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 propose 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.
<b>And C. Diagnosis</b>			
8.		A repeatable and 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 <i>Aquatic Manual</i> .) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

Article ~~1.2.2-1.2.3.~~

**Criteria for listing an emerging aquatic animal disease**

~~An newly recognised~~ **emerging disease** ~~or a known disease behaving differently~~ may be proposed for listing if it meets the criteria 1 or 2, and 3 or 4. Such proposals should be accompanied by a *case definition* for the *disease* under consideration.

**EU comment**

**The EU can support the proposed changes to the first sentence of this article.**

No.	Criteria for listing	Explanatory notes
1.	Infectious aetiology of the disease is proven.	
Or		
2.	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.
And		
3.	The agent is of public health concern.	
Or		
4.	Significant spread in naive populations of wild or cultured aquatic animals.	The disease has exhibited significant morbidity, mortality or production losses at a zone, compartment or country level. 'Naive' means animals previously unexposed either to a new disease or a new form of a known disease.

#### EU comment

**The explanatory notes of point 4 above, which describe the consequences of the disease, do not seem to match well with the corresponding criteria, which speak only of spread. The EU therefore suggests adding the words "and impact" after the words "significant spread" in criteria number 4.**

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— Text deleted



## CHAPTER 1.3.

## DISEASES LISTED BY THE OIE

**EU comments**

**The EU thanks the OIE and supports the proposed changes to this chapter.**

**However, for ISA and OsHV-1  $\mu$ var, the concurrent adoption of the corresponding Aquatic Manual chapters, reviewed accordingly, should be ensured.**

**Preamble:** The following *diseases* are listed by the OIE according to the criteria for listing an *aquatic animal disease* (see Article 1.2.2.) or criteria for listing an *emerging aquatic animal disease* (see Article 1.2.3.).

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

## Article 1.3.1.

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

- Epizootic haematopoietic necrosis
- ~~Epizootic ulcerative syndrome~~ Infection with *Aphanomyces invadans* (epizootic ulcerative syndrome)
- Infection with *Gyrodactylus salaris*
- Infection with salmon pancreas disease virus
- Infectious haematopoietic necrosis
- Infectious salmon anaemia (infection with HPR-deleted or HPR0 infectious salmon anaemia virus)
- Koi herpesvirus disease
- Red sea bream iridoviral disease
- Spring viraemia of carp
- Viral haemorrhagic septicaemia.

## Article 1.3.2.

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

- Infection with abalone herpes virus
- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*
- Infection with ostreid herpesvirus-1  $\mu$ var (OsHV-1  $\mu$ var)<sup>1</sup>.

Annex 6 (contd)

Article 1.3.3.

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

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

Article 1.3.4.

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

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

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— Text deleted

<sup>1</sup> Listed according to Article 1.2.3.

## CHAPTER 10.5.

## INFECTIOUS SALMON ANAEMIA

**EU comments**

**The EU supports option number 2 as described above, which is also the approach recommended by the OIE Aquatic Animal Commission and is consistent with the recent EFSA opinion (cf. <http://www.efsa.europa.eu/en/efsajournal/pub/2971.htm>). However, Chapter 10.5 should clearly distinguish between HPR-deleted or HPR0 ISAV, both in relation to the notification obligations (ISAV strain differentiation should be required when notifying cases of ISAV) and the recommendations for trade, taking into account the different level of risk posed by the virulent HPR-deleted or non-virulent HPR0 ISAV. Nevertheless, the trade recommendations should allow a country free from HPR0 ISAV (or with an eradication program regarding HPR0 ISAV) to prevent the importation of live fish infected or contaminated with HPR0 ISAV.**

**Further comments are inserted in the text below.**

## Article 10.5.1.

For the purposes of the *Aquatic Code*, infectious salmon anaemia (ISA) means *infection* with ISA virus (ISAV) of the genus *Isavirus* of the family Orthomyxoviridae. This includes infection with HPR-deleted ISAV or HPR0 ISAV.

There is a link between non-pathogenic HPR0 ISAV and the emergence of pathogenic HPR-deleted ISAV, with some outbreaks potentially occurring as a result of the emergence of HPR-deleted from HPR0.

There are 3 possible levels of disease status with respect to ISAV: (i) HPR-deleted ISAV and HPR0 ISAV free; (ii) HPR0 ISAV endemic (but HPR-deleted ISAV free); (iii) HPR-deleted ISAV and HPR0 ISAV endemic.

**EU comment**

**The EU supports this concept of 3 possible levels of disease status. However, this needs also to be reflected in different recommendations for trade, taking into account the different level of risk associated with animals and products originating from countries, zones or compartments with different disease status.**

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

## Article 10.5.2.

**Scope**

The recommendations in this Chapter apply to: Atlantic salmon (*Salmo salar*), brown trout (*S. trutta*) and rainbow trout (*Oncorhynchus mykiss*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

## Article 10.5.3.

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



1. *Competent Authorities* should not require any ISA related conditions, regardless of the ISA status of the *exporting country, zone or compartment* when authorising the importation or transit of the following *aquatic animals* and *aquatic animal products* from the species referred to in Article 10.5.2. intended for any purpose and complying with Article 5.3.1.:
  - a) heat sterilised, hermetically sealed fish products (i.e. a heat treatment at 121°C for at least 3.6 minutes or any time/temperature equivalent);
  - b) pasteurised fish products that have been subjected to a heat treatment at 90°C for at least 10 minutes (or to any time/temperature equivalent which has been demonstrated to inactivate ISAV);
  - c) mechanically dried, eviscerated fish (i.e. a heat treatment at 100°C for 30 minutes or any time/temperature equivalent which has been demonstrated to inactivate ISAV);
  - d) fish oil;
  - e) fish *meal*; and
  - f) fish skin leather.

#### **EU comment**

**The points d) and e) above should be revised. As these products may be used as fish feed, the production process should ensure the inactivation of the virus.**

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.5.2., other than those referred to in point 1 of Article 10.5.3., *Competent Authorities* should require the conditions prescribed in Articles 10.5.10. to 10.5.17. relevant to the ISA status of the *exporting country, zone or compartment*.
3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country, zone or compartment* not declared free of ISA of a species not covered in Article 10.5.2. but which could reasonably be expected to pose a *risk* of transmission for ISA, *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code*. The *exporting country* should be informed of the outcome of this assessment.

#### Article 10.5.4.

#### **Country free of infectious salmon anaemia**

In this article, all statements refer to a country free of infection with ISAV for any detectable ISAV, including HPR0 ISAV.

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from ISA if all the areas covered by the shared water are declared ISA free countries or *zones* (see Article 10.5.5.).

1. A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from ISA when *basic biosecurity conditions* have been continuously met in the country for at least the past two years.

OR

2. A country where the species referred to in Article 10.5.2. are present but there has been no detectable occurrence of the any ISA virus may make a *self-declaration of freedom* from ISA when:
  - a) *basic biosecurity conditions* have been continuously met for at least the past two years; and

- b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV.

OR

- 3. A country that has made a *self-declaration of freedom* from ISA but in which any ISAV is subsequently detected may make a *self-declaration of freedom* from ISA again when the following conditions have been met:
  - a) on detection of any ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
  - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV; and
  - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past two years.

In the meantime, part of the non-affected area may be declared a *free zone* provided that such part meets the conditions in point 3 of Article 10.5.6.

#### Article 10.5.5.

#### Country free of infection with HPR-deleted infectious salmon anaemia virus

In this article, all statements refer to a country free of infection with HPR-deleted ISAV but not necessarily free from HPR0 ISAV.

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

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from infection with HPR-deleted ISAV if all the areas covered by the shared water are declared countries or *zones* free of infection with HPR-deleted ISAV (see Article 10.5.6.).

- 1. A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the country for at least the past two years.

OR

- 2. A country where the species referred to in Article 10.5.2. are present but there has been no observed occurrence of the *disease* for at least the past ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may make a *self-declaration of freedom* from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the country for at least the past ten years.

OR

- 3. A country where the last observed occurrence of the *disease* was within the past ten years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the *Aquatic Manual*) may make a *self-declaration of freedom* from infection with HPR-deleted ISAV when:
  - a) *basic biosecurity conditions* have been continuously met for at least the past two years; and
  - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of HPR-deleted ISAV.

OR

4. A country that has made a *self-declaration of freedom* from infection with HPR-deleted ISAV but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from infection with HPR-deleted ISAV again when the following conditions have been met:
- a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
  - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
  - c) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of HPR-deleted ISAV; and
  - d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past two years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that such part meets the conditions in point 3 of Article 10.5.6.

Article 10.5.6.

**Zone or compartment free of infectious salmon anaemia virus**

In this article, all statements referring to a zone or compartment free of ISAV are for any detectable ISAV, including HPR0.

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

1. A *zone* or *compartment* where none of the *susceptible species* is present may be declared free from ISA when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past two years.

OR

2. A *zone* or *compartment* where the species referred to in Article 10.5.2. are present but there has been no detectable occurrence of ISA virus (including HPR0) may be declared free from ISA when
  - a) *basic biosecurity conditions* have been continuously met for at least the past two years; and
  - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV.

OR

3. A *zone* or *compartment* previously declared free from any ISA virus but in which any ISA virus is detected, may be declared free from ISA again when the following conditions have been met:
  - a) on detection of ISAV, the affected area was declared an *infected zone* and a *protection zone* was established; and
  - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of ISAV; and
  - c) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past two years.

## Article 10.5.7.

**Zone or compartment free of infection with HPR-deleted infectious salmon anaemia virus**

In this article, all statements referring to a zone or compartment free of infection with HPR-deleted ISAV but not necessarily free from HPR0 ISAV.

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

1. A *zone* or *compartment* where none of the *susceptible species* is present may be declared free from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past two years.

OR

2. A *zone* or *compartment* where the species referred to in Article 10.5.2. are present but there has been no observed occurrence of the *disease* for at least the past ten years despite conditions that are conducive to its clinical expression, as described in the corresponding chapter of the *Aquatic Manual*, may be declared free from infection with HPR-deleted ISAV when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past ten years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past ten years or where the *infection* status prior to *targeted surveillance* was unknown (e.g. because of the absence of conditions conducive to clinical expression as described in the corresponding chapter of the *Aquatic Manual*) may be declared free from infection with HPR-deleted ISAV when:
  - a) *basic biosecurity conditions* have been continuously met for at least the past two years; and
  - b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of HPR-deleted ISAV.

OR

4. A *zone* previously declared free from infection with HPR-deleted ISAV but in which the *disease* is detected may be declared free from infection with HPR-deleted ISAV again when the following conditions have been met:
  - a) on detection of the *disease*, the affected area was declared an *infected zone* and a *protection zone* was established; and
  - b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the *risk* of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and
  - c) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last two years without detection of HPR-deleted ISAV; and
  - d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past two years.

Annex 7 (contd)

## Article 10.5.8.

**Maintenance of free status for infectious salmon anaemia virus**

A country, *zone* or *compartment* that is declared free from ISA following the provisions of point 1. of Articles 10.5.4. or 10.5.7. (as relevant) may maintain its status as ISA free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from ISA following the provisions of point 2 of Articles 10.5.4. or 10.5.7. (as relevant) must continue *targeted surveillance* to maintain its status as ISA free and *basic biosecurity conditions* are continuously maintained.

## Article 10.5.9.

**Maintenance of free status for infection with HPR-deleted infectious salmon anaemia virus**

A country, *zone* or *compartment* that is declared free from infection with HPR-deleted ISAV following the provisions of points 1 or 2 of Articles 10.5.4. or 10.5.6. (as relevant) may maintain its free status provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from infection with HPR-deleted ISAV following the provisions of point 3 of Articles 10.5.4. or 10.5.6. (as relevant) may discontinue *targeted surveillance* and maintain its free status provided that conditions that are conducive to clinical expression of ISA, as described in the corresponding chapter of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in an infected country and in all cases where conditions are not conducive to clinical expression of ISA, *targeted surveillance* needs to be continued at a level determined by the *Aquatic Animal Health Service* on the basis of the likelihood of *infection*.

## Article 10.5.10.

**Importation of live aquatic animals from a country, zone or compartment declared free from infectious salmon anaemia**

When importing live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* certifying that, on the basis of the procedures described in Articles 10.5.4. or 10.5.6. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from ISA.

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

This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

## Article 10.5.11.

**Importation of live aquatic animals from a country, zone or compartment declared free from infection with HPR-deleted infectious salmon anaemia virus**

When importing live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* declared free from infection with HPR-deleted ISAV, 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 10.5.5. or 10.5.7. (as applicable), the place of production of the *aquatic animal* is a country, *zone* or *compartment* declared free from infection with HPR-deleted ISAV.

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

This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.12.

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

1. When importing, for *aquaculture*, live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following *risk* mitigation measures:
  - a) the direct delivery to and lifelong holding of the consignment in biosecure facilities for continuous isolation from the local environment; and
  - b) the treatment of all effluent and waste materials in a manner that ensures inactivation of ISAV.
2. If the intention of the introduction is the establishment of a new stock, relevant aspects of the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES) should be considered.
3. For the purposes of the *Aquatic Code*, relevant aspects of the ICES Code (full version see: <http://www.ices.dk/pubs/Miscellaneous/ICESCodeofPractice.pdf>) may be summarised to the following points:
  - a) identify stock of interest (cultured or wild) in its current location;
  - b) evaluate stock health/disease history;
  - c) take and test samples for ISAV, pests and general health/disease status;
  - d) import and quarantine in a secure facility a founder (F-0) population;
  - e) produce F-1 generation from the F-0 stock in *quarantine*;
  - f) culture F-1 stock and at critical times in its development (life cycle) sample and test for ISAV and perform general examinations for pests and general health/disease status;
  - g) if ISAV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country, zone* or *compartment*, the F-1 stock may be defined as ISA free or specific pathogen free (SPF) for ISAV;
  - h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.
4. With respect to point 3e), *quarantine* conditions should be conducive to multiplication of the pathogen and eventually to clinical expression. If *quarantine* conditions are not suitable for pathogen multiplication and development, the recommended diagnostic approach might not be sensitive enough to detect low *infection* level.

Annex 7 (contd)

## Article 10.5.13.

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

When importing, for processing for human consumption, *aquatic animals* or *aquatic animal products* of species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

- 1 the consignment is delivered directly to and held in *quarantine* or containment facilities until processing into one of the products referred to in point 1 of Article 10.5.3., or products described in point 1 of Article 10.5.16., or other products authorised by the *Competent Authority*; and
- 2 all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV or is disposed in a manner that prevents contact of waste with *susceptible species*.

**EU comment**

**The EU proposes to amend point 2 above as follows:**

**"2 water used in transport and all effluent and waste materials from the processing are treated in a manner [...]."**

**Indeed, also the water used in the transport of the consignment should be treated so as to ensure inactivation of ISAV.**

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

## Article 10.5.14.

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

When importing, for use in animal *feed*, or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of the species referred to in Article 10.5.2. from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require that:

- 1 the consignment is delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the *Competent Authority*; and
- 2 all effluent and waste materials from the processing are treated in a manner that ensures inactivation of ISAV.

**EU comment**

**As above, the EU proposes to amend point 2 of this article as follows:**

**"2 water used in transport and all effluent and waste materials from the processing are treated in a manner [...]."**

**Indeed, also the water used in the transport of the consignment should be treated so as to ensure inactivation of ISAV.**

This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

## Article 10.5.15.

**Importation of aquatic animal products from a country, zone or compartment declared free from infection with infectious salmon anaemia virus**

When importing *aquatic animal products* of the species referred to in Article 10.5.2. from a country, zone or compartment declared free from infection with ISAV, 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 10.5.4., 10.5.5., 10.5.6. or 10.5.7. (as applicable), the place of production of the *commodity* is a country, zone or compartment declared free from ISA.

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

This Article does not apply to *commodities* referred to in point 1 of Article 10.5.3.

Article 10.5.16.

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

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

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

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

2. When importing *aquatic animals or aquatic animal products*, other than those referred to in point 1 above, of the species referred to in Article 10.5.2. from a country, zone or compartment not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* and apply appropriate *risk* mitigation measures.

Article 10.5.17.

**Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infectious salmon anaemia**

1. When importing disinfected eggs of the species referred to in Article 10.5.2. for *aquaculture*, from a country, zone or compartment not declared free from ISA, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

a) the ISA virus status of the water to be used during the *disinfection* of the eggs;

b) the level of *infection* with ISA virus in broodstock (ovarian fluid and milt); and

c) the temperature and pH of the water to be used for *disinfection*.

2. If the *Competent Authority* of the *importing country* concludes that the importation is acceptable, it should apply the following *risk* mitigation measures including:

a) the eggs should be disinfected prior to importing, according to the methods described in Chapter 1.1.3. of the *Aquatic Manual* (under study) or those specified by the *Competent Authority* of the *importing country*; and

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

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



Annex 7 (contd)

3. When importing disinfected eggs of the species referred to in Article 10.5.2. for aquaculture, from a country, zone or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of this article have been fulfilled.

**EU comments**

**It is not clear from the wording of the article above if vertical transmission of ISAV has scientifically been demonstrated not to occur. The text should therefore be amended so that the risk associated with disinfected eggs is clear.**

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## AQUATIC ANIMALS COMMISSION WORK PLAN 2012–2014

### *Aquatic Code*

Tasks	Sept 2012 – Feb 2013	March 2013	May GS 2013	Sept 2013	March 2014	May GS 2014
<b>Chapter 10.5. Infectious salmon anaemia</b> – revise text based on the guiding principles established by the AHG on pathogen differentiation and comments from Member Countries		Consider Members comments	Propose for adoption			
<b>OsHV-1 <math>\mu</math>var</b> - propose for listing as an emerging disease		Consider Members comments	Propose for adoption		Review status as emerging disease	
<b>OsHV-1 <math>\mu</math>var</b>		Develop Disease Card				
<b>Infection with salmon pancreas disease virus</b> - propose for listing		Consider Members comments	Propose for adoption	If adopted for listing develop <i>Code</i> chapter		
<b>Chapter 6.1. Chapter on control of hazards in feed</b>		Develop a Concept Note on revised scope, purpose and content		Consider Members comments	Convene AHG to undertake redraft of chapter	

Annex 8 (contd)

<b>Chapter 1.2. Import risk analysis</b>	OIE Trade Dept. to revise text to harmonise with <i>Terrestrial Code</i> chapter	Review revised text	Propose for adoption			
<b>Develop Chapter 6.X. Risk analysis for antimicrobial resistance in aquaculture</b>	Convene AHG to develop chapter	Review report of AHG and circulate draft chapter for MC		Consider Members comments	Consider Members comments	Propose for adoption
<b>Develop a new chapter with the criteria for listing susceptible species</b>		Develop Concept Note				
<b>Chapter on Evaluation of AAHS</b>				Consider development of new chapter		
<b>Revision of Section 4 to improve guidance on the control of disease</b>		Develop Concept Note for revision of this section				
<b>Negligible risk concept for disease specific chapters</b>		Develop a Concept Note exploring the negligible risk concept for disease specific chapters (e.g. EUS).				

*Aquatic Manual*

<b>Manual Tasks</b>	<b>Sept 2012 – Feb 2013</b>	<b>March 2013</b>	<b>May 2013</b>	<b>Sept. 2013</b>	<b>Mar 2014</b>	<b>May GS 2014</b>
<b>Revise Chapter 2.3.5. infection with ISAV</b>	Author to revise chapter	Consider revised chapter taking into account MCs and align with the <i>Code</i> chapter	Revised chapter proposed for adoption			
<b>Revise Chapter 2.4.9 to focus information on OshV-1 <math>\mu</math>var</b>	Author to revise chapter	Consider revised chapter	Revised chapter proposed for adoption			
<b>Chapter on SPD</b>	Request expert to develop a Disease card	Develop a disease card				
<b>Revise Chapter 2.3.1 EUS, based AHG recommendations</b>	Author to revise chapter	Consider revised chapter	Revised chapter proposed for adoption			

Annex 8 (contd)**Other Items**

<b>Tasks</b>	<b>Mar 2013</b>	<b>May 2013</b>	<b>Sept. 2013</b>	<b>Mar. 2014</b>	<b>May 2013</b>	<b>late 2014</b>	<b>early 2015</b>
<b>OIE Conference on Implementation of OIE standards, including compartmentalisation</b>	Develop concept Note					Possible date for Conference	Possible date for Conference



Organisation  
Mondiale  
de la Santé  
Animale

World  
Organisation  
for Animal  
Health

Organización  
Mundial  
de Sanidad  
Animal

Annex 9

Original: English  
August 2012

**MEETING OF THE OIE AD HOC GROUP  
ON EVALUATION OF AQUATIC ANIMAL HEALTH SERVICES  
Paris, 21–23 August 2012**

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The *ad hoc* Group on Evaluation of Aquatic Animal Health Services (*ad hoc* Group) met at OIE headquarters on 21–23 August 2012.

The list of participants and the adopted agenda are attached as Annexes I and II.

## **1. Welcome**

On behalf of Dr Bernard Vallat, OIE Director General, Dr Monique Eloit, Deputy Director General, welcomed participants to the meeting and thanked them for their support for the OIE. Dr Monique Eloit noted that a key objective of the OIE is to assist Member Countries to improve animal health and public health. Dr Monique Eloit emphasised the importance of the PVS Pathway, as the OIE's key contribution to capacity building of veterinary services, and the need for good governance globally. Dr Monique Eloit explained that initially the OIE *Tool for the Evaluation of Performance of Veterinary Services* (OIE *PVS Tool*) was developed and applied to the evaluation of Veterinary Services regarding terrestrial animal issues. Its application to the evaluation of Aquatic Animal Health Services (AAHS) commenced in 2009 when the OIE undertook a pilot mission in Vietnam. Following this mission and several subsequent missions, it was clear that the OIE should consider the development of a stand-alone tool for the evaluation of an Aquatic Animal Health Service, which is the task of this *ad hoc* Group. Dr Monique Eloit thanked all members of the *ad hoc* Group for their valuable contributions to this new work.

Dr Alicia Gallardo Lagno, Chairperson of the Group, presented the agenda for the meeting and all participants introduced themselves.

## **2. PVS Pathway**

### **2.1. PVS Pathway**

Dr Mara Elma Gonzalez Ortiz, Deputy Head of the Regional Activity Department, updated the *ad hoc* Group on progress with the OIE PVS Pathway. Dr Gonzalez's Powerpoint presentation is at Annex III.

### **2.2. OIE *Tool for the Evaluation of Performance of Veterinary Services* (draft sixth edition)**

Dr Herbert Schneider, Chair of the *ad hoc* Group on Evaluation of Veterinary Services, informed members that the *ad hoc* Group on Evaluation of Veterinary Services had met on 17–19 July 2012 to develop the sixth edition of the OIE *PVS Tool*.

Annex 9 (contd)**2.3. Veterinary Education**

Dr Gillian Mylrea, Deputy Head, International Trade Department, updated the Group regarding the OIE's work on veterinary education, with particular reference to the 'OIE recommendations on the Competencies of graduating veterinarians ('Day 1 graduates') to assure National Veterinary Services of quality'. Dr Gillian Mylrea noted that this document is publically available on the OIE website at: [http://www.oie.int/fileadmin/Home/eng/Support\\_to\\_OIE\\_Members/Vet\\_Edu\\_AHG/DAY\\_1/DAYON\\_E-B-ang-vC.pdf](http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/Vet_Edu_AHG/DAY_1/DAYON_E-B-ang-vC.pdf)

She also informed the Group that the *ad hoc* Group on Veterinary Education met on 24–25 July 2012 to start work on the development of a core/basic curriculum, which provides for Day 1 graduates to possess the competencies recommended by the OIE.

**3. Definition of 'Aquatic Animal Health Professional'**

The Group reviewed comments made by Member Countries at the 80<sup>th</sup> General Session and those submitted by Thailand, Canada and European Union following the General Session.

Several Member Countries commented that the proposed definition was not clear regarding the qualification and the required years of postgraduate experience. In light of these comments, the *ad hoc* Group proposed that the definition for 'Aquatic animal health professional' (AAHP) should not focus on what qualifications are required, as this will vary widely between the needs and capacity of each Member Country. The definition should describe what the person is given the authority to undertake and that the Competent Authority is responsible for considering the appropriate level of qualification/expertise relative to the defined task.

The *ad hoc* Group recommended the following definition:

*'Aquatic Animal Health Professional*

*means a person who, for the purposes of the Aquatic Animal Health Code, is authorised by the Competent Authority to carry out certain designated tasks in a territory, and delegated to them under the responsibility and direction of the Competent Authority, depending on qualifications, training, and need.'*

This proposed definition has been adapted from the existing definition for 'veterinary paraprofessional' as described in the *Terrestrial Code* to include both university level professionals and technical personnel.

The *ad hoc* Group noted that should this definition be adopted, the following consequential change should be made to the definition for AAHS because paraprofessionals are included in the proposed definition for AAHP:

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

**4. OIE Tool for the Evaluation of Performance of Aquatic Animal Health Services**

The *ad hoc* Group reviewed the draft sixth edition of the OIE *PVS Tool* and amended specific critical competencies (CC), Levels of Advancement and Indicators so that the Tool was appropriate for the evaluation of performance of AHHS.

Annex 9 (contd)**General recommendations**

As this OIE *PVS Tool* should be used when evaluating an AAHS, irrespective of whether the AAHS is under the control and direction of a Member Country's Veterinary Service or another authority. Therefore, the *ad hoc* Group recommended that 'or AAHS' be added after 'VS' throughout the document.

Also, as many highly qualified professionals working in an AAHS are not veterinarians, 'aquatic animal health professional' be added after 'veterinarian' throughout the document.

**Critical Competencies (CC)**

The *ad hoc* Group reviewed the critical competencies and noted that the majority of CC were applicable to the evaluation of AAHS. However, the following CC were amended because of differences when considering aquatic animal health systems:

- CC I-1 Professional and technical staffing of the Veterinary Services or Aquatic Animal Health Services
- CC I-2 Competencies of veterinarians or aquatic animal health professionals, and other technical personnel
- CC II-8 Food safety
- CC II-12 Traceability
- CC III-5 Veterinary Statutory Body and other professional authorities

**Indicators**

In line with the recommendations of the *ad hoc* Group on Evaluation of Veterinary Services, the *ad hoc* Group recommended that indicators/sources of verification be placed in the *Manual of the Assessor*.

The *ad hoc* Group reviewed the indicators and made some amendments relevant to the evaluation of an AAHS but noted that the majority were applicable to the evaluation of AAHS.

**5. New draft Chapter 3.2. Evaluation of Aquatic Animal Health Services**

The Group recommended that the Aquatic Animals Commission develop a new Chapter 3.2. Evaluation of Aquatic Animal Health Services, to align the *Aquatic Code* with the *Terrestrial Code* as this chapter is needed to provide an important cross reference to the CCs in the *Aquatic PVS Tool*.

The *ad hoc* Group reviewed Chapter 3.2. Evaluation of Veterinary Services in the *Terrestrial Code* and agreed it was generally applicable with necessary amendments to ensure applicability to an AAHS. However, it contained too much prescriptive detail that could be more appropriately placed in a separate Guideline document.

**6. PVS Tool Harmonisation**

Considering the commonality between the OIE *PVS Tool* and the PVS Tool adapted to aquatic species, the *ad hoc* Group recommended that the two *ad hoc* Groups be combined or conducted simultaneously to strengthen communication between the work of the two Groups and ensure harmonisation.

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.../Annexes





Annex 9 (contd)Annex I

**MEETING OF THE OIE AD HOC GROUP  
ON EVALUATION OF AQUATIC ANIMAL HEALTH SERVICES  
Paris, 21–23 August 2012**

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**List of participants**

**MEMBERS OF THE AD HOC GROUP**

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Annex 9 (contd)

Annex II



**MEETING OF THE OIE AD HOC GROUP  
ON EVALUATION OF AQUATIC ANIMAL HEALTH SERVICES  
Paris, 21–23 August 2012**

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**Adopted agenda**

1. Welcome
  2. The PVS Pathway – update
    - 2.1. The PVS Pathway including GAP analysis and veterinary legislation
    - 2.2. OIE *Tool for the Evaluation of Performance of Veterinary Services* (draft sixth edition)
    - 2.3. Other relevant work of the OIE – veterinary education (Day 1 competencies document)
  3. Definition of ‘Aquatic Animal Health Professional’: review Member Country comments
  4. Develop the PVS *Tool for the evaluation of Performance of Aquatic Animal Health Services*
    - 4.1. Critical Competencies: review Critical Competencies in the OIE *PVS Tool* (draft sixth edition) and amend as relevant for AAHS
    - 4.2. Indicators: review Indicators in the OIE *PVS Tool* (draft sixth edition) and amend as relevant for AAHS
  5. New draft Chapter 3.2. Evaluation of Aquatic Animal Health Services for the *Aquatic Code*
  6. Draft a report for consideration by the OIE Aquatic Animal Health Standards Commission meeting to be held on 24–28 September 2012.
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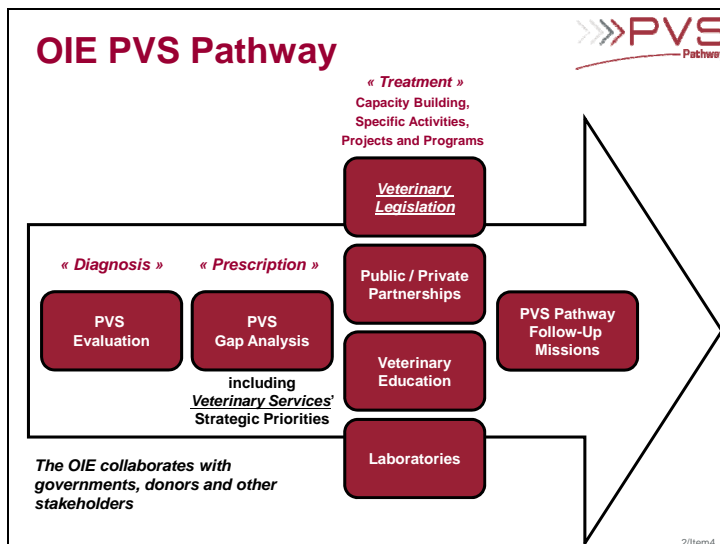




# The PVS Pathway

Ad hoc Group on the Evaluation  
of Aquatic Animal Health Services  
21 – 23 August 2012

Dr. Mara Gonzalez  
Deputy head of the OIE Regional Activities Department



# PVS Evaluation the diagnosis

3/Item4

Annex 9 (contd)Annex III (contd)

## OIE PVS Evaluation Missions

### State of play (up to 13 August 2012)

	OIE Members	PVS Evaluation requests received	PVS Evaluation missions implemented	Reports available for (restricted) distribution to Donors and Partners	Publication on the OIE website
Africa	52	51	47	36	6
Americas	29	22	21	18	8
Asia, the Far East and Oceania	32	18	18	11	1
Europe	53	15	14	12	1
Middle East	12	12	11	5	1
<b>TOTAL</b>	<b>178</b>	<b>118</b>	<b>111</b>	<b>82</b>	<b>17</b>

4/Item4

## Future missions

- > **OIE Members not having requested a PVS Evaluation**
  - > **Africa:** Cape Verde, Sao Tome & Principe
  - > **Americas:** Argentina, Bahamas, Canada, Cuba, Guatemala, USA, Venezuela
  - > **Asia:** Australia, **China (People's Rep. of)**, Chinese Taipei, India, Japan, Korea (Rep. of), Malaysia, Micronesia (Fed. States of), New Caledonia, New Zealand, Pakistan, Papua New Guinea, Singapore, Vanuatu
  - > **Europe:** Andorra, Belarus, Croatia, Former Yug. Rep. of Macedoine, Iceland, Liechtenstein, Moldavia, Montenegro, Norway, Russia, San Marino, Switzerland, Turkmenistan, **EU**
  - > **Middle East:** Iraq
- > **Use of the OIE PVS Tool for**
  - > **New requests**
  - > **Self-assessment**
  - > **PVS Pathway Follow-Up missions**

6/Item4

## PVS Gap Analysis

### *the prescription*

7/Item4

Annex 9 (contd)Annex III (contd)

## PVS Gap Analysis Missions

*State of play (up to 13 August 2012)*

	OIE Members	PVS Gap Analysis requests received	PVS Gap Analysis missions implemented	PVS Gap Analysis missions reports received	Reports available for (restricted) distribution to Donors and Partners
Africa	52	37	32	30	19
Americas	29	13	9	9	6
Asia, the Far East and Oceania	32	12	10	9	6
Europe	53	6	6	6	2
Middle East	12	8	3	2	0
<b>TOTAL</b>	<b>178</b>	<b>76</b>	<b>60</b>	<b>56</b>	<b>33</b>

8/Item4

## The treatment

### *OIE Support Programme for Veterinary Legislation*

10/Item4

## Veterinary Legislation Missions

*State of play (up to 13 August 2012)*

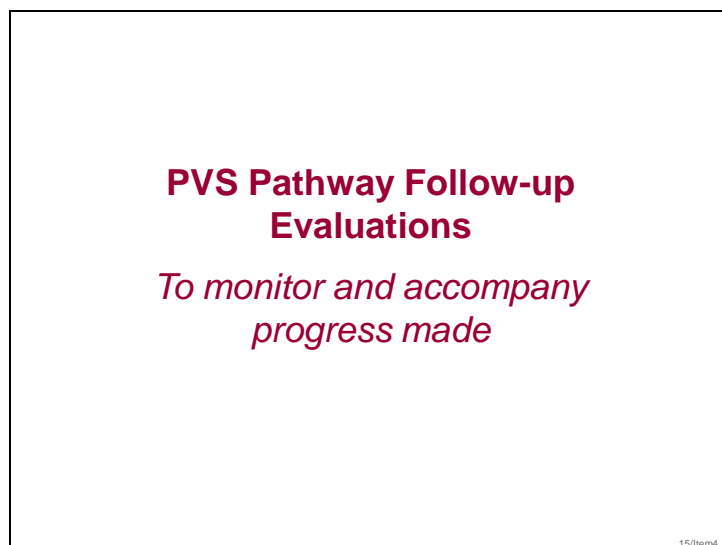
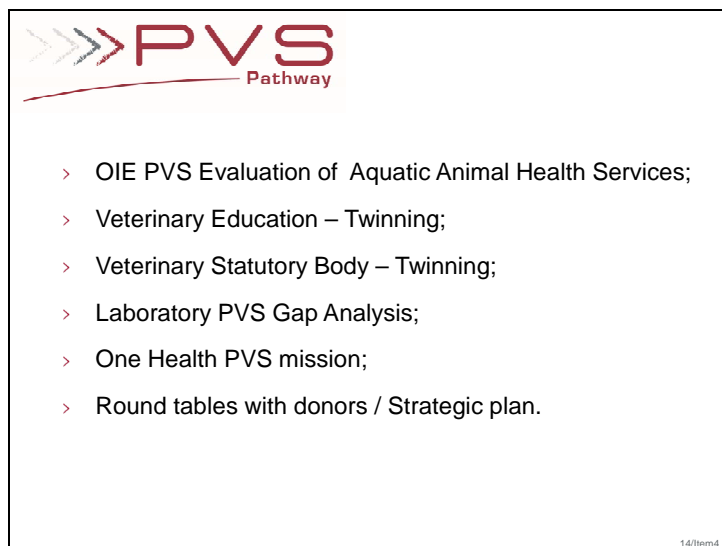
	OIE Members	PVS Legislation mission requests received	PVS Legislation missions implemented	PVS Legislation documents received
Africa	52	22	15	15
Americas	29	5	3	3
Asia, the Far East and Oceania	32	5	4	4
Europe	53	3	2	2
Middle East	12	4	4	4
<b>TOTAL</b>	<b>178</b>	<b>39</b>	<b>28</b>	<b>28</b>

11/Item4



Annex 9 (contd)

Annex III (contd)



[Annex 9](#) (contd)[Annex III](#) (contd)

### PVS Pathway Follow-Up Missions State of play (up to 13 August 2012)

	OIE Members	PVS Pathway Follow-up missions requested / proposed	PVS Pathway Follow-up missions implemented	Reports available for (restricted) distribution to Donors and Partners
Africa	52	7	4	0
Americas	29	2	1	1
Asia, the Far East and Oceania	32	2	2	2
Europe	53	4	4	0
Middle East	12	0	0	0
<b>TOTAL</b>	<b>178</b>	<b>15</b>	<b>11</b>	<b>3</b>

16/Item4

### OIE PVS Evaluations of Aquatic Animal Health Services

*Pilot stage*

17/Item4

### OIE PVS Evaluation of AAHS Missions State of play (up to 13 August 2012)

	OIE Members	AAHS PVS Evaluation requests received	AAHS PVS Evaluation missions implemented
Africa	52	3	2 *
Americas	29	1	0
Asia, the Far East and Oceania	32	3	2 *
Europe	53	0	0
Middle East	12	0	0
<b>TOTAL</b>	<b>178</b>	<b>7</b>	<b>4</b>

\* 2 requests were partially addressed within a standard OIE PVS Evaluation

18/Item4





Organisation  
Mondiale  
de la Santé  
Animale

World  
Organisation  
for Animal  
Health

Organización  
Mundial  
de Sanidad  
Animal

Annex 10

Original: English

September 2012

## REPORT OF THE MEETING OF THE OIE AD HOC GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES (FINFISH)

Paris, 11–13 September 2012

The OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Finfish) (the *ad hoc* Group) met at OIE Headquarters in Paris on 11–13 September 2012.

The members of the *ad hoc* Group are listed at [Annex I](#). The agenda adopted is given at [Annex II](#).

The *ad hoc* Group was convened to undertake an assessment of epizootic ulcerative syndrome (EUS) against the Criteria for Listing Aquatic Animal Diseases provided in Chapter 1.2. of the *Aquatic Animal Health Code (Aquatic Code)*, taking into consideration an assessment provided by Canada, proposing that EUS be delisted (presented at [Annex III](#)).

The *ad hoc* Group concluded that EUS should remain listed because it meets the criteria for listing.

The assessment undertaken by the *ad hoc* Group against the criteria is provided below.

### Item 1. Assessment of EUS against the criteria for listing

#### A. Consequences

1. **The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.**

The *ad hoc* Group considered that this criterion was met.

Infection with *Aphanomyces invadans* (EUS) has been reported from Asia, Australia, North America and Southern Africa. The disease has been reported from pond aquaculture facilities, integrated fish production in rice fields (Asia), and wild fish populations in fresh or brackish waters, in lakes, rivers and estuaries. So far, the disease had the biggest impact in Asia and Africa. In Asia and Africa the disease has been reported in aquaculture facilities. In North America, Australia and Africa, reports are mainly of disease in wild fish populations. Production losses are due to mortalities, morbidity and marketability of the product.

Annex 10 (contd)

EUS is a disease that had the most serious socio-economic impacts affecting freshwater aquaculture and capture fisheries in developing countries of Asia with direct economic losses due to high mortalities of wild and cultured fish and indirect losses due to collapsed markets for fish, resulting in loss of employment opportunities. FAO (2009) summarised examples of estimates of losses in capture fishery and aquaculture due to EUS from Lilley *et al.* (1998) as: (1) Thailand: USD 100 million during 1983–1993 (Chinabut, 1994), (2) Bangladesh: USD 4.8 million during 1988–1989 (Barua, 1990); (3) Indonesia: USD 235 000 during 1980–1987 (ADB/NACA, 1991); (4) Pakistan: USD 300 000 in 1996 (AAHRI, ACIAR, IoA and NACA, 1997); and (5) Australia: USD 700 000 annually in Eastern Australia (Callinan *et al.*, 1996).

Further data are available for the impact of EUS on farmed fish populations in Asia:

- India: State of West Bengal: first epizootic during 1988–1989 – more than 73% of the cultured ponds were affected with fish losses ranging from 31–40% (India Country Report in ADB/NACA, 1991).
- Indonesia: West Java, North Sumatera, North Sulawesi and Kalimantan: EUS during 1980–1983, total loss of cultured fish amounted to USD 119,000.00 (Indonesia Country Report in ADB/NACA, 1991).
- Nepal: Eastern Development Region: EUS second outbreak in October 1989 affected about 328 ha of water area, particularly ponds in 5 districts valued at approximately NRs 30 million (September 2012 current exchange rate value = USD 338, 000.00) equivalent to about 15–20% of total fish production; EUS spread to 13 districts of Central and Western regions in 1990 (Nepal Country Report in ADB/NACA, 1991).
- Thailand: severe losses due to EUS were recorded at nearly US\$ 9 million during the second outbreak during late 1982 to early 1983 (Tonguthai, 1985). The second (1982–1983) and third (1983–1984) EUS outbreaks were particularly devastating affecting intensive fish culture systems of Central Thailand (Lilley *et al.*, 1998).

Lilley *et al.* (2002) quoted a number of references that indicated the impact EUS had on farmed fish populations in Bangladesh:

- 68% of 200 ponds were affected in March–April 1988 (Hossain *et al.*, 1992);
- 50% of 234 ponds in 1991–92 (Ahmed and Rab, 1995);
- 13% of 96 extensive/semi-intensive fish farms in 1992–1995 (ADB/NACA, 1995);
- 16% of 6,401 farmed fish in November 1998–March 1999 (Khan and Lilley, 2002).

OR

2. **The disease has been shown to or scientific evidence indicates that it is likely to cause significant morbidity or mortality in wild aquatic animal populations.**

The *ad hoc* Group considered that this criterion was met.

Estimates of losses due to EUS (both capture fishery and aquaculture) include the following: (i) US\$100 million in Thailand during 1983–1991; (ii) US\$4.8 million in Bangladesh during 1988–1989; (iii) US\$235,000 in Indonesia during 1980–1987; (iv) US\$300,000 in Pakistan in 1996; and (v) US\$700,000 annually in Eastern Australia (FAO, 2009).

Annex 10 (contd)

In India, a study on the landings of EUS infected species from a capture fishery in the Brahmaputra River system before (1987–1988) and during the initial (1988–1991) three years of the outbreaks in India showed declines of as much as 97% (Das, 1994, in Arthur, 2005).

Further data available for the impact of EUS on wild fish populations in Asia:

- India: States of Tripura and Assam: first epizootic during 1988–1989, about 50% of the total fisheries in these states were affected. A total ban was imposed on the sale and consumption of fish which caused serious economic losses (India Country Report in ADB/NACA, 1991).
- Myanmar: EUS, during the outbreaks in 1985–1987, affected wild freshwater fishes in 35 townships in 1985, 22 in 1986 and 20 in 1987 (Myanmar Country Report in ADB/NACA, 1991).
- Philippines:
  - Reduction of daily income of subsistence fishermen from USD 4.00 to USD 1.50 due to rejection of affected fish (Philippine Country Report in ADB/NACA, 1991).
  - First outbreak in Laguna Lake in December 1985 continued to spread to at least 11 other provinces affecting wild fish in lakes, rice-fields and swamps (Bondad-Reantaso *et al.*, 1994) and a lagoon in Cagayan Province (Reantaso, 1991).
- Sri Lanka: EUS first occurred in 1987 in rivers and natural water bodies: estimated annual loss (1988 and 1989) was more than 1 million SLRs (Sri Lanka Country Report in ADB/NACA, 1991).

The importance of fisheries in Africa for food security is documented by the WorldFish Center (2005). The advent of EUS in Zambia, Botswana and Namibia was reported to have significant effects on fisheries and the local communities in these countries (Musumali *et al.*, 2009 and Tweddle 2009). The Western Province of Zambia, has a human population of 850,000 who are solely dependent on subsistence fishing. This is one of the poorest regions of Zambia, where more than 85 percent of the population are living in villages along the Zambezi River. In countries affected by EUS (Botswana, Namibia and Zambia), EUS negatively impacted on the livelihood and food fish source of the communities dependent on subsistence farming (Bondad-Reantaso *et al.*, 2012, in press).

In the USA, significant mortalities in menhaden have been associated with a high prevalence of EUS lesions (Blazer *et al.*, 1999; 2002; Noga and Dykstra, 1986). At times, in estuaries along the East Coast of the USA, the prevalence of typical *A. invadans* lesions has been reported to be as high as 90% of the young-of-the-year menhaden (Arhenholz *et al.*, 1987). In Florida, infections with *A. invadans* in 21 species of estuarine and freshwater fish were reported (Sosa *et al.*, 2007a).

In Australia EUS outbreaks have been reported in wild fish populations. Economic losses were estimated at USD 700 000 annually in Eastern Australia (Callinan *et al.*, 1996).

**OR**

**3. The agent is of public health concern.**

The *ad hoc* Group considered that this criterion was not met.

**B. Spread**

**4. Infectious aetiology of the disease is proven.**

The *ad hoc* Group considered that this criterion was met.

Annex 10 (contd)

*A. invadans* is a necessary cause of EUS and many predisposing factors contribute to the severity of the outbreak. Infection with *A. invadans* leads to the typical pathology of granulomatous mycosis associated with invasive fungal hyphae. The infectious aetiology of EUS was reviewed by an expert consultation in 2002 and concluded that *A. invadans* was the necessary cause (Baldock *et al.*, 2005); this has been supported by further studies (Kiryu *et al.*, 2002, 2003; Sosa *et al.*, 2007b, Andrew *et al.*, 2008 and FAO 2009).

**OR**

**5. An infectious agent is strongly associated with the disease, but the aetiology is not yet known.**

The *ad hoc* Group considered that this criterion was not applicable.

**AND**

**6. Likelihood of international spread, including via live animals, their products or fomites.**

The *ad hoc* Group considered that this criterion was met.

Oidtmann (2012) undertook a review and concluded that there is strong evidence for the transmission of *A. invadans* from fish to fish.

A risk analysis undertaken by EFSA identified the importation of ornamental fish as a pathway for the introduction of *A. invadans*. The report concluded that it is likely that *A. invadans* repeatedly entered into the European Union via the importation of live ornamental fish (EFSA, 2011). Evidence for this pathway has also been presented by Whittington and Chong (2007) and Hatai *et al.*, (1994).

It is suspected that *A. invadans* was introduced into Sri Lanka with the importation of infected ornamental fish from Southeast Asia (Costa and Wijeyaratne, 1989) and into Zambia via the illegal importation of infected fish bait (Andrew *et al.*, 2008 and Anonymous, 2010).

**AND**

**7. Several countries or countries with zones may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.4. of the Aquatic Code.**

The *ad hoc* Group considered that this criterion was met.

In some African countries (Cameroon, Ghana, Nigeria, Uganda) species have been identified (Brummett, 2007) that are known to be susceptible to EUS but no outbreaks have been recorded in these countries despite having conditions conducive to the clinical expression of EUS.

*A. invadans* has a very broad susceptible species range (OIE *Aquatic Manual*, 2012). When the infection is detected in a new geographical area, new susceptible species are usually identified (as reported in Africa, FAO, 2009). *A. invadans* is currently not known to occur in South America and the Pacific Islands although it is likely that susceptible species are present.

**C. Diagnosis**

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

The *ad hoc* Group considered that this criterion was met.

Numerous repeatable and robust diagnostic tests are available (OIE *Aquatic Manual*, 2012). Used in combination, a diagnosis can be achieved. For example, the disease can be recognised by clinical signs; observing the unique granulomatous response surrounding invading hyphae in histopathology; in situ hybridization or PCR or culture, followed by sequencing.

Annex 10 (contd)**Item 2. General comments and recommendations**

Whilst undertaking the assessment, the *ad hoc* Group considered a number of issues and made the following recommendations:

1. Rename EUS ‘Infection with *Aphanomyces invadans*’ to ensure consistency with the approach taken in other chapters in the *Aquatic Code*.
2. Revise Chapter 2.3. in the *Aquatic Manual* (section 7. Corroborative diagnostic criteria) to ensure that the definitions for ‘suspect case’ and ‘confirmed case’ take account of differences in geographical distribution of the pathogen. Such an approach has been taken in Chapter 2.4.3. Infection with *Bonamia ostreae* and could be applied in the EUS chapter.
3. The *ad hoc* Group recognised that targeted surveillance to demonstrate freedom from infection in the absence of clinical manifestation of the disease, i.e. when environmental conditions are not conducive, may be impossible to achieve with a reasonable level of confidence. While detection of *A. invadans* by histopathology has high sensitivity and specificity in fish presenting with typical clinical signs (stratified sampling), in the absence of clinical disease the sensitivity of surveillance to detect infection is very low. Therefore, the *ad hoc* Group recommended that provisions in Article 10.2.4. of the *Aquatic Code* should be further developed to specifically address the context of countries where conditions may not be suitable for development of clinical infection, as well as countries currently not known to be infected, but which are expected to have conditions (at least seasonally) conducive for expression of clinical disease.

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.../Annexes

Annex 10 (contd)Annex I

## MEETING OF THE OIE AD HOC GROUP ON THE OIE LIST OF AQUATIC ANIMAL DISEASES (FINFISH)

Paris, 11–13 September 2012

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Annex 10 (contd)

Annex II

**MEETING OF THE OIE AD HOC GROUP ON THE OIE LIST OF AQUATIC ANIMAL  
DISEASES (FINFISH)**

**Paris, 11–13 September 2012**

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**Adopted agenda**

Welcome

1. Undertake an assessment of epizootic ulcerative syndrome against the *Criteria for Listing Aquatic Animal Diseases* provided in Chapter 1.2. of the *Aquatic Animal Health Code*, taking into consideration the assessment provided by Canada.
  2. Draft a report for consideration by the OIE Aquatic Animal Health Standards Commission meeting to be held on 24–28 September 2012.
  3. Any other business.
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Annex 10 (contd)Annex III**Canada's submission re delisting EUS****Case for delisting Epizootic Ulcerative Syndrome (EUS) from the *Aquatic Animal Code and Manual of Diagnostic Tests for Aquatic Animals***

The *Aquatic Animal Health Code* criteria for listing of diseases are outlined in Chapter 1.2, Article 1.2.1 which states:

“*Diseases* proposed for listing should 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* should have the following characteristics: 1 or 2 or 3; and 4 or 5; and 6; and 7; and 8. Such proposals should be accompanied by a *case definition* for the *disease* under consideration.”

Epizootic Ulcerative Syndrome (EUS) has been listed by the Aquatic Animal Code since 1995. It is the opinion of Canada that EUS does not meet fully Criteria A1, A2 A3, B4, B5, B6, B7, or C8 and should therefore be removed from the OIE list of diseases.

**Canada's Position:**

Epizootic Ulcerative Syndrome has been evaluated against the criteria of the OIE for listing of diseases. Canada asserts that the purported disease agent, *Aphanomyces invadans*; (1) is found globally; (2) does not cause disease unless there is an inciting cause; (3) is dependent on environmental factors; (4) can be managed/controlled in culture situations using environmental manipulation; and (5) there is no reliable, robust and repeatable test method for its diagnosis, nor is there any test that can detect it in healthy populations of fish other than observation of the lack of gross clinical signs which is highly subjective. Therefore, accurate surveillance for this disease is lacking for declaration of freedom and the known distribution remains suspect leading to inaccurate declarations of disease freedom. Canada therefore proposes that Epizootic Ulcerative Syndrome be removed from the OIE's list of aquatic animal diseases for finfish.

**Criterion A: Consequences***Criterion A1:*

*The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.*

*Rationale provided in the Code for Criterion A1:*

*There is a general pattern that the disease will lead to losses in susceptible<sup>1</sup> 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.*

<sup>1</sup>: ‘Susceptible’ is not restricted to ‘susceptible to clinical disease’ but includes ‘susceptible to covert infections’.

**Canada's position:** Criterion A1 for disease listing of EUS has not been satisfied.

In order to meet criterion #1, morbidity or mortality associated with Epizootic Ulcerative Syndrome (EUS) should be related primarily to the agent of EUS, *Aphanomyces invadans*, and not to management or environmental factors. Canada proposes this “syndrome” and any associated morbidity and mortality are not primarily related to the disease agent alone. Canada contends that epizootic ulcerative syndrome is a multifactorial disease and that inciting causes are necessary for *Aphanomyces invadans* to infect finfish and cause disease. Management and environment factors have a significant impact on the expression of this disease and are necessary. If these factors are not present, *Aphanomyces invadans* will not cause disease. Canada concludes that *Aphanomyces invadans* is an opportunistic or secondary infection which contributes to the morbidity or mortality of the already compromised animals.



Annex 10 (contd)Annex III (contd)

Strong evidence that the morbidity or mortality associated with EUS is not related primarily to the agent *Aphanomyces invadans* has already been noted in the *Manual of Diagnostic Tests for Aquatic Animals* (online version)(1). Under section 2.3.5, Environmental factors, the Manual states:

“The *Aphanomyces* oomycete needs predisposing factors that leads to skin damage, such as parasites, bacteria or virus infection or acid water, to initiate the clinical signs of EUS disease (2).” and,

“Normally, a bath infection of *A. invadans* in healthy susceptible fish species does not result in clinical signs of disease. (3)” and,

“EUS occurs mostly during periods of low temperatures or 18–22 °C (7) and after periods of heavy rainfall (3). These conditions favour sporulation of *A. invadans* (4), and low temperatures have been shown to delay the inflammatory response of fish to oomycete infection (5, 6).”

Canada in fact agrees with the author of the Manual chapter and the references provided in the Manual chapter, that in order for *Aphanomyces invadans* to result in the “disease/syndrome” of EUS, there must first be an inciting cause in the host animal **before** the agent can contribute to its morbid state or mortality.

The second statement, provided above, is perhaps the most relevant as healthy animals will not show clinical signs in the presence of the disease agent (3). In references cited, it has been demonstrated that animals require trauma (13,14) and/or pre-existing or concurrent infections with viruses, bacteria, parasites, other fungi and/or dinoflagellates allowing subsequent infection with *Aphanomyces invadans* (2, 8,9,10,11,12). There have been studies described where fish exhibited EUS after challenge with no apparent inciting causes (3,14), however, capture and holding methods and/or the pre-exposure health status of the experimental animals were not described.

With respect to EUS leading to significant mortality, it is Canada’s position that *Aphanomyces invadans* is most likely a secondary invader to a primary stressor which then results in the increased likelihood of mortality in a weakened or compromised host especially if there is no intervention to support/treat the animals and there are environmental factors that favour propagation of *Aphanomyces invadans* and infection in the host. Since there are instances where animals infected with *Aphanomyces invadans* have recovered (7), mortality of the host does not always result as the final outcome.

*Criterion A2:*

*The disease has been shown to or scientific evidence indicates that it is likely to negatively affect wild aquatic animal populations.*

*(Proposed wording for 2012 publication: The disease has been shown to or scientific evidence indicates that it is likely to cause significant morbidity or mortality in ~~negatively affect~~ wild aquatic animal populations.)*

*Rational for Criterion A2:*

*“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.*

**Canada’s position:** Criterion A2 has not been fully satisfied.

Canada notes that in the 2011 Scientific Opinion of the European Food Safety Authority (15) “*There is evidence of economic impact on EUS-affected countries, both by decline in capture fisheries and mortality in aquaculture. Impact on biodiversity is probably high in affected water bodies but there is a lack of studies documenting this effect. More recent outbreaks (with exception of the large outbreak in the Zambezi River) have been reported as low or no mortality. Possible effects on productivity have not been investigated.*”

Annex 10 (contd)

Annex III (contd)

Canada recognizes that when the syndrome of EUS occurs there can be an impact on wild and capture fisheries. However, Canada notes that in its own experience with EUS, this negative impact may not always be realized. Again Canada contends that this is related to the fact that *Aphanomyces invadans* is not the sole cause of the disease (13) and environmental factors influence the expression of the disease and therefore, changes in such factors may mitigate the impact.

Similar to the position of the EFSA, Canada notes that there is evidence to support that when conditions are conducive for EUS occurrence, EUS may impact cultured populations; however further research is required to validate that management of the environment and culture conditions would significantly mitigate this impact considering that the expression of EUS is multifactorial.

*Criterion A3:*

*The agent is of public health concern.*

**Canada's position:** There is no evidence that this disease represents a public health concern. This criterion has not been satisfied.

EUS has not been shown to cause human illness at this time.

**Criterion B: Spread**

*Criterion B4:*

*Infectious aetiology of the disease is proven.*

**Canada's position:** This criterion is not satisfied.

The evidence that this criterion is not met is provided in the *Manual for Diagnostic Procedures for Aquatic Animals* which states: “*The Aphanomyces oomycete needs predisposing factors that lead to skin damage, such as parasites, bacteria or virus infection or acid water, to initiate the clinical signs of EUS disease (2)*” and “*Normally, a bath infection of A. invadans in healthy susceptible fish species does not result in clinical signs of disease. (3)*”.

Although Canada agrees that the infectious agent, *Aphanomyces invadans* is a pathogenic agent associated with clinical expression of the EUS, it is *clearly not the sole cause* for the disease but a *necessary component* for the syndrome to be expressed.

Canada argues that that the “disease” referred to as EUS is, as the name states, a “syndrome” not a disease. There are a variety of factors that must be in place before the *Aphanomyces invadans* agent can contribute to the morbidity or mortality and clinical expression of EUS. Infections by other pathogens or physical or chemical injuries to a host contribute with *Aphanomyces invadans* to expression of EUS- hence the aetiology of this syndrome is not solely infectious.

*Criterion B5:*

*An infectious agent is strongly associated with the disease, but the aetiology is not yet known.*

**Canada's position:** Canada proposes that this criterion is not satisfied as the aetiological risk factors that result in clinical expression of EUS expression are known. As EUS is a syndrome, clinical expression will be different each occurrence and the specific case-based aetiology will vary in the details but the overall outcome will be the same.

Annex 10 (contd)Annex III (contd)*Evidence:*

As indicated in the *Manual*, expression of EUS requires: (a) a breach in the integument of a host, (b) the presence of *Aphanomyces invadans* and (c) variable environmental factors that favour propagation of this pathogen and (d) compromise the immunity of the host (2). The aetiology is therefore known.

**Criterion B6:**

Likelihood of international spread, including via live animals, their products or fomites.

**Rationale provided in the Code:**

*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 likely.*

**Canada's position:**

Canada asserts that if the agent can be present in apparently healthy animals but there is no surveillance or detection possible unless animals are grossly clinically affected, it is impossible to provide evidence of spread through trade.

*Evidence:*

From the *Manual of Diagnostic Tests for Aquatic Animals* (online version) under section 2.3.3. Geographical distribution (1), *Aphanomyces invadans* is known to be present in four continents and 24 countries. Given this wide global distribution and that the fact that *Aphanomyces invadans* is a water mould, it is likely ubiquitous, hence already established globally. Canada asserts that absence of EUS outbreaks in countries may be the result of environmental influences and also a result of the lack of ability to conduct surveillance/testing in apparently healthy animals. The *Manual* indicates that surveillance must be targeted to animals with gross clinical lesions with no recommendations for random surveillance in apparently healthy populations. It is unclear as to how control of spread can be achieved with the routine trade of animals and a lack of any method of surveillance and detection in apparently healthy populations. If establishment of freedom is based on gross examination, there will be no effort to actually determine if the agent is ubiquitous.

Canada also agrees with the EFSA Scientific Opinion (15) which states: "*There is little or no information on surveillance for EUS in countries which have not yet reported EUS. It is possible that the actual geographic range of EUS is broader than the countries listed in Table 3 would suggest.*"

**Criterion B7:**

*Several countries or countries with zones may be declared free of the disease based on the general surveillance principles outlined in Chapter 1.4. of the Aquatic Code.*

**Rationale provided by the Code:**

*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 propose 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.*

**Canada's position:** Given the surveillance for freedom is based on "gross lesions" and there is an absence of random/general surveillance in apparently healthy fish, *Aphanomyces invadans* has a high probability of being ubiquitous and is widespread. Until such time as generalized surveillance is conducted, countries are not in a strong scientific position to argue freedom from this disease except at the compartment level.

Annex 10 (contd)

Annex III (contd)

*Evidence:*

Canada provides the following evidence to demonstrate that EUS does not meet this criterion. In Chapter 1.4 of the Aquatic Animal Health Code, number one objective of surveillance is to “*demonstrate the absence of disease*”. When referring to the Manual for guidance on how to conduct the surveillance, the Manual recommends targeted surveillance for gross clinical lesions to establish freedom from of this disease. The Manual does not prescribe a method for general surveillance in apparently healthy animals. One is left to assume that “freedom” is based solely on the absence of clinical lesions. Yet it is clear in the Manual that apparently healthy animals can carry the agent as it states in Article 2.3.5 *Environmental factors*: “*Normally, a bath infection of A. invadans in healthy susceptible fish species does not result in clinical signs of disease*”. Canada asserts that unless there is surveillance to show that apparently healthy animals are not affected by EUS, freedom cannot be met by the absence of gross lesions/clinical signs alone.

In addition, the EFSA Scientific Opinion states (15), “*There is little or no information on surveillance for EUS in countries which have not yet reported EUS. It is possible that the actual geographic range of EUS is broader than the countries listed in Table 3 would suggest*”. Canada supports this view particularly if countries have been relying on the absence of clinical lesions to declare freedom.

Canada does conclude that it is possible to have freedom from this disease at the compartment level as long as there are proper screening and sufficient biosecurity measures in place.

**Criterion C: Diagnosis**

**Criterion C8:**

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

**Rationale provided in the Code:**

*A diagnostic test should be widely available and preferably has undergone a formal standardisation and validation process using routine field samples (See Aquatic Manual.) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.*

**Canada’s position:**

To remain listed, EUS must meet this criterion and ensure repeatable and robust testing using objective, validated methods that “remain unaffected by small changes or variations in the testing environment.” The test used should also have a known specificity and sensitivity. Of the methods provided there is no single or combination of tests which, at this time, fulfill these requirements. There is also no means of testing for *Aphanomyces invadans* in healthy populations of fish other than observation of the absence of clinical signs and gross lesions which is highly subjective.

Canada therefore proposes that EUS does not fulfill this criterion for disease listing.

*Evidence:*

The recommended method in the *Manual of Diagnostic Tests for Aquatic Animals* Section 4 indicates that the diagnosis of EUS be based on clinical signs and confirmed by histopathology. As well, diagnosis of EUS in clinically affected fish may be achieved by histopathology or by oomycete isolation. A positive diagnosis of EUS is made by demonstrating the presence of mycotic granulomas in histological sections or isolation of *A. invadans* from internal tissues.

Furthermore, the *Manual of Diagnostic Tests for Aquatic Animals* Section 6, Test(s) (1), recommends that “the test for targeted surveillance to declare freedom from EUS is examination of gross signs”. Targeted surveillance is conducted twice a year to cover the range of seasonal variation, at least once during the season that favours EUS occurrence or when water temperatures are about 18–22°C or below 25°C.

Annex 10 (contd)Annex III (contd)

Canada is in agreement with the Scientific Opinion Report of the EFSA (15), with respect to diagnosing EUS which states “*Clinical signs are too non-specific to decide whether a fish might be infected with A. invadans and Histopathology provides a presumptive diagnosis. However, due to limitations in specificity (e.g. other pathogenic oomycetes also possess aseptate hyphae) further molecular analysis and/or culture are required as confirmatory diagnostic tools.*”

Canada also agrees with the ESFA opinion that suitable diagnostic procedures should include *A. invadans*-specific PCR and, for isolated oomycetes, confirmation of identity by either bioassay is the most reliable methods for disease confirmation.

Canada also support the ESFA position that “*there are limited data on the diagnostic sensitivity and specificity of any of the current tests. The level and sensitivity of surveillance applied for the detection of EUS is likely to vary hugely across exporting countries.*”

The tests for EUS are not practical, validated, nor suitable for a reliable diagnosis of EUS. The test for targeted surveillance, examination of gross signs, is highly subjective and not pathognomonic for EUS or infection with *Aphanomyces invadans*. They methods lack available data on sensitivity and specificity to provide reliable diagnosis.

According to the *Manual of Diagnostic Tests for Aquatic Animals* (online version) Section 7, Corroborative diagnostic criteria, subsection 7.1, the definition of suspect case and subsection 7.2 definition of confirmed case of EUS are given respectively (1):

“*A suspect case of EUS disease is defined as the presence of typical clinical signs, a single or multiple red spot(s) or ulcer(s) on the body, in a population of susceptible fish at water temperatures between 18 and 25°C. OR the presence of branching non-septate oomycete hyphae in a muscle squash preparation OR the isolation of slow-growing Aphanomyces without further identification of the agent.*”

“*A confirmed case of EUS is defined as a suspect case that has produced typical mycotic granulomas in affected tissues or organs OR that has been identified as positive by the PCR or FISH detection techniques OR that Aphanomyces invadans has been isolated and confirmed by either bioassay, PCR, or sequence analysis.*”

According to the *OIE Quality Standard and Guideline for Veterinary Laboratories: Infectious Diseases* (16):

“*Repeatability* is defined as the level of agreement between replicates of a sample both within and between runs of the same test method by the same method in different laboratories.

*Robustness* is defined as the measure of an assay’s capacity to remain unaffected by small changes or variations introduced in test conditions to mimic anticipated routine laboratory operation, part of optimization studies and reflected in repeatability assessments (e.g. incubation times, reaction temperatures, buffer pH/ionic strength, reagent dilutions, sample condition and/or preparation, etc.).”

Since clinical signs and histopathology are based on human evaluation i.e. subjective assessments, repeatability and robustness are difficult to achieve between laboratories and diagnosticians. Methods such as PCR, do not yet have established levels for sensitivity and specificity. As such the surveillance applied for the detection of EUS is likely to vary tremendously across exporting countries. (15). There is also no means of testing for *Aphanomyces invadans* in healthy populations of fish other than observation which is highly subjective. Since there are no current gold standard tests and the molecular tests are still being validated, a diagnosis of EUS still remains difficult.

[Annex 10](#) (contd)[Annex III](#) (contd)

The last concern with diagnosis arises from the *Manual of Diagnostic Tests for Aquatic Animals* (online version) under section 5. Rating of tests against purpose of use (1):

“The methods currently available for surveillance, detection, and diagnosis of EUS are listed in Table 5.1. The designations used in the Table indicate: a = the method is the recommended method for reasons of availability, utility, and diagnostic specificity and sensitivity; b = the method is a standard method with good diagnostic sensitivity and specificity; c = the method has application in some situations, but cost, accuracy, or other factors severely limits its application; and d = the method is presently not recommended for this purpose. *These are somewhat subjective as suitability involves issues of reliability, sensitivity, specificity and utility. Although not all of the tests listed as category a or b have undergone formal standardisation and validation, their routine nature and the fact that they have been used widely without dubious results, makes them acceptable.*”

The italicized words in this last sentence do not agree with the rationale nor the definitions for repeatability and robustness provided for this criterion. The phrase “... *the fact that they have been used widely without dubious results, makes them acceptable.*” is misleading. For results obtained by clinical signs, squash preparations and histopathology there are a multitude of differential diagnoses that can explain what is being observed in an infected host. The lesions and vegetative structures observed are not pathognomonic for EUS. Finally, isolation and growth of the organism is slow and subject to contamination and often there is failure to provide pure cultures.

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Annex 10 (contd)Annex III (contd)

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## APPENDIX

(cf. EU comments on point 1 "General discussion and work plan" of the AAHSC report, p. 4)

### Annual return to OIE on animal population data – a discussion paper

*Allan Reese and Ed Peeler (Cefas, Weymouth, UK), 20 November 2012*

OIE members are asked to complete an annual return described as “animal populations” (see appendix 1). The rubric for the table states the figures should be for numbers of animals and of establishments; but the rubric for fish, molluscs and crustaceans asks for “Production” in weight. The aquatic animals are also specified as “farmed” or “wild”, with “wild” described as “samples in nature”. OIE do not request data on wild terrestrial animal populations.

If these figures are to be useful in an epidemiological context, they must measure a “population at risk”, either suffering a disease or at risk of diseases that are introduced. Some domestic terrestrial animals (e.g. cattle) are subject to individual registration or annual censuses, so a meaningful figure is available and can be compared year to year; wild or feral populations may be insignificant or absent. Other species may occur as both farmed and wild: pigs and wild boar for example. Deer are “farmed” in the sense of enclosed herds to a very small extent; they are “ranching” as managed herds on large areas; but they are also present as wild animals. Rabbit farming is important in some MS and present as wild populations across the EU. Bovine TB is a disease maintained in the wild badger population as well as in affected cattle. The question for disease control may be the extent of contact between farmed and wild susceptible species. The vast majority of farmed birds are kept inside buildings with biosecurity measures to exclude other birds and rodent vermin.

Aquatic animals are more difficult to census when alive, hence the reliance on production figures (links to production data from the UK and Finland are given in Appendix 2). Production figures, however, have no obvious relationship to the standing stock in the production system. The annual production weight might be considered the economic measure at risk, but is clearly not comparable with the number of cattle as an epidemiological risk. Without explicit guidance, the “wild production” could be the amount of fish, etc, harvested or could be the estimated biomass in the stock. The volume of a harvest of a wild population is even less closely linked to the stock size than farmed production; furthermore many wild animal populations are not harvested.

Questions for the OIE (Aquatic Animals Commission) to consider are:

1. Is this Annual report return intended to indicate sizes of animal populations at risk from disease, for use in modelling and policy making? If not what is intended?
2. For these purposes, are actual estimates of the populations needed, or proxy measures or index values, that track changes over time but would be country-specific not comparable between OIE members?
3. Should populations of fish be reported at species group level (e.g. salmonids, cyprinids etc.). A return for “fish” combines marine salmon and trout with freshwater salmon and trout (brown and rainbow) and various cyprinid species.
4. To clarify that “establishments” is a count of the number of farm sites, since for most purposes aquatic diseases are measured by number of infected sites rather than counts or weights of animals. Guidance on whether managed recreational fisheries are establishments would be helpful.
5. What estimates are expected of wild populations? It is extremely unlikely an annual census is made except for rare and specially-protected species. For UK data on distribution of wild aquatic animal species are available (Appendix 2). What is feasible to measure, that could be compared?
6. Would a qualitative scale for wild populations be acceptable: e.g., 1. Absent from country 2. Rare visitor but not part of the ecosystem 3. Present but rare and local 4. Widespread but scarce [e.g. wild boar in UK] 5. Common but does not come into regular contact with farmed stock. 6. Common, widespread and has to be considered as human/farm contact [e.g. brown

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(cf. EU comments on point 1 "General discussion and work plan" of the AAHSC report, p. 4)

trout]. If this is adopted, the return would have to be subdivided into susceptible species groups. For example, one approach might be to adapt the current data-entry form from three to four columns for each animal group (see Table 1).

Table 1. Proposed format for recording aquatic animal populations

Administrative division	Species group	Farmed production (t)	No. Farm sites	Wild caught harvest (t)	Wild status (1-6)
UK	Salmonids	168,000	750	150 (mainly salmon)	6
	Cyprinids	500	200 (mainly producing fish for angling)		6
	Amphibians	0			5

### Appendix 1. OIE instructions on completing the annual return for animal populations

#### **SECTION 4. ANIMAL POPULATION**

Please indicate animal population figures for each species and the number of livestock production establishments in your country.

If the Veterinary Services are not the competent authority for aquatic animals in your country, please obtain the appropriate information from the relevant authority (e.g. Ministry of Fisheries, Aquatic Animal Health Services, etc.).

#### **HOW TO COMPLETE THE TABLE ON ANIMAL POPULATION**

This section is for information about the number of animals and animal production establishments in your country for the year under report.

For animal populations, information can be provided by the first administrative division or for the entire country for the year under report. In either case, the same template can be used (pp 66-69).

For each of the species indicated, please enter the number of animals and establishments present in your country during the year under report, either by first administrative unit or for the entire country.

If one or more species exist in your country but no data are available on "Animal population" or "Number of establishments", enter "..." in the relevant column(s).

If any of the species do not exist in your country, enter "0" in both columns.

For sheep and goats, please enter the number of animals and establishments for each species. If there are mixed flocks and you cannot differentiate between the exact number of sheep and the

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(cf. EU comments on point 1 "General discussion and work plan" of the AAHSC report, p. 4)

exact number of goats in your country, then enter under "Sheep/goats (mixed flocks)", on page 67, the number of animals and establishments for mixed flocks.

For fish, molluscs and crustaceans, enter in the "Production" column the quantity produced during the year. Indicate which unit of weight you are using: "kg" for "kilogramme" and "T" for metric ton (one metric ton is equivalent to 1,000 kilogrammes or 2,205 pounds).

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(cf. EU comments on point 1 "General discussion and work plan" of the AAHSC report, p. 4)

**ANIMAL POPULATION**

**AQUATIC ANIMALS**

Name of the first administrative division	Fish			Molluscs			Crustaceans			Amphibians		
	Production <sup>1</sup>		Establishments	Production <sup>1</sup>		Establishments	Production <sup>1</sup>		Establishments	Production <sup>1</sup>		Establishments
	Farmed <sup>2</sup>	Wild <sup>3</sup>		Farmed <sup>2</sup>	Wild <sup>3</sup>		Farmed <sup>2</sup>	Wild <sup>3</sup>		Farmed <sup>2</sup>	Wild <sup>3</sup>	

(1): If you use kilogrammes, enter "kg" after the number. If you use tonnes, use "T" after the number.

(2): Farmed = aquaculture

(3): Wild = samples in nature

## **APPENDIX**

(cf. EU comments on point 1 "General discussion and work plan" of the AAHSC report, p. 4)

### **Appendix 2. Resources Member States aquatic animal population and production data**

#### **UK aquaculture production data:**

##### ***Finfish production***

All production recorded as tonnes and value based on farm gate prices. Data are not broken down by purpose (i.e. food, restocking, ornamental).

<http://www.cefas.defra.gov.uk/publications/finfishnews/ffn13.pdf>

##### ***UK wild species distribution:***

Atlases of the distribution of wild aquatic animals on a species by species based on recorded observations from a large range of sources are available as interactive maps:

<http://data.nbn.org.uk/>

#### **Finland aquaculture production data:**

Food fish production is measured in weight and fish and crayfish for restocking is measured in million individuals.

[http://www.rktl.fi/www/uploads/pdf/uudet%20julkaisut/tilastoja\\_6\\_2012.pdf](http://www.rktl.fi/www/uploads/pdf/uudet%20julkaisut/tilastoja_6_2012.pdf)