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

Paris, 5–9 March 2012

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The OIE Aquatic Animal Health Standards Commission (the Aquatic Animals Commission) met at the OIE Headquarters in Paris from 5 to 9 March 2012.

Details of participants and the adopted agenda are given at Annexes 1 and 2.

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Gillian Mylrea, Deputy Head of the OIE International Trade Department, welcomed members and thanked them for their on-going work in support of the OIE. Dr Monique Eloit, OIE Deputy Director General, joined the meeting later in the week to acknowledge Dr Barry Hill's enormous contribution to the OIE work in aquatic animals. He has been a member of the Aquatic Animals Commission since 1988 and will end his term as President of the Commission in May this year.

The Aquatic Animals Commission strongly encouraged Members to participate in the development of the OIE's international standards by sending comments on this report. The Aquatic Animals Commission reiterated that it would be very helpful if comments were submitted as specific proposed text changes, supported by a scientific rationale. Members are requested not to use the automatic 'track-change' function provided by word processing software in preparation of their comments. The Commission also reminded Members that they should follow the established convention in recommending modification of text in the OIE *Aquatic Animal Health Code* (hereinafter referred to as the *Aquatic Code*), i.e. propose new text (shown as double underline) and propose text deletions (shown as ~~strike-through~~) and provide a scientific justification for all changes proposed.

The Aquatic Animals Commission reviewed various *Aquatic Code* draft texts from its October 2011 report in the light of Member comments. The outcome of the Commission's work is presented at Annexes 3 to 23 in this report. Amendments made to the *Aquatic Code* chapters during the October 2011 meeting are shown as double underlined text, with deleted text in ~~strike-through~~, while amendments made at this meeting (March 2012) are shown in a similar manner but with coloured background to distinguish the two groups of amendments.

Members are invited to comment on the proposed amendments. The Aquatic Animals Commission emphasised that Members need only comment on non-amended text where there is an error or need for significant change to remove ambiguity or to take account of new scientific information.

The table below summarises the texts as presented in the Annexes. Annexes 3 to 16 are proposed texts for adoption at the 80th General Session in May 2012; Annex 17 to 19 are presented for Member comments; Annexes 20 to 25 for Members information.

Members are invited to submit their comments to the OIE on Annexes 17 to 19 of this report. Comments must reach OIE Headquarters prior to **27 August 2012** in order to be considered at the next meeting of the Aquatic Animals Commission, which will be held on 24–28 September 2012. Comments should be sent to the International Trade Department at: trade.dept@oie.int.

Texts proposed for adoption	**Annex number**
Glossary	Annex 3
Criteria for listing aquatic animal diseases (Chapter 1.2.)	Annex 4
Diseases listed by the OIE (Chapter 1.3.): - revision of Article 1.3.2. (listing Infection with ostreid herpesvirus [OsHV-1 and OsHV-1 µvar] as an emerging disease) - revision of Article 1.3.2. (Infection with abalone herpes virus)	Annex 5
Import risk analysis (Chapter 2.2.)	Annex 6
Communication (new Chapter 3.2.)	Annex 7
Example article to be applied to all disease specific chapters under point 1 of Articles X.X.12. (amphibian and fish disease chapters) and X.X.11. (crustacean and mollusc disease chapters)	Annex 8
Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals (new Chapter 6.4.)	Annex 9
Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals (new Chapter 6.5.)	Annex 10
Welfare of farmed fish during transport (Chapter 7.2.)	Annex 11
Welfare aspects of stunning and killing of farmed fish for human consumption (Chapter 7.3.)	Annex 12
Killing of farmed fish for disease control purposes (new Chapter 7.4.)	Annex 13
Disinfection of salmonid eggs (Article 10.4.13., Article 10.5.13. and Article 10.9.13.)	Annex 14
Revision of Article 2.1.2. (Obligation of WTO Members)	Annex 15
Chapter 1.1. Notification of Diseases and Epidemiological Information	Annex 16
Texts for Members' comment	**Annex number**
Control of hazards in aquatic animal feeds (Chapter 6.1.)	Annex 17
Revision of Article 1.3.1. (Infectious salmon anaemia)	Annex 18
Infectious salmon anaemia (Chapter 10.5.)	Annex 19
Annexes for Members' information	**Annex number**
Aquatic Animal Health Standards Commission Work Plan for 2012/2013	Annex 20
Report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Finfish Team)	Annex 21
Report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals	Annex 22
Report of the *ad hoc* Group on Assessing the criteria for Listing Aquatic Animal Species as Susceptible to Infection with a Specific Pathogen	Annex 23
Report of the OIE *ad hoc* Group on Veterinary Education	Annex 24
Report of the OIE Expert Meeting: Brainstorming on invasive alien species	Annex 25

1. Activities and progress of *ad hoc* groups

1.1. Report of the *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Finfish Team)

Dr Barry Hill, Aquatic Animals Commission representative in this *ad hoc* Group, gave a summary of work undertaken during the *ad hoc* Group's electronic consultations, which were held in January and February 2012.

The Aquatic Animals Commission considered the report of the *ad hoc* Group. The *ad hoc* Group reviewed the additional information provided by Chile for criteria 6 and 7 of the Criteria for Listing Aquatic Animal Diseases provided in Article 1.2.1. of the *Aquatic Animal Health Code* (*Aquatic Code*) in support of the listing of pancreas disease. The *ad hoc* Group also considered other information obtained on recent international trade and concluded that there is evidence that there is trade that could spread the virus, so criterion 6 was therefore met. Concerning criterion 7, the *ad hoc* Group concluded that while the information provided by Chile suggested that several countries or zones could possibly be in a position to declare freedom, the evidence presented remained insufficient to conclusively demonstrate pancreas disease freedom for any of the countries identified.

The Commission recommended that countries that consider themselves to be free of pancreas disease, make available scientific evidence regarding the absence of the disease. This information would be used to further evaluate pancreas disease against criterion 7.

The Commission noted the *ad hoc* Group's comment that criteria 6 and 7, and the explanatory notes in Article 1.2.1. use words such as 'may be', 'likely' and 'likelihood' and that these are rather vague and need to be replaced by more precise terms or expansion of explanatory notes. The Commission agreed to review these criteria once the revised criteria in Chapter 1.2. of the OIE *Terrestrial Animal Health Code* (the *Terrestrial Code*) are adopted (see Item 2.3.).

The Commission agreed with the conclusion of the *ad hoc* Group that there was insufficient evidence to satisfy criterion 7 and therefore pancreas disease does not meet the criteria for listing.

The report of the *ad hoc* Group is at Annex 21 for information.

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

Dr Ricardo Enriquez, Aquatic Animals Commission representative in this *ad hoc* Group, gave a summary of work undertaken during the *ad hoc* Group's meeting, which was held from 31 January to 2 February 2012.

The Aquatic Animals Commission reviewed the report of the *ad hoc* Group on Responsible Use of Antimicrobials in Aquatic Animals and addressed the following issues:

Chapter 6.4. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals: Refer to agenda Item 2.9. for details on this draft chapter.

Chapter 6.5. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals: Refer to agenda Item 2.10. for details on this draft chapter.

Antimicrobial resistance risk analysis in aquaculture: The Commission noted the *ad hoc* Group's view that work on a new chapter in the *Aquatic Code* on risk analysis in aquaculture was important to progress and agreed that this work should be advanced by the *ad hoc* Group.

The report of the *ad hoc* Group is at Annex 22 for information.

1.3. Report of the OIE *ad hoc* Group on Assessing the Criteria for Listing Aquatic Animal Species as Susceptible to Infection with a Specific Pathogen

Dr Olga Haenen, Aquatic Animals Commission representative in this *ad hoc* Group, gave a summary of work undertaken electronically by the *ad hoc* Group since the Commission's last meeting in October 2011.

The Commission, at its October 2011 meeting, had provided a number of comments for the *ad hoc* Group to consider when further developing, reviewing and refining the criteria for listing aquatic animal species as susceptible to infection with a specific pathogen and expanding the explanatory notes. Dr Haenen presented the document that had been revised by the *ad hoc* Group in light of the Commission's input and drew attention to the worked example applying the criteria to koi herpes virus. The Commission agreed that it was now sufficiently advanced to seek comments from the OIE Reference Laboratory experts, some of whom were also the authors of the *Manual of Diagnostic Tests for Aquatic Animals* (*Aquatic Manual*) chapters. It considered that the best format for the final document would be a guidance document with explanatory text that would eventually be published on the OIE web site. The authors of the specific disease chapters of the *Aquatic Manual* would then be asked to apply the criteria at the next update of relevant chapters in the *Aquatic Manual*.

The report of the *ad hoc* Group is at Annex 23 for information.

2. OIE *Aquatic Animal Health Code* – Member Country comments

2.1. General comments

The Aquatic Animals Commission welcomed the contribution of African Member Countries, Australia, Canada, Chile, China (People's Republic of), Chinese Taipei, European Union (EU), Japan, New Zealand, Norway, Switzerland, Thailand and the United States of America (USA), OIE experts and the International Council for Animal Welfare (ICFAW).

The Aquatic Animals Commission noted that some Member Country comments were on the proposed amendments to the text while others were comments on text not proposed for amendment. The Commission wished to emphasis that Member Countries should comment on proposed amendments and only on other text where there is an error or need for significant change to remove ambiguity or to take account of new scientific information. The Commission proposed to prepare a schedule for periodical full review of adopted chapters which will provide the opportunity for Member Countries to propose additions, deletions or other amendments to any part of the text.

In response to Member Country comments requesting consideration be given to the drafting of a new chapter on the welfare of aquatic animals used in research, education and training, the Aquatic Animals Commission re-iterated its previous consideration on this issue (Commission's October, 2011 report), that the use of aquatic animals in scientific studies can be an important aid to research. However, given that the focus of animal welfare standards in the *Aquatic Code* is currently on farmed fish, and that there is still work to be done to finalise relevant chapters and to encourage Member Countries to implement them, the Commission was of the view that this should take priority before drafting new text on the welfare of aquatic animals used in research and education.

2.2. Glossary

Whilst reviewing Member Country comments and relevant chapters, the Aquatic Animals Commission amended several definitions:

1. The definition for *'Aquaculture establishment'* was amended to include amphibians as they are included in the definition of aquatic animals, and marketing was changed to sale to clarify the meaning of this term.

Aquaculture establishment

means an establishment in which amphibians, fish, molluscs or crustaceans for breeding, stocking or ~~marketing~~ sale are raised or kept.

2. The Commission drew to the attention of Member countries the need to define the term 'aquatic animal health professional' which is used throughout the *Aquatic Code*. This is important in the context of work that will be undertaken in 2012 by a new *ad hoc* Group on the Evaluation of Aquatic Animal Health Services.

In response to several Member Country comments, the Commission changed 'animal sciences' to 'biological sciences' as this was considered to be a more inclusive term. The Commission noted that both 'animal sciences' and 'biological sciences' could include veterinarians. However, a veterinarian, in order to meet the proposed definition of 'aquatic animal health professional' would need to have received post graduate training in aquatic animal health or to have several years practical experience in aquatic animal health.

The Commission did not agree with a proposal to include, as an essential requirement, several scientific publications in peer reviewed journals as it did not consider that this was appropriate for inclusion in the definition.

Aquatic animal health professional

means an individual holding a tertiary (university) level qualification in ~~animal~~ biological sciences and who has had post graduate training in *aquatic animal* health or has had several years practical experience in *aquatic animal* health.

3. A number of Member Country comments were received that indicated there was some confusion about the definition for 'disease' used in the *Aquatic Code*. The Aquatic Animals Commission had proposed the deletion of the reference to the *Aquatic Code* in the definition because this term is used throughout the *Aquatic Code* in relation to both OIE listed diseases and the horizontal chapters. The Commission did not agree with a proposal to delete the reference to 'non clinical' infection because infection without clinical signs is common in aquatic animals and presents a significant risk of spreading pathogens through trade.

Disease

means clinical or non clinical *infection* with one or more ~~of the~~ aetiological agents ~~of the *diseases* referred to in the *Aquatic Code*~~.

4. In response to several Member Country comments, the Commission amended the definition for *feed* to harmonise it with the definitions used in the *Terrestrial Code* and Codex Alimentarius, with the exception of the inclusion of live organisms, which are specific to aquaculture.

Feed

means any ~~material~~ material ~~product~~ (single or multiple), ~~of~~ whether ~~whether~~ processed, semi-processed or raw ~~unprocessed plant or animal material~~, as well as live organisms, ~~that~~ which is intended to be fed directly to *aquatic animals*.

5. No Member Country comments were received regarding the proposal to delete the definition for *live feed*.

~~***Live feed***~~

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

6. No Member Country comments were received regarding the proposed amendments to *self-declaration of freedom from disease*.

Self-declaration of freedom from disease

means declaration by the *Competent Authority* of the country concerned that the country, *zone* or *compartment* is free from a *listed disease* based on implementation of the provisions of the *Aquatic Code* and the *Aquatic Manual*. [NOTE: The Member is encouraged to inform the OIE of its claimed status and the OIE may publish the claim but publication does not imply OIE endorsement of the claim.] ~~The *Veterinary Authority* of the country may wish to transmit this information to the OIE *Headquarters*, which may publish the information.~~

The revised Glossary, proposed for adoption, is at Annex 3.

2.3. Criteria for listing aquatic animal diseases (Chapter 1.2.)

The Aquatic Animals Commission considered Member Country comments and made relevant amendments.

Noting that the OIE Terrestrial Animal Health Standards Commission (the Code Commission) is in the process of modifying the disease listing criteria in the *Terrestrial Code* (Chapter 1.2.), the Aquatic Animals Commission proposed to await the decision of Member Countries on this work before proposing any major modifications to the equivalent text in the *Aquatic Code*. Member Country comments on non-amended text would be held over for future consideration.

The revised Chapter 1.2., proposed for adoption, is at Annex 4.

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

2.4.1. Assessment for listing Infection with ostreid herpesvirus (OsHV-1 and OsHV-1 µvar) as an emerging disease

The Aquatic Animals Commission reviewed comments received from Japan, Norway, EU, Canada, USA, New Zealand, and Australia. The Commission noted the opposing positions amongst some Member Countries on the proposal to list Infection with ostreid herpesvirus-1 as an emerging disease. However, no Member Countries opposed the listing of OsHV-1 µvar as an emerging disease.

The Commission reiterated that:

- Following notification by several Member Countries to the OIE on significant epidemiological changes in relation to infection with OsHV-1 µvar, the Commission proposed its listing under the provisions of Article 1.2.2., as emerging aquatic animal disease.
- Since the causative agent is a variant of the otherwise known oyster herpes virus OsHV-1, the Commission has proposed to follow the approach recommended by the *ad hoc* Group on Pathogen Differentiation (see details in the *ad hoc* Group in Annex 22 at http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/Aquatic_Commission/A_AAC_Feb_2011.pdf), that is, to ensure gathering of epidemiological information, as per the proposed case definition, for all variants over a period of time before making a decision on the listing of certain variants.

Against this background, the Commission wished to clarify that the objectives of listing of both forms (OsHV-1 and OsHV-1 µvar) are to:

1. Enable the collection of epidemiological information in a harmonised and systematic way in areas that may be affected by OsHV-1 µvar; and
2. Provide objective information on the respective role of OsHV-1 µvar compared to OsHV-1 as well as other possible variants of the virus.

To this effect, a *Manual* chapter was drafted to provide guidance on diagnosis, typing, and reporting of increased mortality of Pacific oysters associated with OsHV-1 and OsHV-1 µvar. This chapter was circulated to Member Countries and will be proposed for adoption at the 80th General Session in May 2012.

Some Member Countries commented that reporting of all types of OsHV-1 would lead to the submission of a large amount of information about types of the virus that are widespread and known to have little impact on the host. The Commission noted that the case definition was specifically designed such that Member Countries need only report outbreaks with increased mortality.

Some Member Countries proposed that the reporting obligations should focus on OsHV-1 µvar only. The Commission noted that there is some evidence suggesting that the mortality events involving herpesvirus in Pacific oyster have mostly been caused by OsHV-1 µvar. However it cannot be excluded that other variants of the virus may also have played a role in recent mortality events.

For these reasons, the Commission proposed the listing of Infection with ostreid herpesvirus (OsHV-1 and OsHV- µvar) as an emerging disease.

The revised Article 1.3.2., proposed for adoption, is at Annex 5.

2.4.2. Infection with abalone herpes-like virus

The Aquatic Animals Commission agreed with a Member proposal to amend the name to 'Infection with abalone herpes ~~-like~~ virus' since there is now sufficient evidence to justify that this virus can be classified as a herpesvirus *bona fide* (Savin K.W., Cocks B.G., Wong F., Sawbridge T., Cogan N., Savage D. & Warne S. [2010]. A neurotropic herpesvirus infecting the gastropod, abalone, shares ancestry with oyster herpesvirus and a herpesvirus associated with the amphioxus genome. *Virological Journal*, **7**, 308).

The revised Article 1.3.2., proposed for adoption, is at Annex 5.

2.4.3. Epizootic ulcerative syndrome

The Aquatic Animals Commission considered the assessment provided by Canada in support of its proposal that epizootic ulcerative syndrome be delisted. The Commission was unable to reach a decision regarding the case made by Canada because it had concerns about some of the reasoning used in the assessment.

The Commission was mindful of the recent large scale EUS disease outbreaks in southern Africa which caused serious socio-economic impacts to the affected countries in the Zambezi river basin (FAO. 2009. Report of the International Emergency Disease Investigation Task Force on a Serious Finfish Disease in Southern Africa, 18–26 May 2007. Rome, FAO).

The Commission recommended that an *ad hoc* Group be convened to reassess EUS against the criteria for listing in Chapter 1.2.

2.4.4. Infectious salmon anaemia

As a consequence of proposed changes to Chapter 10.5. (see also Item 2.14. in this report) and following consideration of the approach taken in the *Terrestrial Code*, for the high and low virulent forms of avian influenza, the Commission amended the listed disease name for infectious salmon anaemia (ISA) in Article 1.3.1. as follows: 'Infectious salmon anaemia (infection with HPR-deleted or HPR0 forms of ISAV)' to clarify that for the purpose of notification ISA means infection with ISAV, including its pathogenic forms (having deletions in the HPR region: HPR-deleted) and its non pathogenic form (HPR0).

The revised Article 1.3.1. is at Annex 18 for Member Country comment.

2.5. Import risk analysis (Chapter 2.2.)

The Aquatic Animals Commission noted that Member Countries had supported the amendment proposed to this chapter in October 2011. The Commission will make the same amendment in other relevant parts of the *Aquatic Code* as appropriate upon the adoption of this chapter.

The Commission also noted several more extensive amendments proposed by a Member Country. However, because the Commission considered that these would not significantly improve the current text and were already well covered by the OIE *Handbook on Import Risk Analysis for Animals and Animal Products*, the Commission decided not to make the proposed amendments. A proposal to include a new diagram was not accepted because it illustrated a process different from that of the OIE and used some terms not used by the OIE.

The revised Chapter 2.2., proposed for adoption, is at Annex 6.

2.6. Communication (new Chapter 3.2.)

The Commission reviewed the comments from several Member Countries including amendments proposed by the Code Commission relevant to the *Terrestrial Code* Chapter 3.3.

The Commission amended the text accordingly, to ensure harmonisation with the *Terrestrial Code* Chapter 3.3.

The revised text of the new Chapter 3.2., proposed for adoption, is at Annex 7.

2.7. Example article to be applied to all disease specific chapters under point 1 of Articles X.X.12. (amphibian and fish disease chapters) and X.X.11. (crustacean and mollusc disease chapters)

The Aquatic Animals Commission agreed with a Member Country proposal to add a new sentence in all disease specific chapters under point 1 of Articles X.X.12. (amphibian and fish disease chapters) and X.X.11. (crustacean and mollusc disease chapters). This new text is to recognise that aquatic animal products listed in these articles are safe only under certain conditions where the assumptions of Article 5.3.2. apply. The proposed new text is:

'Certain assumptions have been made in assessing the safety of aquatic animals and aquatic animal products listed above. Member Countries should refer to these assumptions at Article 5.3.2. and consider whether the assumptions apply to their conditions.'

The Aquatic Animals Commission drafted an 'example article' to be included in all disease chapters under point 1 of Articles X.X.12. (amphibian and fish disease chapters) and X.X.11. (crustacean and mollusc disease chapters).

The draft 'example article', proposed for adoption, is at Annex 8.

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

In response to Member Country comments, the Aquatic Animals Commission, at its October 2011 meeting, had asked an expert to review Chapter 6.1. and to provide advice to the Commission on whether the animal production food safety risks had been comprehensively addressed. The Commission reviewed the advice provided by the expert and amended the chapter as appropriate.

The revised Chapter 6.1., for Member Country comment, is at Annex 17.

2.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals (draft new Chapter 6.4.)

The Aquatic Animals Commission considered the recommendations of the *ad hoc* Group on Responsible Use of Antimicrobial Agents in Aquatic Animals, which had reviewed the draft new Chapter 6.4. 'Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals' to address Member Country comments. The Commission agreed with the proposed amendments – see Item 1.2. for details.

The revised text of the new Chapter 6.4., proposed for adoption, is at Annex 9.

2.10. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals (new draft Chapter 6.5.)

The Aquatic Animals Commission considered the recommendations of the *ad hoc* Group on Responsible Use of Antimicrobial Agents in Aquatic Animals, which had reviewed the draft new Chapter 6.5. 'Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals' to address Member Country comments. The Commission agreed with the proposed amendments – see Item 1.2. for details.

The revised text of the new Chapter 6.5., proposed for adoption, is at Annex 10.

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

The Aquatic Animals Commission received Member Country comments on this chapter, some of which were suggested changes to the proposed amendments to the text while others were comments on text not proposed for amendment. The Commission reviewed comments on the proposed amendments to the text and amended the text accordingly but decided not to consider any comments made on adopted text and will hold these for future consideration.

The revised Chapter 7.2., proposed for adoption, is at Annex 11.

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

The Aquatic Animals Commission received Member Country comments on this chapter, some of which were suggested changes to the proposed amendments to the text while others were comments on adopted text, which had not been proposed for amendment. The Commission reviewed comments on the proposed amendments to the text and amended the text accordingly, but decided not to consider any comments made on adopted text and will hold these for future consideration.

The revised Chapter 7.3., proposed for adoption, is at Annex 12.

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

The Aquatic Animals Commission reviewed Member Country comments and made relevant amendments.

In response to a Member Country's comment that words "pain" and "anxiety" are unsuitable terms for use in the fish welfare chapters as there is a lack of evidence that these states occur in fish, the Commission agreed to delete the word 'anxiety' but did not agree to delete 'pain' as there is scientific evidence that some fish species have brain structures potentially capable of experiencing pain (see: EFSA, 2009 General approach to fish welfare and the concept of sentience in fish).

The Commission did not agree with a Member Country's proposal to delete the text in point 3 of Article 7.4.2. referring to 'aversive'. The Commission noted that although some methods are clearly aversive (e.g. use of CO_2, leading to very low pH of the water), other methods (such as isoeugenol) may or may not be aversive. Therefore, the article states that the recommended methods should be as non aversive as possible.

A Member Country proposed amending point 6 of Article 7.4.3. to clarify the example provided regarding legal issues, i.e. use anaesthetic agents. The Commission did not agree with the proposal, noting that the purpose of this example is to highlight issues not directly related to the welfare of fish that may need to be considered and anaesthetic use was provided as an example of a legal issue.

The Aquatic Animals Commission did not agree with some of the other proposed amendments as the intent was already covered or the proposals did not significantly improve the existing text.

A Member Country proposed that killing with the use of disinfectant chemicals was an applicable method and it be added to Article 7.4.5. The Commission requested that the Member Country provide the scientific rationale for this proposed amendment, including references.

The revised text of the new Chapter 7.4., proposed for adoption, is at Annex 13.

2.14. Infectious salmon anaemia (Chapter 10.5.)

The Aquatic Animals Commission reviewed comments received from Canada, Chile, China (People's Republic of), Chinese Taipei, EU, New Zealand, Norway, Thailand and United States of America. The Commission noted that all commenting Member Countries supported the proposal to include in this chapter at least HPR-deleted forms of ISA virus (ISAV). However, some Member Countries did not support the inclusion of articles specifically dealing with HPR0 with regard to declaration of zone or country freedom. The Commission proposed to follow the approach recommended by the *ad hoc* Group on Pathogen Differentiation **(see details in the *ad hoc* Group report in Annex 22 at: http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/Aquatic_Commission/A_AAC_Feb_2011.pdf),** that is, to ensure gathering of epidemiological information over a period of time before making a decision on the delisting of certain forms of ISAV.

Following consideration of the approach taken in the *Terrestrial Code*, the Commission amended the listed disease name for infectious salmon anaemia (ISA) in Article 1.3.3. as follows: 'Infectious salmon anaemia (HPR-deleted and HPR0 ISAV)', to clarify that for the purpose of notification ISA means infection with ISAV, including its pathogenic forms (having deletions in the HPR region: HPR-deleted) and its non pathogenic form (HPR0).

In Chapter 10.5. the Commission added new text 'The provisions in this chapter only apply to the pathogenic forms of ISAV (HPR-deleted)'.

The Commission amended Chapter 1.3. (see also Item 2.4.4. in this report) and Chapter 10.5. to reflect this approach.

The revised Article 1.3.1., for Member Country comment, is at Annex 18.

The revised Chapter 10.5., for Member Country comment, is at Annex19.

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

The Aquatic Animals Commission reviewed Member Country comments and made relevant amendments.

The revised Articles 10.4.13., 10.5.13. and 10.9.13., proposed for adoption, are at Annex 14.

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

3.1. Proposed revision of Article 2.1.2.

The Aquatic Animals Commission reviewed the Code Commission's proposal to modify Article 5.3.1. (Obligations of WTO Members), noting that this arose from concerns raised by the Secretariat of the World Trade Organization (WTO) Sanitary and Phytosanitary Committee. The Commission noted that the obligation of notification was for WTO Members only, and that not all OIE Member Countries are WTO Members. The Commission revised the proposed text for better alignment with the obligation in the WTO SPS Agreement.

The Aquatic Animals Commission also noted that the *Terrestrial Code* Chapter 5.3. includes several articles on equivalence which do not appear in the *Aquatic Code* and that this text was included in a separate chapter in the *Terrestrial Code*. The Commission requested that OIE Headquarters consider inclusion of the relevant articles on equivalence in the *Aquatic Code* and harmonisation with the relevant chapter in the *Terrestrial Code*.

The revised Chapter 2.1., proposed for adoption, is at Annex 15.

3.2. Harmonisation of chapters with the OIE Terrestrial Animal Health Code where relevant

3.2.1. Chapter 1.1. Notification of Diseases and Epidemiological Information

The Aquatic Animals Commission was informed by the OIE Animal Health Information Department that some text in point 1 of Article 1.1.3. required amendment to harmonise the two Codes.

The revised Chapter 1.1., proposed for adoption, is at Annex 16.

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

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

4.1. Review of the authors' responses to comments received on the draft chapters

Responses to the Member Country comments had been received from all the authors of the 34 draft chapters for the next edition of the *Aquatic Manual.* For those comments that had been taken into account, the text was amended and the changes highlighted for ease of reference. Where the comments were rejected, a table had been put at the end of the chapter with the rejected comments and the author's rationale for not accepting them. The Commission discussed and further amended some of the chapters. All the revised chapters would shortly be made available on the OIE website and would be proposed for adoption by the World Assembly of Delegates of the OIE in May 2012. Once adopted, the hard copy version of the seventh edition of the *Aquatic Manual* would be published.

4.2. Draft sampling texts on the three model diseases (white spot disease, viral haemorrhagic septicaemia, *Bonamia*)

Dr Hill informed the Commission that the experts involved were still working on drafting the texts on sampling for the three chapters, and that two of the chapters were close to completion. Given the difficulty the six authors were experiencing in coordinating the contents of the three chapters through electronic communication, the Commission decided to ask the Director General to reconvene the *ad hoc* Group to bring the authors together to finalise the chapters.

5. OIE Reference Centres

5.1. New applications for Reference Centre status

No applications had been received.

5.2. Review nominations for replacement experts

The OIE had been notified of the following change of expert at an OIE Reference Laboratory. The Commission recommended its acceptance:

Viral encephalopathy and retinopathy

Dr Giovanni Cattoli to replace Dr Giuseppe Bovo at the Istituto Zooprofilattico Sperimentale delle Venezie, Legnaro, PD, ITALY.

5.3. Review of annual reports of OIE Reference Centre activities in 2011

Reports had been received from all 43 Reference Laboratories and from the two Collaborating Centres. The Commission expressed its on-going appreciation of the enthusiastic support and expert advice given to the OIE by the Reference Centres. It was noted that it had been decided by OIE Headquarters to discontinue routine distribution of the CD-ROM and to keep the annual reports available on line.

The Aquatic Animals Commission carefully reviewed the reports received. It was impressed, in general, with the quality of the work carried out by the laboratories. Once again however, the Commission noted significant differences across the reports in the nature of the information provided under different headings, the amount of content and the style. The Commission suggested that question 7 on quality assurance, biosafety and biosecurity should be divided into three parts to avoid confusion or misreporting.

The Commission was joined by Dr Rafaella Nisi of the OIE Scientific and Technical Department, who, as part of a USAID-funded project, had analysed the 2010 reports of 62 OIE Reference Laboratories covering 13 terrestrial animal diseases. Dr Nisi gave a presentation of her analysis, which, while highlighting the high level of activities, particularly capacity building activities, carried out by OIE Reference Laboratories to the benefit of Member Countries, also revealed a number of shortcomings with the current annual report template.

The Commission agreed that the template needed to be re-evaluated to better fit the mandate and to increase the usefulness of the information gathered. The Commission was interested in the proposal to develop a web-based format with more close-ended questions for quantitative analyses and looked forward to reviewing a revised template should it be available at its next meeting.

6. Laboratory Twinning Projects

Dr Keith Hamilton (Scientific and Technical Department of the OIE) provided an update on OIE Laboratory Twinning. OIE Laboratory Twinning projects for aquatic animal diseases were considerably under represented when compared to terrestrial animal diseases. Out of 35 twinning projects so far approved only one covered an aquatic animal disease (Canada with Chile for infectious salmon anaemia). The Commission decided that OIE should further promote OIE Laboratory Twinning in the aquatic animal health sector. Dr Hamilton agreed that he would contact Dr Kibenge (lead expert in the only active aquatic twinning) with the aim of drafting a case study and seeking publication. OIE focal point trainings and aquatic animal health meetings also provided opportunities to promote twinning. The new and improved Twinning Guide was circulated to the Commission members and is available on the OIE website at:

http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/Twinning_Guide2012.pdf

7. Other relevant activities

7.1. OIE *PVS Tool*: Application to Aquatic Animal Health Services

Dr Sarah Kahn advised the Commission of the state of play with the PVS evaluation of Aquatic Animal Health Services (AAHS). Since the Panama conference on 'The Contribution of Aquatic Animal Health Programmes to Food Security', the OIE has been pleased to receive more requests for PVS evaluations of AAHS and is prioritising such missions. To date, most requests have been for Member Countries with relatively small aquaculture activities.

The Commission agreed that the OIE should take steps to encourage OIE Members to engage on the PVS Pathway with respect to national Aquatic Animal Health Services (AAHS). The Commission noted that the

Director General has agreed to convene an *ad hoc* Group on the Evaluation of AAHS to make recommendations on refining the OIE *PVS Tool* to facilitate application to AAHS. This Group will review the existing PVS Tool and draft additions and modifications as appropriate, including the development of specific indicators, using the experience gained from missions conducted to date.

The Commission noted that the definition of an aquatic animal health professional proposed for adoption this year (see Item 2.2.) is an important step. In the fullness of time, the OIE should consider the competencies and educational qualifications that aquatic animal health professionals should have.

The Commission endorsed these developments 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.

7.2. OIE *ad hoc* Group on Veterinary Education – update

Dr Sarah Kahn outlined the work of the *ad hoc* Group on Veterinary Education, which had finalised a document 'Minimum Competencies expected of Day 1 Veterinary Graduates to assure delivery of high quality National Veterinary Services.'

Dr Sarah Kahn explained that OIE Headquarters was in the process of preparing a publication of the Day 1 Competencies, for distribution to Delegates at the 80th General Session in May 2012.

OIE Headquarters is also producing Guidelines on Twinning for Veterinary Education Establishments, based on the successful Laboratory Twinning Programme.

The Commission noted the report of the *ad hoc* Group, including the proposed future work on the core veterinary curriculum, and was pleased to see that aquatic animal health was included in the 'Day 1 Competencies' and in the draft document on Graduate and Continuing Education for Graduate Veterinarians. The Commission requested that they be kept informed on this matter.

The report of the *ad hoc* Group is at Annex 24 for information.

7.3. OIE ad hoc Group on Veterinary Legislation – update

Dr Sarah Kahn outlined the work of the *ad hoc* Group on Veterinary Legislation, which most recently met in January 2012. This Group has developed a new draft Chapter 3.4. 'Veterinary Legislation' for inclusion in the *Terrestrial Code* Section 3 'Quality of Veterinary Services'. Dr Sarah Kahn noted that this text would be proposed for adoption at the 80th General Session (2012).

The Commission noted the report of the *ad hoc* Group.

7.4. OIE Brainstorming meeting on invasive alien species

Dr Sarah Kahn briefly reported on the brainstorming meeting convened by the OIE, with participation of representatives of the Secretariat of the Convention on Biological Diversity and the Secretariat of the WTO SPS Committee. This meeting produced 'OIE Guidelines for assessment of the risk of non-native animal species becoming invasive'.

Dr Kahn advised that the Guidelines would be published on the OIE website later this year for guidance of Member Countries. She also informed the Commission that the OIE was collaborating with the WTO Standards and Trade Development Facility on a seminar to be held on 12–13 July 2012 in Geneva, on 'Invasive alien species and international trade'. More information can be obtained at the WTO/STDF website: http://www.standardsfacility.org/en/TAIAS.htm

The Commission reviewed the Guidelines and concluded that they appear to satisfactorily address the issue in the aquatic context.

The report of the brainstorming meeting, including the 'Guidelines for assessment of the risk of non-native animal species becoming invasive', is at Annex 25 for information.

8. OIE Regional Aquatic Animal Focal Points Seminars

Dr Gillian Mylrea reported that 162 Member Countries have nominated National Focal Points for aquatic animals. The OIE continues to hold regional seminars for focal points in aquatic animals as part of the OIE's global programme of capacity building for Aquatic Animal Health Services. A Member of the Aquatic Animals Commission will attend and deliver presentations at the OIE regional aquatic animal focal points seminars for African countries (that are not members of SADC) in Accra (Ghana) on 20–22 March 2012.

9. Cooperation with FAO

Dr Subasinghe gave a brief account of FAO's current aquatic animal health management activities worldwide. He mentioned that there will be three main FAO projects will become operational soon; (a) in Viet Nam assisting the recent outbreak of shrimp disease, (b) in Western Balkan region assisting six countries to improve their capacities in compliance to international standards on aquatic animal health, and (c) an inter-regional project linking ten countries in Latin America and Asia. He also mentioned and appreciated the close collaboration between FAO and OIE during recent investigations of the shrimp disease outbreaks in Viet Nam and Mozambique. He stressed the importance of continuing assistance to Zambezi basin countries on the current EUS outbreak and its potential spread. Dr Subasinghe said that the Sixth Session of the FAO Committee on Fisheries, Sub-Committee on Aquaculture, will be held in Cape Town (South Africa) from 26–30 March 2012 and that OIE has been invited.

10. Review of the Commission's work plan for 2011/2012

The Aquatic Animals Commission reviewed and updated its work plan, which is provided at Annex 20 for Member Countries' information.

11. Date of the next meeting

The next meeting will take place on 24–28 September 2012.

.../Annexes

Annex 1

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5–9 March 2012

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Annex 1 (contd)

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Annex 2

MEETING OF THE OIE
AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5–9 March 2012

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Adopted agenda

1. Activities and progress of *ad hoc* groups

1.1. Report of the *ad hoc* Group on the OIE List of Aquatic Animals Diseases (Finfish Team)

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

1.3. Report of the OIE *ad hoc* Group on Assessing the Criteria for Listing Aquatic Animal Species as Susceptible to Infection with a Specific Pathogen

2. OIE *Aquatic Animal Health Code* – Member Country comments

2.1. General comments

2.2. Glossary

2.3. Criteria for listing aquatic animal diseases (Chapter 1.2.)

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

2.4.1. Assessment for listing Infection with ostreid herpesvirus (OsHV-1 and OsHV-1 µvar) as an emerging disease

2.4.2. Infection with abalone herpes-like virus

2.4.3. Epizootic ulcerative syndrome

2.4.4. Infectious salmon anaemia

2.5. Import risk analysis (Chapter 2.2.)

2.6. Communication (new Chapter 3.2.)

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

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

2.9. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals (new Chapter 6.4.)

2.10. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals (new Chapter 6.5.)

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

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

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

Annex 2 (contd)

2.14. Infectious salmon anaemia (Chapter 10.5.)

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

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

3.1. Proposed revision of Article 2.1.2. (Obligation of WTO Members)

3.2. Harmonisation of chapters with the OIE *Terrestrial Animal Health Code* where relevant

3.2.1. Chapter 1.1. Notification of Diseases and Epidemiological Information

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

4.1. Review of the authors' responses to comments received on the draft chapters

4.2. Draft sampling texts on the three model diseases (white spot disease, viral haemorrhagic septicaemia, *Bonamia*)

5. OIE Reference Centres

5.1. New applications for Reference Centre status

5.2. Review nominations for replacement experts

5.3. Review of annual reports of OIE Reference Centre activities in 2010

6. Laboratory Twinning Projects

7. Other relevant activities

7.1. OIE *PVS Tool*: Application to Aquatic Animal Health Services

7.2. OIE *ad hoc* Group on Veterinary Education – update

7.3. OIE *ad hoc* Group on Veterinary Legislation – update

7.4. OIE *ad hoc* Group on Invasive alien species – update

8. OIE Regional Aquatic Animal Focal Points Seminars

9. Cooperation with FAO

10. Review of the OIE Aquatic Animal Health Standards Commission's work plan for 2011/2012

11. Date of the next meeting

Annex 3

GLOSSARY

Aquaculture establishment

means an establishment in which amphibians, fish, molluscs or crustaceans for breeding, stocking or ~~marketing~~ sale are raised or kept.

Aquatic animal health professional

means an individual holding a tertiary (university) level qualification in ~~animal~~ biological sciences ~~(including veterinary science)~~ and who has had post graduate training in *aquatic animal* health or has had several years practical experience in *aquatic animal* health.

Disease

means clinical or non clinical *infection* with one or more ~~of the~~ aetiological agents ~~of the *diseases* referred to in the *Aquatic Code*~~.

Feed

means any ~~material~~ material ~~product~~ (single or multiple), ~~of~~ whether ~~whether~~ processed, semi-processed or raw ~~raw unprocessed plant or animal material~~, as well as live organisms, ~~that~~ which is intended to be fed directly to *aquatic animals*.

~~***Live feed***~~

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

Self-declaration of freedom from disease

means declaration by the *Competent Authority* of the country concerned that the country, *zone* or *compartment* is free from a *listed disease* based on implementation of the provisions of the *Aquatic Code* and the *Aquatic Manual*. [NOTE: The Member is encouraged to inform the OIE of its claimed status and the OIE may publish the claim but publication does not imply OIE endorsement of the claim.] ~~The *Veterinary Authority* of the country may wish to transmit this information to the OIE *Headquarters*, which may publish the information.~~

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Annex 4

CHAPTER 1.2.

CRITERIA FOR LISTING AQUATIC ANIMAL DISEASES

Article 1.2.1.

Criteria for listing an aquatic animal disease

Diseases proposed for listing should meet ~~all of~~ the relevant ~~parameters set for each of the~~ criteria, as set out in ~~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.

No.	~~Criteria (A-C)~~	~~Parameters that support a listing~~ Criteria for listing	Explanatory notes
		A. Consequences	
1.		The disease has been shown to cause significant production losses at a national or multinational (zonal or regional) level.	There is a general pattern that the *disease* will lead to losses in *susceptible*~~s~~ *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 quality.
2.	Or	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.	Wild aquatic animal populations can be populations that are commercially harvested (wild fisheries) and hence are an economic asset. However, the asset could be ecological or environmental in nature, for example, if the population consists of an endangered species of aquatic animal or an aquatic animal potentially endangered by the disease.
3.	Or	The agent is of public health concern.	
		And **B. Spread**	
4.		Infectious aetiology of the disease is proven.	
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.

Annex 4 (contd)

No.	~~Criteria (A-C)~~	~~Parameters that support a listing~~ Criteria for listing	Explanatory notes
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 *Aquatic 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.
		And **C. Diagnosis**	
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 *Aquatic Manual*.) or a robust case definition is available to clearly identify cases and allow them to be distinguished from other pathologies.

Article 1.2.2.

[…]

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

Annex 5

CHAPTER 1.3.

DISEASES LISTED BY THE OIE

Preamble: The following *diseases* are listed by the OIE according to the criteria for listing an *aquatic animal disease* (see Article 1.2.1.) or criteria for listing an *emerging aquatic animal disease* (see Article 1.2.2.).

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

[…]

Article 1.3.2.

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

– Infection with abalone herpes~~-like~~ 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 (OsHV-1 and OsHV- µvar)[1].

[…]

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[1]Listed according to Article 1.2.2.

Annex 6

CHAPTER 2.2.

IMPORT RISK ANALYSIS

Article 2.2.1.

Introduction

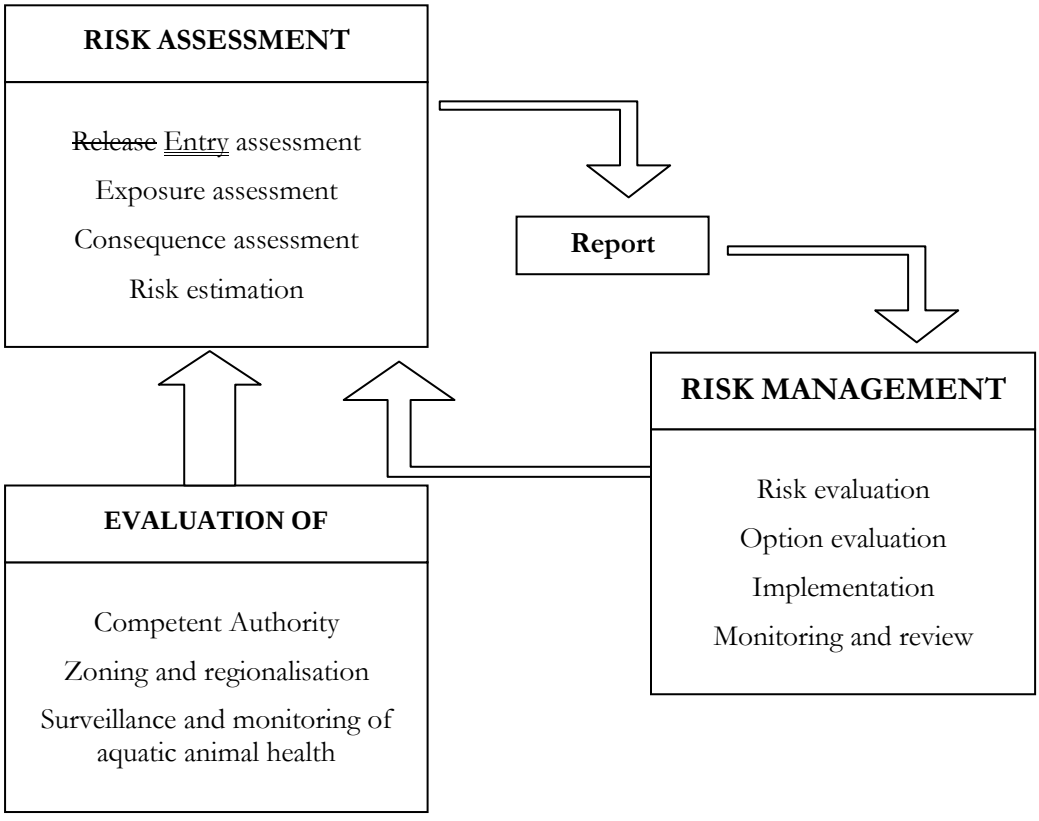
An import *risk analysis* begins with a description of the *commodity* proposed for import and the likely annual quantity of trade. It should be recognised that whilst an accurate estimate of the anticipated quantity of trade is desirable to incorporate into the *risk* estimate, it may not be readily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

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

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

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

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



Annex 6 (contd)

Article 2.2.2.

Hazard identification

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

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

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

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

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

Article 2.2.3.

Principles of risk assessment

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

2. Both qualitative and quantitative *risk assessment* methods are valid.

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

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

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

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

7. The *risk assessment* should be amenable to updating when additional information becomes available.

Article 2.2.4.

Risk assessment steps

1. Entry~~Release~~ assessment

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

a) Biological factors

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

b) Country factors

- *Incidence/prevalence*
- Evaluation of *Aquatic Animal Health Services*, *surveillance* and control programmes, and zoning systems of the *exporting country*.

c) Commodity factors

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

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

2. Exposure assessment

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

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

Annex 6 (contd)

a) Biological factors

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

b) Country factors

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

c) Commodity factors

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

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

3. Consequence assessment

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

a) Direct consequences

- *Aquatic animal infection*, *disease*, production losses and facility closures
- Adverse, and possibly irreversible, consequences to the environment
- Public health consequences.

b) Indirect consequences

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

4. Risk estimation

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

For a quantitative assessment, the final outputs may include:

– The various populations of *aquatic animals* and/or estimated numbers of *aquaculture establishments* or people likely to experience health impacts of various degrees of severity over time

– Probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates

– Portrayal of the variance of all model inputs

– A sensitivity analysis to rank the inputs as to their contribution to the variance of the *risk* estimation output

– Analysis of the dependence and correlation between model inputs.

Article 2.2.5.

Principles of risk management

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

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

Article 2.2.6.

Risk management components

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

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

Annex 6 (contd)

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

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

Article 2.2.7.

Principles of risk communication

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

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

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

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

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

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

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Annex 7

CHAPTER 3.2.

COMMUNICATION

Article 3.2.1.

General considerations

In general, communication entails the exchange of information between various individual, institutional and public groups for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages according to situations, objectives and target audiences.

The recognition of communication as a discipline of the *Aquatic Animal Health Services* and its incorporation within it is critical for their operations. The integration of *aquatic animal* health and communication expertise~~s~~ is essential for effective communication. Communication between the *Aquatic Animal Health Services* and *Veterinary Services* (particularly where *Aquatic Animal Health Services* are separate from, and independent of *Veterinary Services)* is especially important.

Communication should be an integral part of all the activities of the *Aquatic Animal Health Services* including animal health (*surveillance*, early detection and rapid response, prevention and control), *aquatic animal* welfare and veterinary public health (food safety, *zoonoses*) and veterinary medicine.

Objectives of this chapter on communication for the *Aquatic Animal Health Services* are to provide guidance for the development of a communication system, strategic and operational communication plans and elements to assess their quality.

Article 3.2.2.

Principles of communication

1. *Aquatic Animal Health Services* should have the authority and capability to communicate on matters within their mandate.

2. *Aquatic animal* health and communication expertises should be combined.

3. Communication should be targeted and follow the fundamental criteria of transparency, consistency, timeliness, balance, accuracy, honesty and empathy and respect the fundamental principles of quality of *Aquatic Animal Health Services* (Article 3.1.2.).

4. Communication should be a continuous process.

5. *Aquatic Animal Health Services* should ~~be responsible for~~ have oversight of planning, implementing, monitoring, evaluating and revising their strategic and operational communication plans.

Article 3.2.3.

Definitions

Communication: means the discipline of informing, guiding and motivating individual, institutional and public groups, ideally on the basis of interactive exchanges, about any issue under the competence of the *Aquatic Animal Health Services*.

Crisis: means a situation of great threat, difficulty or uncertainty when issues under the competence of the *Aquatic Animal Health Services* require immediate action.

Annex 7 (contd)

Crisis communication: means the process of communicating information as accurately as possible, albiet ~~of~~ potentially incomplete~~, nature~~ within time constraints in the event of a crisis.

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

Article 3.2.4.

Communication system

In addition to the Principles ~~for~~ of Communication the following elements should be used in conjunction with Chapter 3.1., when planning, implementing and assessing a communication system:

1. Organisational chart indicating a direct link between the communication personnel and the Competent Authority, through the chain of command such as ~~(e.g.~~ dedicated communication unit, communication officer~~)~~

2. Human resources

   a) Identified and accessible official communication focal point

   b) Job descriptions of communication personnel identifying roles and responsibilities

   c) Sufficient number of qualified personnel with knowledge, skills, attitude and abilities relevant to communication

   d) Continuous training and education on communication provided to communication personnel.

3. Financial and physical resources

   a) Clearly identified budget for communication that provides adequate funding

   b) Provision ~~and/~~or access to appropriate material resources in order to carry out roles and responsibilities: suitable premises~~/~~or accommodation that is adequately equipped with sufficient office and technical equipment, including information technology and access to the Internet.

4. Management of the communication system

   a) Roles and responsibilities of the communication personnel

      i) Report to the *Competent Authority*

      ii) Engage in decision-making process by providing guidance and expertise on communication issues to the *Competent Authority*

      iii) Be responsible for the planning, implementation and evaluation of the strategic and operational plans for communication and relevant standard operating procedures

      iv) Function as contact point on communication issues for the *Aquatic Animal Health Services*

      ~~v) Provide guidance and expertise on communication issues to the *Aquatic Animal Health Services*~~

v~~i~~) Provide and coordinate continuous education on communication for the *Aquatic Animal Health Services*.

b) Strategic plan for communication

A well-designed strategic plan for communication should support the *Aquatic Animal Health Services* strategic plan and have management support and commitment. The strategic plan for communication should address all high level organization-wide long-term communication objectives. ~~The plan should be a long-term plan.~~

A strategic plan for communication should be monitored, periodically reviewed and should identify measurable performance objectives and techniques to assess the effectiveness of communication.

The strategic plan for communication should consider the different types of communication: routine communication, risk communication, outbreak communication and crisis communication, to allow individuals, affected ~~and/~~or interested parties, an entire community or the general public to make the best possible decisions and be informed of ~~and/or accept~~ policy decisions and their rationale.

The key outcomes in effectively implementing a strategic plan for communication are increased knowledge and awareness of issues by the public and stakeholders, higher understanding of the role of the Aquatic Animal Health Services, higher visibility of and improved trust and credibility in the Aquatic Animal Health Services. These will enhance understanding and/or acceptance of policy decisions and subsequent change of perception, attitude and/or behaviour.

c) Operational plans for communication

Operational plans for communication should be based on the assessment of specific issues and should identify specific objectives and target audiences such as staff, partners, stakeholders, media and the general public.

Each operational plan for communication should consist of a well-planned series of activities using different techniques, tools, messages and channels to achieve intended objectives and utilizing available resources within a specific timeframe.

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Annex 8

Example article to be applied to all disease specific chapters under point 1 of Articles X.X.12. (amphibian and fish disease chapters) and X.X.11. (crustacean and mollusc disease chapters).

[…]

Article 10.1.12.

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

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

   Certain assumptions have been made in assessing the safety of aquatic animals and aquatic animal products listed above. Member Countries should refer to these assumptions at Article 5.3.2. and consider whether the assumptions apply to their conditions.

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

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Annex 9

CHAPTER 6.4.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIALS ~~S~~ AGENTS USED IN AQUATIC ANIMALS

Article 6.4.1.

Purpose

The purpose of these recommendations is to describe approaches to the monitoring of quantities of antimicrobial agents used in *aquatic animals*, including species reared for food and ornamental purposes.

These recommendations are intended for use ~~by OIE Members to~~ in the collection of objective and quantitative information to evaluate usage patterns by antimicrobial class, route of administration and *aquatic animal* species in order to evaluate exposure of microorganisms to antimicrobial agents.

The collection of data on the use of antimicrobial agents in *aquaculture* may be constrained in some countries by the lack of available resources, lack of accurately labelled products, ~~and~~ poorly ~~understood~~ documented distribution channels and lack of professional consultation or supervision. This chapter may therefore be seen as indicating the direction in which countries should develop with regard to collecting data and information on the use of antimicrobial agents in *aquatic animals*.

Article 6.4.2.

Objectives

The information provided in these recommendations is essential for conducting *risk analyses* and for planning purposes. This information can be helpful in interpreting antimicrobial resistance surveillance data and can assist in the ability to respond to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information would help identify trends in the use of antimicrobial agents in *aquatic animals* and the potential association with antimicrobial resistance in *aquatic animal* bacteria, including potentially zoonotic bacteria. This information may also assist in *risk management* when evaluating the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies and indicate where alteration of prescribing practices for antimicrobial agents in *aquatic animals* might be appropriate. The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.4.3.

Definitions

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that at *in vivo* concentrations exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Annex 9 (contd)

Article 6.4.~~3~~4.

Development and standardisation of monitoring systems for antimicrobial agents

Competent Authorities may, for reasons of cost and administrative efficiency, collect medical, agricultural, aquacultural and other antimicrobial agent use data in a single programme. Where livestock and *aquatic animal* industries are under multiple authorities in a single country, collaboration between the authorities to develop a coordinated monitoring system is necessary to facilitate the collection of data. Additionally, a consolidated programme would facilitate the comparison of *aquatic animal* use data with human use data necessary for a comprehensive risk analysis.

Systems to monitor usage of antimicrobial agents may consist of the following elements:

1. Sources of data on antimicrobial agents

   a) Basic sources

      Data from basic sources may include general information without specific attribution (such as, weight, quantity and class of antimicrobial agents).

      Sources of data will vary from country to country. Such sources may include customs, import, export, manufacturing and sales data.

   b) Direct sources

      Data from direct sources may include more specific information (such as target *aquatic animal* species, route of administration and active ingredient).

      Data from veterinary medicinal product registration authorities, manufacturers, wholesalers, retailers, feed stores and feed mills might be useful sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by veterinary antimicrobial manufacturers to the registration authority one of the requirements of marketing authorisation (registration of the antimicrobial agent).

   c) End-use sources ~~(veterinarians, aquatic animal health professionals and producers)~~

      Data from end-use sources has the advantage of providing more detailed information on the type and purpose of use and can be complimentary to the other sources.

      End-use sources of data may include *veterinarians*, *aquatic animal* health professionals and *aquatic animal* producers. ~~This source has the advantage of providing more detailed information on the type and purpose of use and can be complementary to the other sources. This~~ End-use sources may be useful when more accurate and locally specific information is needed (such as extra-/off-label use).

      ~~Because c~~Collection of this type of information can be resource intensive, therefore, periodic collection of this type of information may be sufficient. Data collection should be targeted to the most relevant period of use.

      In some countries end-use sources may be the only practical source of information ~~at the moment~~.

   d) Other sources

      Pharmaceutical industry associations and *aquatic animal* producer associations, veterinary and allied health professional associations, and other stakeholders with indirect knowledge of the quantities of antimicrobial agents used may be another source of this information.

Non-conventional sources including Internet sales data related to antimicrobial agents may ~~could~~ be collected where available. Internet sales data may be particularly useful with respect to ornamental species.

~~Registration of products with labeling that accurately reflects the intended use of the antimicrobial agent will facilitate collection of information on the quantities and usage patterns. OIE Members are encouraged to support each other in the development of this infrastructure.~~

~~OIE Members may also wish to consider, for reasons of cost and administrative efficiency, collecting medical, agricultural, aquacultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for relative *risk analysis* and help to promote optimal usage of antimicrobial agents. Additionally, where livestock and aquatic animal industries are under multiple authorities in a single country, coordination between the authorities is encouraged.~~

2. Elements for data collection ~~Types~~ and reporting ~~formats of antimicrobial usage data~~

~~If a Member has the infrastructure for capturing basic animal use data for a specific antimicrobial agent, then additional information can be considered to cascade from this in a series of subdivisions or levels of detail. Such a cascade of levels should include the following:~~

a) Basic data to be collected should include:

i) the ~~A~~absolute amount in kilograms of the active ingredient of the antimicrobial agent(s) used per year, divided into antimicrobial class/subclass.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antimicrobial agents expressed in International Units, the calculation required to convert these units to mass of active entity should be stated. It may be possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, export/import data or any combination of these;

ii) the total number of *aquatic animals* treated ~~cultured~~ and their weight in kilograms ~~is important basic information~~.

b) ~~Subdivision of antimicrobial use into species of finfish, crustacean, or mollusc treated.~~ Additional data may be collected to further categorise the exposure of microorganisms to antimicrobial agents and may include:

i) species of fish, crustaceans, molluscs or amphibians treated;

~~c~~ii) ~~Subdivision by~~ purpose e.g. *aquatic animals* for human consumption, use as ornamental species ~~fish~~ and baitfish;

~~d~~iii) ~~Subdivision of the data into the~~ route of administration (medicated feed, bath treatment, parenteral delivery) and the method used to calculate the dose (biomass of ~~fish~~ *aquatic animals*, volume of water treated);

iv) indication for use.

The antimicrobial agents/classes/sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity / antimicrobial resistance mechanism.

Annex 9 (contd)

Nomenclature of antimicrobials agents should comply with international standards where available.

When making information publically available, the *Competent Authority* should ensure confidentiality and anonymity of individual enterprises.

3. Considerations for data collection

Antimicrobial usage data may could be collected on a routine basis and / or at a specific point in time depending on availability of resources and / or the need to monitor usage of antimicrobial agents or address a specific antimicrobial resistance problem.

When collecting and interpreting the data it is important to take into account factors such as Ttemperature, disease conditions (epizootiology), species and age affected, aquacultural systems (i.e. intensive / extensive), dosage and duration of treatment with antimicrobial agents.

Registration of products with labelling that accurately reflects the intended use of the antimicrobial agent will facilitate collection of information on the quantities and usage patterns.

Collection, storage and processing of data from end-use sources requires careful design but should have the advantage of producing accurate and targeted information.

Article 6.4.45.

Elements for interpretation of data on the use of antimicrobial agents

In order to maximize the value of usage data, it may be beneficial to collect additional information. Such information will, w When available, the following information may support aid in the interpretation of antimicrobial usage data and further characterisation of exposure pathways interpretation of usage data:

These are examples of some factors that can be considered:

a) type of aquaculture system (extensive or intensive, ponds or tanks, flow-through or recirculating, hatchery or grow-out, integrated system);

b) animal movements (transfer between facilities or from wild to the facility, grading);

c) species, and life stage, and/or stage of the production cycle;

d) environmental and culture parameters (seasonality, temperature, salinity, pH);

e) geographical location, specific rearing units;

f) weight/biomass, dosage regimes and duration of treatment with antimicrobial agents;

g) basis for treatment (historical, empirical, clinical, clinical with laboratory confirmation and sensitivity testing).

Factors such as the number/percentage of animals / culture units treated, treatment regimens, type of use and route of administration are key elements to consider for *risk assessment*.

When comparing use of antimicrobial agents over time, changes in size and composition of animal populations should also be taken into account.

Regarding data coming from end user sources, analysis of the use of antimicrobial agents may be possible at the regional, local, farm, and the level of the individual *veterinarian* or other *aquatic animal* health professional.

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Annex 10

CHAPTER 6.5.

DEVELOPMENT AND HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES FOR AQUATIC ANIMALS

Article 6.5.1.

Purpose

This chapter provides criteria relevant to *aquatic animals*~~,~~ and ~~products of~~ *aquatic animal products* ~~origin~~ intended for human consumption ~~and their rearing environment~~ for:

1. the development of national antimicrobial resistance surveillance and monitoring programmes and

2. the harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes.

Article 6.5.2.

Objective of surveillance and monitoring programmes

~~Countries~~ *Competent Authorities* should conduct active antimicrobial resistance surveillance and monitoring programmes for *aquatic animals*.

Surveillance and monitoring of antimicrobial resistance is necessary to:

1. establish baseline data on the prevalence of antimicrobial resistant microorganisms and determinants;

2. collect information on antimicrobial resistance trends in relevant microorganisms;

3. explore the potential relationship between antimicrobial resistance in *aquatic animal* microorganisms and the use of antimicrobial agents;

4. detect the emergence of antimicrobial resistance mechanisms;

5. conduct *risk analyses* as relevant to *aquatic animal* and human health;

6. provide recommendations on human health and *aquatic animal* health policies and programmes;

7. provide information to facilitate prudent use, including guidance for professionals prescribing the use of antimicrobial agents in *aquatic animals*.

Cooperation at a regional level between countries conducting antimicrobial resistance surveillance should be encouraged.

Annex 10 (contd)

The findings of surveillance and monitoring programmes should be shared at the regional and international level to maximise understanding of the global risks to *aquatic animal* health and human health ~~and animal health~~. The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.5.3.

Definitions

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that at *in vivo* concentrations exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Article 6.5.~~3~~4.

General considerations for the design of surveillance and monitoring programmes

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in microorganisms from *aquatic animals*, *aquatic animal products* intended for human consumption ~~food~~ ~~,~~ ~~environment~~ and humans constitutes a critical part of *aquatic animal* health and public health strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of antimicrobial agents used in therapy.

For *aquaculture* it is important to conduct surveillance and monitoring of microorganisms that infect *aquatic animals* and microorganisms, including human pathogens, present on food derived from *aquatic animals*. ~~It may be also important to consider surveillance and monitoring of microorganisms that may potentially serve as a reservoir of resistance determinants in the environment.~~

Article 6.5.~~4~~5.

Design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect aquatic animals

An important consideration for the design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect *aquatic animals* is the lack of standardised and validated antimicrobial testing methods for a significant number of bacterial species of aquatic importance. When validated methods are available they should be used. Any deviations from standard methodology should always be clearly reported. For tests performed on bacterial species for which standard methods have not been developed full details of the methods used should be provided.

A preliminary requirement for the development of a surveillance and monitoring programme may be the identification and prioritisation of bacteria isolated from *aquatic animals* for methods development.

1. Selection of microorganisms

   Information on the occurrence of antimicrobial resistance in microorganisms that infect *aquatic animals* should be derived from regular monitoring of isolates obtained from diagnostic laboratories. These isolates should have been identified as primary causal agents of significant disease epizootics in *aquatic animals*.

   It is important that monitoring programmes focus on microorganisms that are associated with the commonly encountered *infections* of the major aquatic species farmed in the region / local growing area.

Selection should be designed to minimise bias resulting from over representation of isolates obtained from severe epizootics or epizootics associated with therapeutic failures.

Microorganisms belonging to a specific species or group may be selected for intensive study in order to provide information on a particular problem.

2. Methods used to analyse microorganism susceptibility to antimicrobial agents

Participating laboratories may perform disc diffusion, minimum inhibitory concentration (MIC) or other susceptibility tests to monitor frequencies of resistance. Protocols that have been standardised internationally and validated for application to the study of ~~aquatic~~ microorganisms isolated from *aquatic animals* should always be used.

3. Requirements for laboratories involved in monitoring resistance

Laboratories involved in national or regional monitoring of antimicrobial resistance should be of sufficient capability and have relevant expertise to comply with all the quality control requirements of the standardised test protocols. They should also be capable of participating in all necessary inter-laboratory calibration studies and ~~on-going validation studies~~ method standardisation trials.

4. Choice of antimicrobial agents

Representatives of all major classes of antimicrobial agents used to treat *disease* in *aquatic animal* species should be included in susceptibility testing ~~programmes~~.

5. Reporting of results

The results of ~~monitoring and~~ surveillance and monitoring programmes, including susceptibility data, should be published and made available for use by relevant stakeholders. Both ~~raw~~ primary quantitative data and the ~~epidemiological cut-off values or clinical breakpoints used to make interpretations of the data~~ interpretive criteria used should ~~always~~ be reported.

6. Surveillance and monitoring for epidemiological purposes

For epidemiological surveillance purposes, use of the epidemiological cut-off value (also referred to as microbiological breakpoint), which is based on the distribution of MICs or inhibition zone diameters of the specific microbial species tested, is preferred.

When reporting interpretations made by application of epidemiological cut-off values, the resultant categories should be referred to as wild type (WT) or non-wild type (NWT). When interpretations are made by the application of breakpoints the resultant categories should be referred to as sensitive, intermediate or resistant.

For microbial species and antimicrobial agent combinations, where internationally agreed epidemiological cut-off values have not been set, laboratories may establish their own laboratory specific values provided the methods they use are clearly reported.

Annex 10 (contd)

7. Surveillance and monitoring for clinical purposes

The application of clinical breakpoints may be appropriate when the aim of the programme is to provide information to facilitate prudent use, including guidance for professionals in prescribing antimicrobial agents in *aquatic animals*. Selecting antimicrobial agents for therapeutic administration on the basis of information gained from the application of validated clinical breakpoints to antimicrobial susceptibility test data for microorganisms isolated from *aquatic animals* is an important element in the prudent use of these agents.

Use of these clinical breakpoints allows microorganisms to be identified as unlikely to respond to the *in-vivo* concentrations of antimicrobial agents achieved by a given standard therapeutic regime. In order to facilitate the development of these breakpoints, data is required that allows clinical correlation to be completed. For this purpose, where possible, data that relates *in-vitro* susceptibility of isolates to the clinical outcome of treatments with specified dose regimes under specific environmental conditions should be collected and reported.

Valuable information with respect to setting clinical breakpoints can be gained from situations where therapeutic failure is reported. The *Competent Authority* should include, in a surveillance and monitoring programme, systems for capturing details of failed treatments and the laboratory susceptibility test of the microorganisms involved.

Article 6.5.~~5~~6.

Design of surveillance and monitoring programmes for microorganisms in or on ~~food derived from~~ aquatic animal~~s~~ product~~s~~ intended for human consumption

For details of the sampling protocols and analytical procedures required for *surveillance* and monitoring programmes for antimicrobial resistance in microorganisms present in ~~products of~~ *aquatic animal products* ~~origin~~ intended for human consumption, ~~the relevant section~~ Chapter 6.7. of the *Terrestrial Animal Health Code* should be consulted.

It is important to note that the word 'commensal' as used in Chapter 6.7. of the *Terrestrial Animal Health Code* has less relevance due to the transient nature of the intestinal microflora of *aquatic animals*. ~~Therefore~~ The inclusion of intestinal microflora ~~commensal bacteria should not be included~~ in surveillance and monitoring programmes should only be considered when there is evidence that these are resident for sufficient time to be a risk factor affected by antimicrobial agents.

When designing a sampling programme it is important to consider that contamination of *aquatic animal products* with resistant microorganisms that are capable of infecting humans may arise from sources other than the *aquatic animal*. All sources of contamination should be taken into account, for example entry of raw manure into the aquatic environment. The number of ~~zoonotic~~ such microorganisms ~~of~~ associated with *aquatic animals* is much less than that found in terrestrial animals. However the following species should be included, as a minimum, in a ~~monitoring or~~ surveillance and monitoring programme:

a) *Salmonella* spp.;

b) *Vibrio parahaemolyticus*;

c) *Listeria monocytogenes*.

Annex 10 (contd)

Article 6.5.6.

~~**Surveillance and monitoring for antimicrobial resistance in microorganisms present in the aquatic environment**~~

~~The development of a reservoir of resistance determinants in microorganisms in the aquatic environment has been identified as a potential risk arising from the use of antimicrobial agents in *aquaculture*. The objective of a surveillance and monitoring programme for these resistance determinants is to generate the data needed to conduct *risk analysis*.~~

~~The development and implementation of these programmes is significantly challenged by the complexity of the biological pathways, the lack of culture and susceptibility testing methods, and the diversity of *aquaculture* operations.~~

~~These programmes should focus on:~~

~~a) resistance determinants rather than on resistant microorganisms;~~

~~b) the use of quantitative molecular methods rather than traditional culture and susceptibility testing methods;~~

~~c) generating baseline data on the prevalence of resistance determinants (a) prior to exposure to the outputs of the aquaculture operation and (b) following exposure to the outputs of the aquaculture operation;~~

~~d) investigating a possible relationship between the emergence and persistence of resistance determinants and the use of antimicrobial agents.~~

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Annex 11

CHAPTER 7.2.

WELFARE OF FARMED FISH DURING TRANSPORT

Article 7.2.1.

Scope

This chapter provides recommendations to minimise the effect of transport on the welfare of farmed fish (hereafter referred to as fish). It applies to their transport by air, by sea or on land within a country and between countries, and only considers the issues related to their welfare.

Recommendations for measures to control the *aquatic animal* health *risks* related to the transport of fish are included in Chapter 5.4. Control of aquatic animal health risks associated with transport of aquatic animals.

Article 7.2.2.

Responsibilities

All personnel handling fish throughout the transportation process are responsible for ensuring that consideration is given to the potential impact on the welfare of the fish.

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

    a) establishing minimum standards for fish welfare during transport, including examination before, during and after their transport, appropriate certification, record keeping, awareness and training of personnel involved in transport;

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

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

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

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

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

    d) ensuring fish have a suitable environment to enter at their destination that ensures their welfare is maintained.

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

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

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

Annex 11 (contd)

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

d) selecting suitable equipment for loading and unloading of the *vehicle*.

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

Article 7.2.3.

Competence

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

1. All persons handling live fish, or who are otherwise responsible for live fish during transport, should be competent according to their responsibilities listed in Article 7.2.2.

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

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

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

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

c) water quality and suitable procedures for water exchange;

d) methods of live fish handling during transport, loading and unloading (species-specific aspects when relevant);

e) methods for inspection of the fish, management of situations frequently encountered during transport such as changes in water quality parameters, adverse weather conditions, and emergencies;

f) methods for the humane killing of fish in accordance with Chapter 7.4. on the killing of fish for disease control purposes (in preparation);

g) logbooks and record keeping.

Article 7.2.4.

Planning the transport

1. General considerations

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

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

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

c) nature and duration of the transport;

d) assessment of the need for acclimatisation of fish to water quality at the site of unloading;

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

~~e~~f) emergency response procedures related to fish welfare;

~~f~~g) assessment of the necessary biosecurity level (e.g. washing and *disinfection* practices, safe places for changing water, treatment of transport water) (refer to Chapter 5.4.).

2. Vehicle design and maintenance, including handling equipment

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

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

c) *Vehicles* (if relevant) and *containers* should have adequate circulation of water and equipment for oxygenation as required to meet variations in the conditions during the journey and the needs of the animals being transported, including the closing of valves in well boats for biosecurity reasons.

d) The fish should be accessible to inspection en route, if necessary, to ensure that fish welfare can be assessed.

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

f) Equipment used to handle fish, for example nets and dip nets, pumping devices and brailing devices, should be designed, constructed and maintained to avoid physical injuries.

3. Water

a) Water quality (e.g. oxygen, CO_2 and NH_3 level, pH, temperature, salinity) should be appropriate for the species being transported and method of transportation.

b) Equipment to monitor and maintain water quality may be required depending on the length of the transport.

Annex 11 (contd)

4. Preparation of fish for the transport

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

b) The ability of the fish to cope with the stress of transport should be assessed based on health status, previous handling and recent transport history of the fish. Generally, only fish that are fit for transport should be loaded. Transport for disease control purposes should be in accordance with Chapter 7.4. on the killing of fish for disease control purposes (in preparation).

c) Reasons for considering of unfitness of fish for transport includes:

i) displaying clinical signs of *disease*;

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

iii) recent exposure to stressors that adversely affect behaviour or physiological state (for example extreme temperatures, chemical agents);

iv) insufficient or excessive length of fasting.

5. Species-specific recommendations

Transport procedures should take account of variations in the behaviour and specific needs of the transported fish species. Handling procedures that are successful with one species may be ineffective or dangerous for another species.

Some species or life stages may need to be physiologically prepared prior to entering a new environment, such as by feed deprivation or osmotic acclimatisation.

6. Contingency plans

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

Article 7.2.5.

Documentation

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

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

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

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

3. The transport log should be made available to the dispatcher and the receiver of the consignment as well as to the *Aquatic Animal Health Service* upon request. Transport logs from previous journeys should be kept after completion of the transport for a period of time as specified by the *Aquatic Animal Health Service*.

Article 7.2.6.

Loading the fish

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

   a) crowding procedure in farm pond, tank, net or cage prior to loading;

   b) equipment (such as nets, pumps, pipes and fittings) that are improperly constructed, e.g. sharp bends or protrusions) or improperly operated (e.g. overloading with fish of incorrect size or number of fish);

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

2. The density of fish in a *vehicle* and/or *container* should be in accordance with scientific data where available and not exceed what is generally accepted for a given species and a given situation.

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

Article 7.2.7.

Transporting the fish

1. General considerations

   a) Periodic inspections should take place during the transport to verify that acceptable welfare is being maintained.

   b) Ensure that water quality is monitored and the necessary adjustments made to avoid extreme conditions.

   c) Travel in a manner that minimises uncontrolled movements of the fish that may lead to stress and cause injury.

2. Sick or injured fish

   a) In the event of a fish health emergency during transport, the *vehicle* operator should initiate the *contingency plan* (see point 6 of Article 7.2.3.).

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

Annex 11 (contd)

Article 7.2.8.

Unloading the fish

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

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

3. Moribund or seriously injured fish should be removed and humanely killed in accordance with Chapter 7.4. on the killing of farmed fish for disease control purposes (in preparation).

Article 7.2.9.

Post-transport activities

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

2. Fish showing abnormal clinical signs should be humanely killed in accordance with Chapter 7.4. on the killing of farmed fish for disease control purposes (in preparation) or isolated and examined by a *veterinarian* or other qualified personnel, who may recommend treatment.

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

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Annex 12

CHAPTER 7.3.

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

Article 7.3.1.

Scope

These recommendations apply to the stunning and killing of farmed fish species for human consumption. These recommendations address the need to ensure the welfare of farmed fish, intended for human consumption, during stunning and killing including transport and holding immediately prior to stunning.

This chapter describes general principles that should be applied to ensure the welfare of fish for stunning and killing for human consumption and also applies to farmed fish killed for disease control purposes. ~~and intended for human consumption. Specific~~ Other measures applicable to emergency killing for disease control purposes ~~not intended for human consumption~~ are addressed in Chapter 7.4. Killing of Farmed Fish for Disease Control Purposes (under development).

As a general principle, farmed fish should be stunned before killing, and the stunning method should ensure immediate and irreversible loss of consciousness. If the stunning is not irreversible, fish should be killed before consciousness is recovered.

Article 7.3.2.

Personnel

Persons engaged in the handling, stunning and killing of fish play an important role in their welfare. Personnel handling fish for stunning and killing should be experienced and competent in the handling of fish, and understand their behaviour patterns as well as the underlying principles necessary to carry out their tasks. Some stunning and killing methods may pose a risk to the personnel; therefore training should cover occupational health and safety implications of any methods used.

Article 7.3.3.

Transport

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

Article 7.3.4.

Design of holding facilities

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

2. The holding facilities should be of a size that allows holding a certain number of fish for processing in a given timeframe without compromising the welfare of the fish.

3. Operations should be conducted with minimal injury and stress to the fish.

4. The following recommendations may help to achieve this:

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a) nets and tanks should be designed and maintained to ~~minimise~~ avoid physical injuries;

b) water quality should be suitable for the fish species and stocking density;

c) equipment for transferring fish, including pumps and pipes, should be designed and maintained to ~~minimise~~ avoid injury.

Article 7.3.5.

Unloading, transferring and loading

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

2. The following points should be considered:

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

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

c) The crowding periods of fish should be as short and infrequent as possible to avoid stressful conditions arising.

d) The handling of fish during transfers should be minimised and preferably fish should not be handled out of water. If fish need to be removed from water, this period should be kept as short as possible.

e) Where feasible, and when applicable, fish should be allowed to swim directly into a stunning device without handling to avoid handling stress.

f) Equipment used to handle fish, for example nets and dip nets, pumping devices and brailing devices, should be designed, constructed and operated to ~~minimise~~ avoid physical injuries (e.g. pumping height, pressure and speed are important factors to consider).

g) Fish should not be fasted (deprived of food) before killing for longer than is necessary (e.g. to clear the gut or to reduce undesirable organoleptic properties).

h) There should be a *contingency plan* to address emergencies and minimise stress during unloading, transferring and loading fish.

Article 7.3.6.

Stunning and killing methods

1. General considerations

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

b) All handling, stunning and killing equipment should be maintained and operated appropriately; it should be tested on a regular basis to ensure that performance is adequate.

c) Effective stunning should be verified by the absence of consciousness.

d) A backup stunning system is necessary. Any fish mis-stunned, or regaining consciousness before death, should be re-stunned as soon as possible.

e) Stunning should not take place if killing is likely to be delayed such that the fish will recover or partially recover consciousness.

f) While absence of consciousness may be difficult to recognise, signs of correct stunning include i) loss of body and respiratory movement (loss in opercular activity); ii) loss of visual evoked response (VER); iii) loss of vestibulo-ocular reflex (VOR, eye rolling).

2. Mechanical stunning and killing methods

a) Percussive stunning is achieved by a blow of sufficient strength to the head applied above or immediately adjacent to the brain in order to damage the brain. Mechanical stunning may be achieved either manually or using specially developed equipment.

b) Spiking or coring are irreversible stunning and killing methods of fish based on physical damage to the brain by inserting a spike or core into the brain.

c) Shooting using a free bullet may be used for killing large fish (such as tuna). The fish may either be crowded in a net and shot in the head from the surface, or individual fish may be killed by shooting in the head from under the water (commonly called lupara).

d) Unconsciousness following m~~M~~echanical stunning is generally irreversible if correctly applied. In cases where the loss of consciousness is transient, fish should be killed before consciousness is recovered.

3. Electrical stunning and killing methods

a) Electrical stunning involves the application of an electrical current of sufficient strength and duration, and suitable frequency to cause immediate loss of consciousness and insensibility of the fish. The conductivity of fresh and brackish water varies, so it is essential to establish the parameters of the electrical current to ensure proper stunning at the site of stunning.

b) The electrical stunning device should be constructed and used for the specific fish species and their environment.

c) Unconsciousness following e~~E~~lectrical stunning may be reversible. In such cases fish should be killed before consciousness is recovered.

d) Fish should be confined beneath the surface of the water, and there should be a uniform distribution of electrical current in the stunning tank or chamber.

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

4. Other killing methods

The following methods are known to be used for killing fish: chilling with ice in holding water, carbon dioxide (CO_2) in holding water; chilling with ice and CO_2 in holding water; salt or ammonia baths; asphyxiation by removal from water; exsanguination without stunning. However, they have been shown to result in poor fish welfare. Therefore, these methods should not be used if it is feasible to use the methods described in points 2 and 3 of this Article, as appropriate to the fish species.

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Article 7.3.7.

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

A combination of methods described in the table below may be used.

Stunning/ killing method	**Specific method**	**Key fish welfare concerns/requirements**	**Advantages**	**Disadvantages**
Mechanical	Percussive stunning	The blow should be of sufficient force and delivered above or adjacent to the brain in order to render immediate unconsciousness. Fish should be quickly removed from the water, restrained and given a quick blow to the head, delivered either manually by a club or by automated percussive stunning. The effectiveness of stunning should be checked, and fish be re-stunned if necessary. It can be a stun / kill method.	Immediate loss of consciousness. Suitable for medium to large sized fish.	Hand operated equipment may be hampered by uncontrolled movement of the fish. Mis-stunning may result from a too weak blow. Injuries may occur. Manual percussive stunning is only practicable for the killing of a limited number of fish of a similar size.
	Spiking or coring	The spike should be aimed on the skull in a position to penetrate the brain of the fish and the impact of the spike should produce immediate unconsciousness. Fish should be quickly removed from the water, restrained and the spike immediately inserted into the brain. It is a stun / kill method.	Immediate loss of consciousness. Suitable for medium to large sized fish. For small tuna, spiking under the water avoids exposure of fish to air. The pineal window of tuna facilitates spiking for this species.	Inaccurate application may cause injuries. Difficult to apply if fish agitated. It is only practicable for the killing of a limited number of fish.
	Free bullet	The shot should be carefully aimed at the brain. The fish should be positioned correctly and the shooting range should be as short as practicable. It is a stun / kill method.	Immediate loss of consciousness. Suitable for large sized fish (e.g. large tuna).	Shooting distance; calibre need to be adapted. Excessive crowding and noise of guns may cause stress reaction. Contamination of the working area due to release of body fluids may present a biosecurity risk. May be hazardous to operators.
Electrical	Electrical stunning	Involves the application of an electrical current of sufficient strength, frequency and duration to cause immediately unconsciousness. It can be a stun / kill method. Equipment should be designed and maintained correctly.	Immediate loss of consciousness. Suitable for small to medium sized fish. Suitable for large numbers of fish, and the fish do not have to be removed from the water.	Difficult to standardise for all species. Optimal control parameters are unknown for some species. May be hazardous to operators.
	Semi-dry electrical stunning	The head of the fish should enter the system first so electricity is applied to the brain first. Involves the application of an electrical current of sufficient strength, frequency and duration to cause immediately unconsciousness. Equipment should be designed and maintained correctly.	Good visual control of stunning and the ability for re-stunning of individual fish.	Misplacement of the fish may result in improper stunning. Optimal control parameters are unknown for some species. Not suitable for mixed sizes of fish

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

Article 7.3.8.

Examples of stunning/killing methods for fish groups

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

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

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Annex 13

CHAPTER 7.4.

KILLING OF FARMED FISH FOR DISEASE CONTROL PURPOSES

Article 7.4.1.

Scope

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

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

Account should also be taken of the guidance given in the following chapters in the *Aquatic Code*: Chapter 4.4. Contingency Planning, Chapter 4.6. Handling, Disposal and Treatment of Aquatic Animal Waste, Chapter 5.4. Control of Aquatic Animal Health Risks Associated with Transport, Chapter 7.2. Welfare of Farmed Fish during Transport and Chapter 7.3. Welfare Aspects of Stunning and Killing of Farmed Fish for Human Consumption.

Article 7.4.2.

General principles

1. Fish welfare considerations should be addressed within contingency plans for disease control (refer to Chapter 4.4.).

2. The killing method should be selected taking into consideration fish welfare and biosecurity requirements as well as safety of the personnel.

3. When fish are killed for disease control purposes, methods used should result in immediate death or immediate loss of consciousness lasting until death; when loss of consciousness is not immediate, induction of unconsciousness should be non-aversive or the least aversive possible and should not cause avoidable ~~anxiety,~~ pain, distress or suffering in fish.

4. The methods described in Chapter 7.3. can also be used for disease control purposes.

5. Some of the methods recommended for disease control purposes (e.g. anaesthetic overdose, maceration) may render the fish unsuitable for human consumption, and this should be specified in the contingency plan.

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

Article 7.4.3.

Operational guidelines for affected premises and approved killing facilities

The following should apply when killing fish:

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1. Operational procedures should be adapted to the specific circumstances on the premises and should address ~~biosecurity and~~ fish welfare and biosecurity specific to the *disease* of concern.

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

3. Handling of fish should be kept to a minimum to avoid stress and to prevent spread of *disease*. This should be done in accordance with the articles described below.

4. Methods used to kill the fish should render them unconscious until death or kill them in the shortest time possible ~~in the circumstances~~, and should not cause avoidable pain or distress.

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

6. Standard operating procedures (SOP's) should be available and followed at the premises.

Procedures ~~A protocol~~ for the killing of fish on affected premises for disease control purposes should be developed by the operator and approved by the *Competent Authority*, taking into consideration fish welfare and biosecurity requirements as well as safety of the personnel and should include consideration of:

1. handling and movement of fish;

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

3. methods for killing the fish;

4. availability of anaesthetic agents suitable to kill the fish;

5. equipment needed to kill the fish;

6. any legal issues (e.g. the use of anaesthetic agents suitable for killing fish);

7. presence of other nearby aquaculture premises;

8. disposal of killed fish in accordance with Chapter 4.6.

Article 7.4.4.

Competencies and responsibilites of the operational team

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

1. Team leader

   a) Competencies

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

      ii) ability to assess biosecurity risks and mitigation measures being applied to prevent spread of *disease*;

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

iv) awareness of the ~~emotional~~ psychological impact on fish farmers, team members and general public;

v) effective communication skills.

b) Responsibilities

i) Determine most appropriate killing method(s) to ensure that the fish are killed without avoidable pain and distress while balancing biosecurity considerations;

ii) plan overall operations on the affected premises;

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

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

v) determine logistics required;

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

vii) report upwards on progress and problems;

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

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

2. On-site personnel responsible for killing of fish

a) Competencies

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

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

iii) trained and competent in the operation and maintenance of equipment.

b) Responsibilities

i) Ensure killing of fish through effective stunning and killing techniques;

ii) assist team leader as required;

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

Annex 13 (contd)

Article 7.4.5.

Killing by an overdose of an anaesthetic agent

This article refers to killing methods using an overdose of an anaesthetic agent.

1. Use of anaesthetic agents

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

   b) when using anaesthetic agents, the operating personnel should ensure that the solution has the correct concentration for the water in which it is to be administered, and that ~~sea~~ water of appropriate quality for the species and life stage of fish is used ~~for marine fish species and freshwater for freshwater species~~;

   c) fish should be kept in the anaesthetic solution until they are dead.

2. Advantages

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

   b) handling is not required until fish are dead ~~anaesthetised~~;

   c) use of anaesthetic agents is a non-invasive technique and thus reduces biosecurity risks.

3. Disadvantages

   a) The method may fail to cause death in fish, e.g. dilution of the anaesthetic solution with prolonged use. In such circumstances, fish that are anaesthetised should be killed before they regain consciousness; ~~May need to be followed by killing if fish are only anaesthetised~~;

   b) some anaesthetic agents may induce a transient aversive reaction in the fish;

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

Article 7.4.6.

Mechanical killing methods

1. Decapitation

   a) Decapitation, using a sharp device such as a guillotine or knife may be used but should be preceded by stunning or anaesthesia if appropriate;

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

   c) contamination of the working area by blood, body fluids and other organic material may present a biosecurity risk and is the major disadvantage of this method.

2. Maceration

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

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

c) contamination of the working area by blood, body fluids and other organic material may present a biosecurity risk and is the major disadvantage of this method.

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Annex 14

DISINFECTION OF SALMONID EGGS (ARTICLE 10.4.13., ARTICLE 10.5.13. AND ARTICLE 10.9.13.)

Article 10.4.13.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from infectious haematopoietic necrosis

1. When importing disinfected eggs of the species referred to in Article 10.4.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

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

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

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

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

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

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

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

3. When importing disinfected eggs of the species referred to in Article 10.4.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from IHN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.4.13. have been fulfilled.

[…]

Article 10.5.13.

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

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

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

   b) the prevalence ~~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*.

Annex 14 (contd)

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.

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

3. When importing disinfected eggs of the species referred to in Article 10.5.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.5.13. have been fulfilled.

[…]

Article 10.9.13.

Importation of disinfected eggs for aquaculture from a country, zone or compartment not declared free from viral haemorrhagic septicaemia

1. When importing disinfected eggs of the species referred to in Article 10.9.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should assess the *risk* associated with at least:

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

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

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

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

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

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

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

3. When importing disinfected eggs of the species referred to in Article 10.9.2. for *aquaculture*, from a country, *zone* or *compartment* not declared free from VHS, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.9.13. have been fulfilled.

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Annex 15

CHAPTER 2.1.

GENERAL CONSIDERATIONS

Article 2.1.1.

Introduction

The importation of *aquatic animals* and animal products, whether of aquatic or terrestrial origin, involves a degree of *disease risk* to the *importing country*. This *risk*, which may be to humans or animals, may be represented by one or several *diseases* not present in the *importing country*.

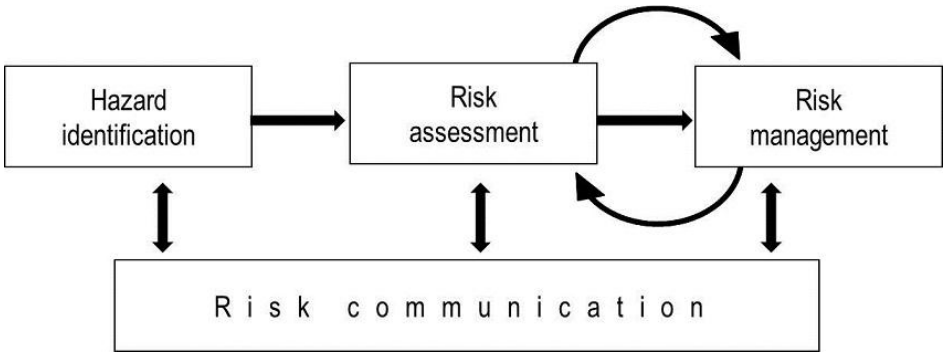
The principal aim of import *risk analysis* is to provide *importing countries* with an objective and defensible method of assessing the *disease risks* associated with the importation of animals, animal products, animal genetic material, feedstuffs, *biological products* and *pathological material*. The principles and methods are the same whether the *commodities* are derived from aquatic and/or terrestrial animal sources. The analysis should be transparent. This is necessary so that the *exporting country* is provided with clear reasons for the imposition of import conditions or refusal to import.

Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

This chapter outlines the role of the OIE with respect to the Agreement on the Application of Sanitary and Phytosanitary Measures (the so-called SPS Agreement) of the World Trade Organization (WTO) and describes the OIE procedure for settlement of disputes.

Chapter 2.2. provides recommendations and principles for conducting transparent, objective and defensible *risk analyses* for *international trade*. However, it cannot provide details on the means by which a *risk analysis* is carried out as the purpose of the *Aquatic Code* is simply to outline the necessary basic steps. The components of *risk analysis* described in Chapter 2.2. are *hazard identification*, *risk assessment*, *risk management* and *risk communication* (Figure 1).

Fig. 1. ***The four components of risk analysis***



The *risk assessment* is the component of the analysis that estimates the likelihood and consequences associated with a *hazard*. *Risk assessments* may be qualitative or quantitative. For many *diseases*, particularly those referred to in the *Aquatic Code* where there are well developed internationally agreed standards, there is broad agreement concerning the likely *risks*, although the status of some *diseases* may differ between countries or even between the Northern and Southern Hemispheres. In many cases it is likely that a qualitative assessment is all that is required. Qualitative assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision-making. No single method of import *risk assessment* has proven applicable in all situations, and different methods may be appropriate in different circumstances.

Annex 15 (contd)

The process of import *risk analysis* on *aquatic animals* and *aquatic animal products* usually needs to take into consideration the results of an evaluation of the *Aquatic Animal Health Services*, zoning and regionalisation, and *surveillance* systems that are in place for monitoring *aquatic animal* health in the *exporting country*. These are described in separate chapters in the *Aquatic Code*.

Article 2.1.2.

The Agreement on the Application of Sanitary and Phytosanitary Measures and role and responsibility of the OIE

The SPS Agreement encourages WTO Members to base their *sanitary measures* on international standards, guidelines and recommendations, where they exist. Members may choose to adopt a higher level of protection than that provided by international texts if there is a scientific justification or if the level of protection provided by the relevant international texts is considered to be inappropriate. In such circumstances, Members are subject to obligations relating to *risk assessment* and to a consistent approach to *risk management*.

The SPS Agreement encourages Governments to make a wider use of *risk analysis*: WTO Members shall undertake an assessment as appropriate to the circumstances of the actual *risk* involved.

The SPS Agreement, in Article 7, obliges WTO Members to notify changes in, and provide relevant information on, sanitary measures which may, directly or indirectly, affect international trade.

The SPS Agreement recognises the OIE as the relevant international organisation responsible for the development and promotion of international animal health standards, guidelines, and recommendations affecting trade in live animals and animal products, whether aquatic or terrestrial in origin.

Article 2.1.3.

The OIE in-house procedure for settlement of disputes

The OIE shall maintain its existing voluntary in-house mechanisms for assisting Members to resolve differences. In-house procedures that will apply are that:

1. Both parties agree to give the OIE a mandate to assist them in resolving their differences.
2. If considered appropriate, the Director General of the OIE recommends an expert, or experts, and a chairman, as requested, agreed by both parties.
3. Both parties agree on the terms of reference and working programme, and to meet all expenses incurred by the OIE.
4. The expert or experts are entitled to seek clarification of any of the information and data provided by either country in the assessment or consultation processes, or to request additional information or data from either country.
5. The expert or experts should submit a confidential report to the Director General, who will transmit it to both parties.

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Annex 16

CHAPTER 1.1.

NOTIFICATION OF DISEASES AND EPIDEMIOLOGICAL INFORMATION

Article 1.1.1.

For the purposes of the *Aquatic Code* and in terms of Articles 5, 9 and 10 of the 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 shall make available to other countries, through the OIE, whatever information is necessary to minimise the spread of *aquatic animal diseases* and their aetiological agents and to assist in achieving better world-wide control of these *diseases*.

2. To achieve this, countries shall comply with the reporting requirements specified in Article 1.1.3.

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 and that the presence of an infectious agent does not necessarily imply the presence of a *disease*, countries shall ensure through their reports that they comply with the spirit and intention of paragraph 1 above. This means that the presence of an infectious agent, even in the absence of clinical *disease*, should be reported.

5. In addition to notifying findings in accordance with Article 1.1.3., countries shall also provide information on the measures taken to prevent the spread of *diseases*, including possible *quarantine* measures and restrictions on the movement of *aquatic animals*, *aquatic animal products*, *biological products* and other miscellaneous objects that could by their nature be responsible for transmission of *disease*. In the case of *diseases* transmitted by vectors, the measures taken against such vectors shall also be described.

Article 1.1.3.

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

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

   a) for *diseases listed by the OIE*, the first occurrence or re-occurrence of a *disease* in a country or *zone* 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

Annex 16 (contd)

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

d) for *diseases listed by the OIE*, if 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.

In deciding whether findings justify immediate *notification* (within 24 hours), countries 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 ~~by fax or electronically~~ subsequent to a notification under paragraph 1 above, to provide further information on the evolution of an incident that justified immediate notification. These reports should continue until the disease has been eradicated or the situation has become sufficiently stable that six-monthly reporting under point 3 will satisfy the obligation of the country to the OIE; in each case, a final report on the incident should be submitted.

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

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

Article 1.1.4.

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 *disease* shall be considered as such until a period exceeding the known *infective period* for the *disease* in question has elapsed after the last reported *outbreak* and when full prophylactic and appropriate *sanitary measures* have been applied to prevent possible reappearance or spread of the *disease*. These measures will be found in detail in the various chapters of Section 1.8. to Section 1.11. of the *Aquatic Code*.

3. A country may 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 chapters of Section 1.8. to Section 1.11. of the *Aquatic Code*.

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.

Article 1.1.5.

1. The *Headquarters* shall send by fax or e-mail ~~electronically~~ 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.

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Annex 17

CHAPTER 6.1.

CONTROL OF HAZARDS IN AQUATIC ANIMAL FEEDS

Article 6.1.1.

Introduction

One of the key objectives of the *Aquatic Code* is to help OIE Members trade safely in *aquatic animals* and *aquatic animal products* by developing relevant *aquatic animal* health and animal production food safety measures. These recommendations address *aquatic animal* health hazards and food safety *hazards* in *aquatic animal feed*. A key objective is to prevent the entry and spread, via *aquatic animal feed*, of *diseases*, including foodborne *diseases*, from an infected country, *zone* or *compartment* to a *free country*, a *free zone* or a *free compartment*.

These recommendations complement the Codex Alimentarius Commission (CAC) Code of Practice on Good Animal Feeding (CAC/RCP 54-2004). The FAO Technical Guidelines for Responsible Fisheries: Aquaculture Development: 1. Good aquaculture feed manufacturing practice (2001) and the FAO/ IFIF Good Practices for the Feed Industry (2010) may be relevant sources of guidance. OIE Members are encouraged to consult these publications.

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

1. Concentration of *aquaculture establishments* heightens the *risk* of *disease* transmission, whether the pathogen enters the culture system via *feed* or other means. Under certain conditions, concentration of *aquaculture establishments* may lead to public health *risks* e.g. via effluent contaminating ground water.

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

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

4. The usage of *feed* in moist form (moisture content equal to or greater than 70%), semi-moist form (moisture content between 15 and 70%), and dry form (a moisture content equal to or less than 15%) implies different levels of *risk* due to the processing applied to the *feed*, its storage and shelf life.

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

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

Annex 17 (contd)

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

Article 6.1.2.

Scope

These recommendations document *risk* mitigation measures, including traceability and certification, to deal with *aquatic animal* health *risks* and public health *risks* associated with trade in *aquatic animal feed* and *feed ingredients*. They recommend the control of hazards through adherence to recommended practices during the production (harvest, handling, storage, processing and distribution) and use of both commercial and on-farm produced *feed* (and *feed ingredients*) for *aquatic animals*. While *aquatic animals* grown for food are the main focus, the same principles apply to *feed* for *aquatic animals* used for other purposes.

Article 6.1.3.

General principles

1. Roles and responsibilities

The *Competent Authority* has the legal power to set and enforce regulatory requirements related to animal *feed*, and has final responsibility for verifying that these requirements are met. The *Competent Authority* may establish regulatory requirements for relevant parties, including requirements to provide information and assistance. Refer to Chapter 3.1. of the *Aquatic Code*.

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

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

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

2. Regulatory standards for feed safety

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

3. Risk analysis

Internationally accepted principles and practices for *risk analysis* (see Section 2. of the *Aquatic Code* and relevant Codex texts) should be used in developing and applying the regulatory framework.

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

4. Good practices

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

Where appropriate, Hazard Analysis and Critical Control Point (HACCP; as defined in the Annex to the Recommended International Code of Practice on General Principles of Food Hygiene [CAC/RCP 1-1969]) principles should be followed to control hazards that may occur in *feed*.

5. Relationship between prions and aquatic animal species

Scientific knowledge ~~is lacking on~~ regarding the relationship between prions and *aquatic animal* species is limited. ~~There is no evidence to suggest~~ However, it cannot be ruled out that the use of terrestrial animal by-products as ingredients in *aquatic animal feed* as currently practiced in *aquaculture* may give~~s~~ rise to public health *risks* in respect of prion *diseases* in fish. More scientific information is desirable to enable *aquaculture* industries to utilise more terrestrial animal by-products as a means of reducing dependency on aquatic protein and lipid sources.

6. Bioaccumulation

Chemical hazards such as heavy metals, dioxins and polychlorinated biphenyls (PCB) persist in certain tissues and therefore tend to accumulate through the food chain. In particular, the use of fish oil should be carefully considered because a high level of dioxin-like PCB can accumulate in it.

7. Geographic and environmental considerations

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

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

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

8. Zoning and compartmentalisation

Feed is an important component~~s~~ of biosecurity and needs to be considered when defining a *compartment* or *zone* in accordance with Chapter 4.1. of the *Aquatic Code*.

9. Sampling and analysis

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

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10. Labelling

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

11. Design and management of inspection programmes

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

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

12. Assurance and certification

Feed manufacturers are responsible for assuring the safety of their feed products. *Competent Authorities* are responsible for providing assurances domestically and to trading partners that regulatory requirements have been met. For *international trade* in *aquatic animal feed*, *Competent Authorities* are responsible to provide *international aquatic animal health certificates*.

13. Hazards associated with aquatic animal feed

a) Biological hazards

Biological hazards that may occur in *feed* and *feed ingredients* include agents such as bacteria, viruses, fungi, biotoxins and parasites. The scope of these recommendations covers *OIE listed diseases* and other agents that cause an adverse effect on animal and/or public health.

Direct transmission occurs when the cultured species consume *feed* containing a *pathogenic agent* (e.g. shrimp larvae consuming rotifer contaminated with white spot syndrome virus) while indirect transmission refers to pathogens in *feed* entering the aquatic environment or infecting non target species, and thereby establishing a mechanism for indirect *infection* of the species of commercial interest. Pathogens that are less host-specific (e.g. white spot syndrome virus, *Vibrio* species) present a greater *risk* of indirect transmission as they can establish reservoirs of *infection* in multiple species. Non-host specific pathogens may present a food safety risk (e.g. *Vibrio*, *Salmonella*, anisakids) because they may colonise fish via feed and affect humans through ingestion of contaminated fishery products.

b) Chemical hazards

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

c) Physical hazards

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

14. Contamination

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

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

15. Antimicrobial resistance

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

16. Management of information

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

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

Animal identification (in the case of *aquatic animals* this will normally be on a group basis) and traceability are tools for addressing animal health and food safety *risks* arising from animal *feed* (see Chapters 4.1. and 4.2. of the OIE *Terrestrial Animal Health Code*; Section 4.3 of CAC/RCP 54-2004).

Article 6.1.4.

Recommended approaches to risk mitigation

1. Commodities

a) Safe commodities

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

b) Commodities not listed as safe commodities

Competent Authorities should consider the following *risk* mitigation measures:

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

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

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

iv) use of *feed* only in populations that are not susceptible to the pathogen(s) in question and where *aquatic animals* that are susceptible to the pathogen(s) in question will not come into contact with the *feed* or its waste products;

v) for hazards other than pathogens, such as heavy metals, resistance to temperature, pressure, pH, irradiation and any other types of processing should be borne in mind.

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

c) Whole fish (fresh or frozen)

The practice of ~~trading~~ using fresh or frozen whole ~~marine~~ fish ~~for use~~ as *aquatic animal feed* may present~~s~~ a ~~significant~~ *risk* of introducing *diseases* into populations of *aquatic animals* and may also pose a *risk* to public health, and therefore should be avoided where possible. *Risk* mitigation measures include sourcing fish only from stocks where there is no evidence of *infection* with any of the *listed diseases*.

2. Feed production

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

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

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

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

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

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

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

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

3. Importing countries

Competent Authorities should consider the following measures:

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

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

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

d) the importation of raw unprocessed *feed* derived from *aquatic animals* to feed *aquatic animal* species should be avoided where possible;

e) introduction of internal measures to address the risks associated with raw commodities for human consumption being diverted to use as *feed*.

4. Certification procedures

When importing *feed* and *feed ingredients* of *aquatic animal* origin other than those mentioned in point 1a) of Article 6.1.4., the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* (or a *certifying official* approved by the *importing country*).

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

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

Article 6.1.5.

Risk pathways of ~~for pathogen~~ hazards ~~transmission and contamination through harvest, manufacture and use of~~ in aquatic animal feed

1. Pathogens can be introduced into feed in the following ways:

a) via the harvest of infected *aquatic animals* for use in *feed*;

b) during storage, processing and transport, due to poor hygienic practices, the presence of pests, or residues of previous batches of feed remaining in processing lines, *containers* or transport *vehicles*.

2. *Aquatic animals* can be exposed to ~~*pathogenic agents*~~ *hazards* in feed in the following ways:

a) Direct exposure

The use of unprocessed feed derived from *aquatic animals* to feed *aquatic animals* presents a potential direct route of exposure. For example feeding salmonid offal to salmonids presents a heightened *risk* of *disease* transmission because tissue from a *susceptible species* is being fed to a *susceptible species*.

The use of unprocessed feed (trash fish, live or whole wild caught fish) may also lead to transmission of zoonotic agents to the farmed fish that may enter the food chain (e.g. anisakids).

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b) Indirect exposure

Pathogens in *feed* may be transmitted to *aquatic animals* in *aquaculture* and wild *aquatic animals* via contamination of the environment or *infection* of non-target species.

Use of wastewater and animal and human excreta as feed or as a source of nitrogen and nutrients for photosynthetic organisms may present a risk for transmission of some human pathogens e.g. bacteria, parasites, viruses, and chemical contaminants.

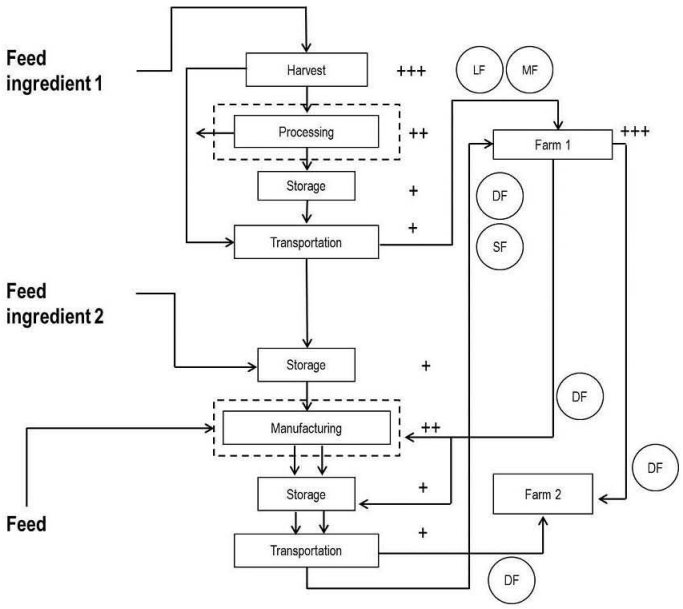
Figure 1 illustrates the possible pathways for transmission of pathogens within the *feed* production and utilisation process.

Feed ingredients of aquatic origin used in *aquaculture* can be a source of pathogens (viruses, bacteria and parasites) to cultured *aquatic animal* species. In *aquaculture establishments* pathogens in *feed* can infect the animals directly (via consumption of *feed*) or indirectly via environmental sources. *Live feed* and moist *feed* are more likely to contain pathogens because their ingredients are either in a raw state or subject to minimal treatment.

Feed and *feed ingredients* harvested from infected countries, *zones* or *compartments* may have a high pathogen load. *Feed* and *feed ingredients* from these sources should be processed (e.g. using heat or chemical treatments) to reduce, or eliminate, the pathogen load. After processing, care should be taken to avoid post processing contamination during storage and transportation of these *commodities*. For example, when two or more batches of *ingredients* of different sanitary status are handled, stored and/or transported together without appropriate biosecurity measures, there is a *risk* of cross-contamination of the *feed*.

An *aquaculture* facility can also be a source of pathogens in *aquatic animal feed*. For example, *feed* can be contaminated with pathogens through poor hygiene practices at an infected *aquaculture establishment*. If the *feed* is redistributed from the *aquaculture* facility to the manufacturing facility for recycling, or distributed to another farm, pathogens can be transferred to other *aquaculture establishments*.

Figure 1: ***Risk chart of pathogen transmission and contamination through harvest, manufacture and use of aquatic animal feed***



LF MF SF DF	Live feed Moist feed Semi-moist feed Dry feed	——> Possibility for risk reduction
+++ ++ +	High risk of pathogen presence Moderate risk of pathogen presence Low risk of pathogen presence	..... Redistribution or recycling of finished feed

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CHAPTER 1.3.

DISEASES LISTED BY THE OIE

Preamble: The following *diseases* are listed by the OIE according to the criteria for listing an *aquatic animal disease* (see Article 1.2.1.) or criteria for listing an *emerging aquatic animal disease* (see Article 1.2.2.).

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 *Gyrodactylus salaris*

– Infectious haematopoietic necrosis

– Infectious salmon anaemia (infection with HPR-deleted or HPR0 forms of ISAV)

– Koi herpesvirus disease

– Red sea bream iridoviral disease

– Spring viraemia of carp

– Viral haemorrhagic septicaemia.

[…]

— Text deleted

Annex 19

CHAPTER 10.5.

INFECTIOUS SALMON ANAEMIA

Article 10.5.1.

For the purpose~~s~~ of Chapter 1.3. ~~of the *Aquatic Code*~~, infectious salmon anaemia (ISA) in its notifiable forms means *infection* with ~~HPR0 ISA virus or with ISA virus (ISAV) having deletions in the HPR region (hereafter named HPR-deleted~~ ISA virus) ~~(ISAV)~~ (ISAV) of the genus *Isavirus* of the family Orthomyxoviridae. This includes the pathogenic forms of ISAV having deletions in the HPR region (HPR-deleted) and the non pathogenic form of ISAV (HPR0).

The provisions in this chapter apply to the pathogenic forms of ISAV (HPR-deleted).

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 and sea trout (*S. trutta*) and rainbow trout (*Onchorynchus 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.

2. When authorising the importation or transit of *aquatic animals* and *aquatic animal products* of a species referred to in Article 10.5.2., other than those referred to in point 1 of Article 10.5.3., *Competent Authorities* should require the conditions prescribed in Articles 10.5.7. to 10.5.12. relevant to the ISA status of the *exporting country*, *zone* or *compartment*.

Annex 19 (contd)

3. When considering the importation or transit of *aquatic animals* and *aquatic animal products* from an *exporting country*, *zone* or *compartment* not declared free of 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.

~~HPR-deleted~~ Infectious salmon anaemia free country

~~In Article 10.5.4, all statements referring to HPR-deleted ISA are only for detectable ISA virus identified as other than HPR0.~~ A country may make a *self-declaration of freedom* from ~~HPR-deleted~~ 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 ~~HPR-deleted~~ ISA if all the areas covered by the shared water are declared ~~HPR-deleted~~ ISA free countries or *zones* (see Article 10.5.6.).

1. A country where none of the *susceptible species* is present may make a *self-declaration of freedom* from ~~HPR-deleted~~ 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 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 ~~HPR-deleted~~ ISA 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 ~~HPR-deleted~~ 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 ~~HPR-deleted~~ ISAV.

OR

4. A country that has made a *self-declaration of freedom* from ~~HPR-deleted~~ ISA but in which the *disease* is subsequently detected may make a *self-declaration of freedom* from ~~HPR-deleted~~ ISA 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 10.5.5.~~

~~**Infectious salmon anaemia (including HPR0) free country**~~

~~In Article 10.5.5, all statements referring to ISA are for any detectable ISA virus, including HPR0. A country may make a *self-declaration of freedom* from ISA (including HPR0) 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 (including HPR0) if all the areas covered by the shared water are declared ISA (including HPR0) 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 (including HPR0) 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 (including HPR0) may make a *self-declaration of freedom* from ISA (including HPR0) when:~~

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

~~b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last four years without detection of ISAV, including HPR0.~~

~~OR~~

~~3. A country that has made a *self-declaration of freedom* from ISA but in which any ISA virus (including HPR0) is subsequently detected may make a *self-declaration of freedom* from ISA (including HPR0) again when the following conditions have been met:~~

~~a) on detection of any ISA virus (including HPR0), 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 four years without detection of ISAV (including HPR0); 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 four 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 10.5.5.~~

Annex 19 (contd)

Article 10.5.~~5.~~65.

~~HPR-deleted~~ Infectious salmon anaemia free zone or free compartment

~~In Article 10.5.6, all statements referring to HPR-deleted ISA are only for detectable ISA virus identified as other than HPR0.~~ A *zone* or *compartment* within the *territory* of one or more countries not declared free from ~~HPR-deleted~~ ISA 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 ~~HPR-deleted~~ 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 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 ~~HPR-deleted~~ ISA 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 ~~HPR-deleted~~ 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 ~~HPR-deleted~~ ISAV.

OR

4. A *zone* previously declared free from ~~HPR-deleted~~ ISA but in which the *disease* is detected may be declared free from ~~HPR-deleted~~ ISA 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.

Article 10.5.7.

Infectious salmon anaemia (including HPR0) free zone or free compartment

In Article 10.5.7, all statements referring to ISA are for any detectable ISA virus, including HPR0. A *zone* or *compartment* within the *territory* of one or more countries not declared free from ISA 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 (including HPR0) 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 (including HPR0) when

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

   b) *targeted surveillance*, as described in Chapter 1.4. of the *Aquatic Code*, has been in place for at least the last four years without detection of ISAV (including HPR0).

OR

3. A *zone* or *compartment* previously declared free from any ISA virus (including HPR0) but in which any ISA virus (including HPR0) is detected, may be declared free from ISA (including HPR0) again when the following conditions have been met:

   a) on detection of ISA virus (including HPR0), 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 four years without detection of ISAV (HPR0 or otherwise); 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 four years.

Article 10.5.6~~8~~7.

Maintenance of ~~HPR-deleted~~ free status

A country, *zone* or *compartment* that is declared free from ~~HPR-deleted~~ ISA following the provisions of points 1 or 2 of Articles 10.5.4. or 10.5.~~5~~6. (as relevant) may maintain its status as ~~HPR-deleted~~ ISA free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from ~~HPR-deleted~~ ISA following the provisions of point 3 of Articles 10.5.4. or 10.5.~~5~~6. (as relevant) may discontinue *targeted surveillance* and maintain its status as ~~HPR-deleted~~ ISA free 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.

Annex 19 (contd)

However, for declared free *zones* or *compartments* in infected countries 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 10.5.9.~~

~~**Maintenance of ISA(including HPR0) free status**~~

~~A country, *zone* or *compartment* that is declared free from ISA(including HPR0) following the provisions of point 1 of Articles 10.5.5. 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(including HPR0) following the provisions of point 2 of Articles 10.5.5. or 10.5.7. (as relevant) must continue *targeted surveillance* to maintain its status as ISA(including HPR0) free and *basic biosecurity conditions* are continuously maintained.~~

Article 10.5.~~7~~10~~9~~.

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 10.5.5. (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.~~8~~.~~11~~10.

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.

Article 10.5.~~9~~.1~~2~~1.

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 1of Article 10.5.12., 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*.

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.~~10~~.1~~3~~2.

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:

Annex 19 (contd)

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.

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

Article 10.5.~~11~~.143.

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

When importing *aquatic animal products* 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~~ or 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.~~12~~.154

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.~~13~~.165.

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*.

3. When importing disinfected eggs of the species referred to in Article 10.5.2. for aquaculture, from a country, *zone* or *compartment* not declared free from ISA, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that the procedures described in point 2 of Article 10.5.~~13~~1~~6~~3. have been fulfilled.

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— Text deleted

Annex 20

AQUATIC ANIMALS COMMISSION WORK PLAN FOR 2012/2013

OIE *Aquatic Animal Health Code*
• Assess EUS for listing against the criteria for listing aquatic animal diseases (Chapter 1.2.) • Proposed listing of infection with ostreid herpesvirus (OsHV-1 and OsHV-1 µvar) as an emerging disease • ISA, ongoing review • On going review of the list of diseases • Review of emerging diseases
• On going review of the Glossary
• Review criteria for listing (Chapter 1.2.) after adoption of revised *Terrestrial Code* Chapter 1.3.
• Harmonise horizontal chapters with those in the *Terrestrial Code*
• Revise Control of hazards in aquatic animal feeds (Chapter 6.1.) regarding animal production food safety
• Complete development of chapters on antimicrobials in aquatic animals
• Complete the chapter on killing for disease control purposes
• Antimicrobial resistance in the field of aquatic animals – contribute to OIE work
• Continue to address the issue of pathogen differentiation including notification
• Develop a chapter on communication
• Prepare text for disease chapters for gaining and regaining freedom for compartments
• Develop a schedule for the review and revision of chapters in the *Aquatic Code*
OIE *Manual of Diagnostic Tests for Aquatic Animals*
• Develop disease specific surveillance model chapters (1 fish, 1 mollusc, 1 crustacean)
• Revise template for disease-specific chapters (on hold)
• Finalise disease specific chapters for 2012 edition
• Finalise guidance document on criteria for susceptible species
• Consider new candidates for OIE Reference Laboratories for listed diseases
Meetings
• Proposed items for the programme for the Ref. Lab. Conference in 2014 (quality assurance, Table 5.1. from the *Manual* disease chapters, implementation of the guidance on susceptible species).
• Make presentations on the activities of the Aquatic Animals Commission at the conferences of the OIE Regional Commissions
• Be proactive in presenting the activities of the Aquatic Animals Commission at scientific conferences
• Contribute to OIE Aquatic Animal Focal Point seminars

Annex 20 (contd)

Other issues
• Continue to assess zoonotic diseases of aquatic animals
• Keep the Commission's web pages up to date
• Provide input into the PVS to ensure its applicability to the evaluation of aquatic animal health services
• Contribute to strengthening FAO/OIE collaboration

Annex 21

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

Original: English

January/February 2012

MEETING OF THE OIE ELECTRONIC *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMALS DISEASES

(FINFISH TEAM)

January–February 2012

The OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases (Finfish) (the *ad hoc* Group) met electronically during January and February 2012.

Details of members and the adopted agenda are given at Annexes 1 and 2.

The *ad hoc* Group was convened to undertake an assessment of pancreas disease (PD) against criteria 6 and 7 of the Criteria for Listing Aquatic Animal Diseases provided in Chapter 1.2. of the *Aquatic Animal Health Code* (*Aquatic Code*), taking into consideration additional information provided by Chile (presented in Annex 3).

Regarding criterion 6, the *ad hoc* Group's view from the original assessment undertaken by the *ad hoc* Group in January, 2011 (refer to Annex 21 of the report of the Meeting of the Aquatic Animal Health Standards Commission, February, 2011, available at http://www.oie.int/fileadmin/Home/eng/Internationa_Standard_Setting/docs/pdf/Aquatic_Commission/A_AAC_Feb_2011.pdf) was that there is a likelihood that salmon pancreas disease virus (SPDV) could be introduced to a free country or zone by imports of live fish but there is need for evidence to confirm that movements of live fish of the SPDV-susceptible species are part of international trade to countries or zones believed to be free of SPDV. The *ad hoc* Group considered additional information on recent international trade and now considers that there is evidence that trade that could spread the virus already exists, so criterion 6 is therefore met.

Concerning criterion 7, the *ad hoc* Group concluded that while the information provided by Chile suggested that several countries or zones could possibly be in a position to declare freedom, the evidence presented remained insufficient to conclusively demonstrate PD freedom for any of the countries identified.

Annex 21 (contd)

Summarised discussions and key recommendations made by the *ad hoc* Group are as follows:

1. Review of the additional information

The *ad hoc* Group reviewed the Chilean submission, particularly the additional supporting evidence to satisfy criteria 6 and 7 of Article 1.2.1. of the *Aquatic Code* and make the following comments.

Comments on criterion 6: the *ad hoc G*roup noted that points a-f in its previous report had been dealt with satisfactorily in the Chilean submission and further information had been provided in relation to points g and h as requested.

Comments on criterion 7: Chile clarified that prior to 2009, testing for SPDV in Chile was based on cell culture, since when samples have been tested in parallel with cell culture and by RT-PCR.

In their initial submission, Chile provided evidence for freedom of infection in Chile and also stated that "Iceland, Denmark and Australia have been declared free..." In their January 2011 report, the *ad hoc* Group stated that:

a) 'Concerning this parameter 7, referring to chapter 1.4. of the *Aquatic Code*, the document from Chile does not give information about the surveillance programmes, the sample sizes for virological analysis, etc.

b) The precise scope of these declarations is not clear- do these relate to (Atlantic) salmon only, or other species also (including rainbow trout; *Oncorhynchus mykiss*).

c) It is not clear on what basis these declarations have been made- are these by the countries themselves, or by Chile on receipt of suitable data? The group are not aware that any of this data in support of freedom has been published via peer-review. It would be helpful if the submission contained more detail, including the basis/bases for such declaration, i.e. consistent with various pathways laid down in Chapter 1.4 of the *Aquatic Code*, including the statistical validity of the approach taken. In relation to the requirements for listing it is recognised that it may be sufficient for Chile alone to be able to demonstrate freedom but parameter 7 of the listing criteria requires that 'several countries or countries with zones may be declared free…', not just one.

d) In relation to the testing described, the group would have have reservations about declarations based solely on cell culture and cytopathic effect (CPE), without either immunostaining or RTPCR to confirm cultures as negative. This is based on the absence of CPE which can occur, particularly at low passage. (Graham *et al.* [2003] and Karlsen *et al.* [2005]).'

The *ad hoc* Group noted that the Chilean document contained substantially more information addressing these points, though not necessarily providing data in relation to each of the points for each country.

No additional data was provided for Denmark, while the most extensive information was provided in relation to the Chilean surveillance programme.

Regarding the additional information provided for Chile, the absence of detection of SPDV in cell culture and more particularly by RT-PCR is consistent with freedom from infection, but still does not fully satisfy the *ad hoc* Group in relation to the points above. In particular, it does not conclusively demonstrate that the programme to date satisfies the requirements of Chapter 1.4 of the *Aquatic Code*. For example, assuming that the starting point in Chile is "Previously unknown disease status", the requirements include at least two surveys per year in consecutive years designed to provide at least 95% confidence at a design prevalence of 2% or lower (Article 1.4.6.3 and subsequently in Article 1.4.8). However the sampling regime applied is stated to target a prevalence of 5%.

In relation to the information on Iceland, the level of sampling is again unlikely to be sufficient to satisfy the above design prevalence, and there is an apparent reliance on the development of CPE in cell culture as a screening method. However, the *ad hoc* Group recognised that it may be possible that a self-declaration of freedom could be made based on historical freedom (Article 1.4.6.).

Evidence was presented for freedom in Australia at national level, regional level (Tasmania) and farm level (Springfield Hatcheries). In all cases, testing would appear to be predominantly cell culture-based, with CPE as the primary indicator of viral growth and again specific details aligning surveillance activities with the requirements Chapter 1.4 of the *Aquatic Code* are not provided. As with Iceland however, the information presented suggested that there could be a case, at least for Tasmania, to declare freedom at zone level based on historical freedom.

In relation to the section of the submission which formally requested listing, and which incorporated responses to the *ad hoc* Group's comments and provided additional evidence in relation to criteria 6 and 7, the *ad hoc* Group made the following comments:

Article 1.2.1. Criterion 6. 'Likelihood of international spread, including via live animals, their products or fomites'.

The evidence provided in the Chilean submission primarily supported horizontal transfer associated with movements of fish. Indeed the additional information in the revised submission provided the results of a semi-quantitative risk assessment conducted by Chile which concluded that the risk of introduction and establishment of SPDV through the import of eggs was insignificant, albeit with a high uncertainty. This is consistent with the view expressed by the *ad hoc* Group in their previous report.

Overall, the *ad hoc* Group's view is unchanged from their previous report dated on 9 January 2011) in relation to the potential for international spread. In its previous report, the *ad hoc* Group concluded that "*there is a likelihood that SPDV could be introduced to a free country or zone by imports of live fish and that it is likely that more trade will develop as and when it becomes economically profitable, but there is need for evidence to confirm that movements of live fish of the SPDV-susceptible species are part of international trade to countries believed to be free of SPDV*". Since its previous report, the *ad hoc* Group has gained a better understanding of the existence of international trade in susceptible species, particularly in northern Europe, that supported its view that more trade will develop as and when it becomes economically profitable. Additionally, the *ad hoc* Group recognised that the criterion in relation to this does not relate specifically to international trade to countries believed to be free of SPDV. Examples of recent relevant international trade include the movement of live smolts from the United Kingdom to Norway, from Ireland to the UK and from the UK to Ireland.

The *ad hoc* Group therefore revised its opinion regarding criteria 6. and now considered that SPDV satisfies this criterion.

Article 1.2.1. Criterion 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*'.

Additional information was provided by Chile in relation to SPDV status of Chile, Iceland and Australia. This information has been commented on already (see above). Results were presented from Chile for a considerable amount of testing, including cell culture and RT-PCR as part of routine surveillance, complemented by additional surveys that included wild fish. It was also stated again that Iceland, Denmark and Australia are declared free, and some evidence in support of this was presented for two of these countries. In the case of Iceland, this included a summary of surveillance, sampling and diagnostic methods and the absence of clinical signs of PD. For Australia, this consisted of lack of detection of SPDV in a cell culture-based active surveillance programme. In addition, Tasmania was stated to have had no cases of PD detected based on testing conducted in accordance with the Tasmanian Salmonid Health Surveillance Programme, with additional information provided for a single hatchery.

The *ad hoc* Group considered that while the information provided by Chile suggested that several countries or zones could possibly be in a position to declare freedom, the evidence as presented by Chile remains insufficient to confirm freedom. Consistent with the OIE definition of "self-declaration of freedom", any declarations of PD freedom by the Competent Authority of these countries, including Chile, should be based on implementation of the provisions of the *Aquatic Code* and the *Aquatic Manual* and sufficient evidence be provided in support of this. The *ad hoc* Group encouraged the Competent Authority of each country that considered itself to be able to self-declare freedom from PD to transmit the evidence to the OIE Headquarters for publication.

Annex 21 (contd)

2. Conclusions

Based on the information provided, the table below summarizes the views of the *ad hoc* Group in relation to each of the criteria for listing as provided in Chapter 1.2. of the *Aquatic Code*.

Disease considered by the AHG	Assessment Against the OIE Listing Criteria in the *Aquatic Code* (Article 1.2.1.)							
	1	2	3	4	5	6	7	8
Infection with SPDV	+	-	-	+	NA	+	?	+

The ad hoc Group was satisfied that criterion 6 was now met, but requested to see published information regarding self-declaration of freedom by Competent Authorities, at which point a further evaluation as to whether criterion 7 is met should be made.

3. References

GRAHAM D.A., JEWHURST V., ROWLEY H., MCLOUGHLIN M. & TODD D. (2003). A rapid immunoperoxidase-based virus neutralization assay for salmonid alphavirus used for a serological survey in Northern Ireland. *Journal of Fish Diseases*, **26**, 407–413.

KARLSEN M., HODNELAND K., ENDRESEN C. AND NYLUND A. (2005). Genetic stability within the Norwegian subtype of salmonid alphavirus (family Togaviridae), *Archives of Virology*, **151**, 861–874.

Annex 21 (contd)

Annex 1

MEETING OF THE OIE ELECTRONIC *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMALS DISEASES
(FINFISH TEAM)
January–February 2012

List of participants

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Annex 21 (contd)

Annex 2

MEETING OF THE OIE ELECTRONIC *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMALS DISEASES
(FINFISH TEAM)
January–February 2012

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Adopted agenda

1. Review the additional information provided by Chile that pancreas disease meets the criteria for listing an aquatic animal disease provided in Article 1.2.1. of the *Aquatic Animal Health Code* in relation to criteria 6 and 7.

2. Submit a report to the OIE Aquatic Animal Health Standards Commission by 20th February 2011.

Annex 21 (contd)

Annex 3

RELEVANT EXTRACTS FROM THE CHILEAN SUBMISSION PROVIDING ADDITIONAL SUPPORTING EVIDENCE IN RESPONSE TO THE REPORT OF THE *AD HOC* GROUP ON THE OIE LIST OF AQUATIC ANIMALS DISEASES (FINFISH TEAM)

Chile thanked the Commission for the creation of ad hoc group to evaluate the incorporation of the Pancreas Disease Virus (SPDV) to the list.

Sernapesca has reviewed and taken into consideration the comments and recommendations made by the *ad hoc* group, submitting in this document further supporting evidence to satisfy Criteria 6 and 7 for the listing of the infection with Salmon Pancreas Disease Virus (SPDV) in the Aquatic Animal Diseases list of the OIE.

The following document is submitted with additional evidence for the evaluation of the incorporation of the Salmon Pancreas Disease Virus (SPDV) in the OIE list of diseases, in response to the comments and suggestions made by the *ad hoc* Group on the OIE list of Aquatic animals diseases /finfish team) between December 2010 and January 2011.

Case definition of Salmonid Pancreas Disease Virus (SPDV): Infection of susceptible species with SPDV**,** with or without manifestation of clinical symptoms.

Below is the information regarding the criteria and parameters that the disease meets for its incorporation in the list, where the suggestions made by the Group have been incorporated along the document, but actual further evidence will be found in parameters N° 6 and 7.

Criterion No. 6: Potential for international spread, including via live animals, their products or fomites.

Studies on horizontal transmission of SPDV, have shown that it can survive for long periods in sea water, with an average life of at least 5.7 days at 10ºC. It has been shown that virus survival is inversely proportional to the temperature and reduces its viral load in the presence of organic matter, where the average half life of the virus may have a range of 61.0 to 1.5 days (4-under sterile conditions, 10, 15 and 20ºC in sea water and sweet, with and without organic matter), which means that the virus can remain in the water and be transferred to adjacent sites through water, without human or animal intervention, directly or indirectly (Graham *et al.*, 2007a, b, c; Viljugrein *et al.*, 2009). Graham *et al.* (2010) conducted a prospective longitudinal study of two outbreaks in Atlantic salmon in Ireland in the marine production phase, which provided supporting evidence for the persistence of the virus in the environment. The partial genome sequence of the virus causing the outbreak was identical to the strain of SAV detected in earlier populations of Atlantic salmon in the affected farms that overlap in time and space to new populations.

Regarding the movement of fish from one marine site to another, a study by McLoughlin *et al.* (2003), found that farms that moved fish during the marine production cycle, in Ireland, were 6 times (OR 6.88, P = 0.064) more likely to have a SPDV outbreak than those farms that do not move fish in the sea. The method of transporting fish in the sea water indicated that the sites that used a towing vessel presented greater risk of a SPDV outbreak (OR=14, P= 0.09), compared to the use of well boats. Between 2003 and 2004, the first outbreak caused by SAV is described in northern Norway, 800 km from the endemic area west of the same country (Karlsen *et al.*, 2006), demonstrating the transmission of the disease from one area to another, a condition that could be related to the transportation of smolts by well boats from the infected area to the free one. In addition, Karlsen *et al.* (2006) reported that three isolated cases of SAV were found with identical genomic regions, on different sites within the same body of water, which could be consistent with local transmission from one site to another, whether it is by water or indirectly via fomites.

On the other hand, the viral RNA can be detected in tissues such as heart and gills for up to 140 days post experimental infection and can be detected by RT-PCR in serum for 14 days or more after infection.

Annex 21 (contd)

Annex 3 (contd)

This suggests that fish can be carriers with persistent or latent infection, which poses a risk to healthy fish who enter the sea with fish that have recovered from SPDV (Christie *et al.*, 2007; Ruane *et al.*, 2008). To support this hypothesis, a study of molecular characterization of strains present in a population of fish was conducted, where there was a case that joined a group of initially healthy fish with one that had recovered from PD, subsequently presenting an outbreak, the strains found were indistinguishable, this leads to establish that the healthy population is infected from fish that had been moved to the sea after recovery from the disease (Ruane *et al.*, 2008).

Kongtorp *et al.* (2010), conducted a study to determine the possibility of vertical transmission of SAV3 in Atlantic salmon gametes, in which the results of all samples were negative, concluding in their study that the disease is not transmitted vertically and in the eventuality of such occurrence, it would not be a path of great importance. On the other hand, it is important to mention that Castric *et al.* (2005) were able to re-isolate SAV2 from ova lots and two months old offspring coming from experimentally infected broodstock. For these reasons, vertical transmission cannot be entirely excluded as a possible via of transmission of different SAV subtypes.

All non-salmonid alphavirus share a common epidemiology, where transmission of infection is through arthropods. To date, no invertebrates vectors have been identified for SAV and it has been shown that SAV infections can be transmitted without an insect vector in fish (McLoughlin *et al.*, 1996), as a result further studies are needed to determine the potential role of lice or other parasites in SAV infections (McLoughlin and Graham, 2007).

Additional information for parameter No. 6

During the year 2008, AVS Chile, carried out a semi-quantitative risk analysis, financed with public government funds, with the objective of evaluating the risk of introduction and spread of high impact diseases in salmon farming. This analysis included relevant factors to SPDV, where the evaluation of the risk of introduction and spread was made through an expert panel composed by Dr. David Graham (Veternary Science Division, Agrifood and Bioscience Institute, Northern Ireland); Dr. Hamish Rodger (Vet-Aqua International, Ireland); Dra. Nina Santi (AquaGen Norway); Dr. Peder Jansen (National Veterinary Institute), Norway; Dr. Paul Midtlyng (VESO, Norway); DVM. Carlos Lobos (AquaGen Chile) and Dr. Pedro Smith (Facultad de Ciencias Veterinarias y Pecuarias, Universidad de Chile), the panel pointed out that the probability of SPDV being introduced and spreading in Chile was insignificant, however, these renowned international researchers, affirmed that the negligible risk estimation for the introduction and establishment of SPDV through the import of eggs, should be taken with caution and that their probability estimates for some of the events considered to have **high uncertainty** due to lack of scientific publications that support this view (Table 2, Table 3) (AVS Chile, 2009).

Table 2. Uncertainty of the risk of SPDV

PHASE 1	**Broodstock selection**	
P1	Probability of selecting female broodstock infected with SPDV (false negative RT-PCR).	There is no scientific, statistical or experience available
P2	Probability of selecting male broodstock infected with SPDV (false negative RT-PCR).	There is no scientific, statistical or experience available
PHASE 2	**Spawning, fertilization, disinfection and incubation**	
P3	Probability that infected female produces internal infection and contaminate eggs. During the process of oogenesis or in the coelomic fluid.	There is no scientific, statistical or experience available
P4	Probability that infected female produces external contamination of eggs with the SPDV.	There is no scientific, statistical or experience available

Annex 21 (contd)

Annex 3 (contd)

PHASE 1	**Broodstock selection**	
P5	Probability that infected breeding male produces external contamination of the eggs with SPDV (via semen).	There is no scientific, statistical or experience available
P6	Probability that internally contaminated eggs with SPDV pass on to the stage of fertilization.	There is no scientific, statistical or experience available
P7	Probability that disinfection is 100% effective (the virus is completely removed from the eggs).	External contamination: it depends on the initial charge.
PHASE 3	**Incubation, picking, shocking, disinfection; selection of egg groups for exportation; and certification**	
P8	Probability that the SPDV inside the egg survives incubation.	There is no scientific, statistical or experience available
P9	Probability that SPDV on outer surface of the eggs survive the incubation.	
P10	Probability that group of eggs infected internally with SPDV is retained.	
P11	Probability that infected egg batch infected externally with SPDV be retained.	
P12	Probability that disinfection is 100% effective (the virus is completely removed from the eggs).	
P13	Probability that infected batches of eggs are not identified, are certified as free of SPDV and exported.	
PHASE 4	**Import, transfer to farms, hatchery, development and establishment of the disease**	
P14	Probability that disinfection in the importing country is 100% effective (the virus is completely removed from the eggs).	
P15	Probability that internally infected eggs survive the hatchery process	There is no scientific, statistical or experience available
P16	Probability that externally infected eggs survive the hatchery process	
P17	Probability that internal infection results in disease and spread producing an outbreak of SPDV in salmon farms.	There is no scientific, statistical or experience available
P18	Probability that external infection results in disease spread and produces an outbreak of SPDV in salmon farms.	

Annex 21 (contd)

Annex 3 (contd)

Table 3. Expert comments

P1 and 2	Several longitudinal studies have shown that the prevalence of the alphavirus genome or virus culture is greatly reduced 3-6 months after infection. The RT-PCR positive fish to disappear between days 200-300 post. The existence of a persistent long-term SAV is still unproven. No information on what proportion of mature fish used for breeding, a group derived from post-smolts infected with SPDV is probably infected in the maturation.
P1 and 2	There is no actual proof or data on the sensitivity or specificity of RT-PCR test in persistently infected adult salmon or mature fish used as broodstock infected with SPDV.
P1 and 2	Compared with RT-PCR test, seronutralization is considered the best tool to identify prior exposure to SPDV and the best method for diagnosing previous exposure of the population to SPDV. The convenience of this test to classify individuals infective state is yet unknown.
P7	For a disinfection to be with a high probability 100% effective, the external contamination of the eggs with the virus should be low.
P10 and 11	The diagnostic procedures to reveal the cause of egg or embrionic mortality are rare, so the likelihood of detecting deaths due to SPDV (although it is shown that SPDV cause mortality in these phases) is low.
P15	It is currently impossible to determine whether transmission of SPDV in the production phase, provided that vertical transmission of the disease actually occurs. In epidemiological terms this is an important point to consider.

Source: AVS Chile, 2009

Criterion No. 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*.

Modifications and additional information

Chile

The active surveillance system implemented in Chile issued by Resolution No. 63 of 2003, which sets the Active Surveillance Program Specific for High Risk Diseases (HRD), indicates that all farms producing species susceptible to HRD listed in Chile, including: Atlantic salmon, Coho salmon, Rainbow trout, Chinook salmon and Brown trout, among others, must be subject to two annual visits to confirm the absence of HRD, along with the assessment of clinical symptoms in the field. Sampling is made estimating a prevalence of 5% and a confidence level of 95%. These visits are performed by veterinarians within the network of diagnostic laboratories of Sernapesca.

The organs sampled for cell culture are: kidney, spleen, brain and heart. To perform the RT-PCR for SPDV, only heart samples are used. The samples are combined and consist in pools of no more than 5 fish.

Analyses of the samples are made based on cell culture, using CHSE-214 cell lines and EPC or BF-2, which are all sensitive to Alphaviruses. Between the years 2003 and 2008, a total of 516.626 fish where analyzed in Chile with this technique (Table 4) none of which have shown the presence of this virus.

In 2009 the diagnostic technique of real-time RT-PCR Taqman probe was introduced in the active surveillance system, according to the technique described by Hodneland and Enders, 2006, therefore, the RT-PCR, is not used to confirm negative cell cultures but cell culture and RT-PCR are performed simultaneously since 2009.

Between the year 2009 and the first semester of 2011, a total of 69.534 fish where analysed with this technique (Table 4).

Annex 21 (contd)

Annex 3 (contd)

Table 4. Active Surveillance Programme analysis between 2003 and 2008

Year	Type of site	N° of Sampled Fish	Techniques
2003	Sea	87.628	Cellular cultura in CHSE-214 + EPC o BF2
	Freshwater	51.933	Cellular cultura in CHSE-214 + EPC o BF2
2004	Sea	53.304	Cellular cultura in CHSE-214 + EPC o BF2
	Freshwater	35.801	Cellular cultura in CHSE-214 + EPC o BF2
2005	Sea	35.125	Cellular cultura in CHSE-214 + EPC o BF2
	Freshwater	25.641	Cellular cultura in CHSE-214 + EPC o BF2
2006	Sea	52.699	Cellular cultura in CHSE-214 + EPC o BF2
	Freshwater	34.677	Cellular cultura in CHSE-214 + EPC o BF2
2007	Sea	41.852	Cellular cultura in CHSE-214 + EPC o BF2
	Freshwater	38.113	Cellular cultura in CHSE-214 + EPC o BF2
2008	Sea	31.312	Cellular cultura in CHSE-214 + EPC o BF2
	Freshwater	28.541	Cellular cultura in CHSE-214 + EPC o BF2
2009	Sea	18.311	Cellular cultura in CHSE-214 + EPC o BF2 + real time RT-PCR
	Freshwater	14.880	Cellular cultura in CHSE-214 + EPC o BF2 + real time RT-PCR
2010	Sea	17.311	Cellular cultura in CHSE-214 + EPC o BF2 + real time RT-PCR
	Freshwater	15.458	Cellular cultura in CHSE-214 + EPC o BF2 + real time RT-PCR
2011*	Sea	1.159	Cellular cultura in CHSE-214 + EPC o BF2 + real time RT-PCR
	Freshwater	2.415	Cellular cultura in CHSE-214 + EPC o BF2 + real time RT-PCR
Total general		**586.160**	

* Only considers the information of the first semester of 2011

During March of 2010, an official Ring Test for Real Time-PCR for Salmonid Alphavirus was performed, along with Dr David Graham, of the Veterinary Science Division, Agrifood, and Bioscience Institute, Northern Ireland. In general, the results of the ring test indicate that all laboratories obtained correct results in identifying positive and negative samples, had a good repeatability, R2, linearity and where efficient.

Annex 21 (contd)

Annex 3 (contd)

In May of 2008, Chile incorporated SPDV in the national List of HRD (List 1), which is of mandatory notification to the authorities, the reason for the listing of the disease was based on the fact that it is an exotic disease, it produces high mortality and therefore, high economic impact, besides being transmissible, conditions required by the enforced regulations to be considered High Risk.

In accordance to the incorporation of SPDV in the HRD List above, an active surveillance in cultivated animals is required by Chilean law from 2009. This surveillance includes biannual surveys of all the sites with susceptible species in accordance with OIE guidelines. Currently, the official technique for this purpose in Chile is real time RT-PCR, with a Taqman probe according to the technology described by Hodneland and Endresen (2006). To date, this monitoring has not detected the presence of Alphaviruses causing the disease.

Given the above, during the 2008-2009 period, Sernapesca completed an Official Investigation assigned to the Austral University of Chile, to determine the SAV status, where samples were collected from blood and organs of Atlantic salmon (*Salmo salar*) and Rainbow trout (*Oncorhynchus mykiss*) from freshwater sites, lakes, processing plants and marine sites in the IX, X, XI, XII and XIV Regions. A total of 36 sampling sites where considered, with a universe of 2.455 fish, obtained through targeted selection, based on productive and sanitary information provided by the aquaculture establishment.

For virus isolation, CHSE-214 cell lines were used, incubated at 14±1ºC, and 3 subcultures where made every 7 to 10 days, according to Graham *et al*, 2008 description. For the detection of alphavirus subtypes qPCR was used applying Hodneland and Endrensen (2006) technique, which is based on 3 independent assays. The first one (Q nsP1) detects all fish alphavirus subtypes, the second (Q SPDV) detects SPDV subtypes and the third (Q NSAV) detects only Norwegian salmonid alphavirus. In addition, to this, a Histological examination was conducted of the exocrine pancreas, skeletal muscle and heart of the Atlantic salmon, based on Ferguson et al (1986), Ferguson et al (1990) y McLoughlin *et al* (2002).

The results from the qRT-PCR SAV where negative, there was no manifestation of CPE in the CHSE-214 cellular line and no histological signs suggestive of SPDV where registered. The conclusion of the study rules out the presence of SPDV and SAV in farmed Atlantic salmon and Rainbow trout in Chile.

Furthermore, two studies were carried out in fifteen (15) lakes in the south of Chile in wild fish samples, also applying the same diagnostic technique. The total of fish sampled was 2.977 and the results where all negative, with no detection of the virus SAV.

Besides Chile, another countries where the disease has not been detected, based on active and passive surveillance programs like Iceland, Denmark and Australia.

It should be noted, for example, that under health certification requirements required by Chile for salmon ova, Iceland, Denmark and Australia, have been declared free of the disease under active surveillance conducted by analysis in cell strings sensitive to Alphaviruses such as the CHSE-214, BF-2 and EPC cellular lines.

According to Chilean law, as set out in the Supreme Decree N ° 626 from the year 2001, imports of eggs from other countries must certify that they are free of SPDV and its causative agent, among other high-risk diseases in List 1. Each country must certify this through the sanitary certificate for salmonid eggs destined to Chile, from countries whose official authority has been recognized by the Sernapesca (Veterinary Certificate).

Chile acknowledges Iceland and Australia as countries free from SPDV, according to an official epidemiological surveillance program recognized by Sernapesca.

Chile acknowledges that the farms, broodstock and hatcheries that export eggs to Chile, are free from SPDV, according to an official epidemiological surveillance program recognized by Sernapesca.

Annex 21 (contd)

Annex 3 (contd)

Iceland

All Icelandic fish farms have been included in the official national health control program since 1985. The surveillance also includes farms dealing with wild salmonids. From 1993, European Union (EU) Directives on disease control measures have been followed in addition to the Canadian requirements since 2003. The surveillance is partly by regular "on-site" health inspections, under the supervision of undersigned, and partly by laboratory work conducted at the official Fish Disease Laboratory at Keldyr in Reykjavik, which has close cooperation with EU Reference Laboratory on virus diseases in Denmark. The sampling and diagnostic methods regarding viral examination has been along the lines given in Commission Division 1001/183/EC, including relevant amendments. EPC, PF-2 and CHSE-214 cell lines are used routinely. Iceland underlines that they have never detected any viral fish disease, with special focus on SPDV and no clinical symptoms have ever been seen that could indicate that type of disease so far (Icelandic Food and Veterinary Authority, 2008).

Table 3. Annual incidence of new outbreaks by farms in Iceland

	Annual Incidence of new outbreaks. Number on farms												
Disease	2010	2009	2008	2007	2006	2005	2004	2003	2002	2001	2000	1999	1998
VHS, IHN, IPN, ISA y PD	0	0	0	0	0	0	0	0	0	0	0	0	0

Source: Sernapesca Report on Official visit to Iceland 2009.

Australia

Australia has implemented an active surveillance program for testing of salmonid populations to demonstrate freedom from exotic pathogens, which specifically tests for a range of viral pathogens of salmonids. Liver, kidney and splenic tissue samples are aseptically collected and forwarded to the Australian Animal Health Laboratory, where they are processed and inoculated onto CHSE-214 and EPC cell lines. Any samples showing cytopathic effect are further tested with PCR or immunochemistry to identify any viral or intracellular pathogens that may be present. Pathogenic agents that would be expected to be detected using these two standard cell lines. In addition to tissues for cell culture, the program actively collects fixed tissue for histopathological examination, kidney swabs for bacterial culture, or other indicated samples from any fish examined showing signs of infectious disease.

In the summary report of the "Tasmanian Salmonid Health Surveillance Program (TSHSP)" activities 2004/05 to 2008/09, prepared for Australia to be authorized to export eggs to Chile, it outlines the activities of the TSHSP for the years since the 2003 Submission. There has been no evidence of SPDV in Tasmanian salmonids throughout this period despite extensive testing under the Program. The Springfield site undertakes testing over and above the TSHSP to maintain its excellent disease free certification status.

Springfield Hatcheries in Tasmania, have a strong claim for specific freedom from Pancreas Disease based on the following:

There have been no imports into Tasmania from Europe of salmon genetic material or non-viable salmon products for human consumption since the early 1970's. Although PD is not listed as a notifiable disease in Tasmania, The *Animal Health Act 1995* requires that any suspect case of a new disease must be reported immediately, and that any disease that is causing deaths or production losses must also be reported immediately and the suspect animal isolated pending further investigation. There has been no report suggesting a case or suspected case of PD in Tasmania.

Annex 21 (contd)

Annex 3 (contd)

Springfield undertakes testing for virological agents over and above that required for the TSHSP using three cell lines (cf. 2 cell lines for TSHSP) CHSE-214, EPC and BF-2 as a standard. During 2008/09, 692 fish from Springfield were tested using cell culture, with the average number sampled annually between 2004/05 to 2008/09 being 826. All have tested negative for viral pathogens.

The TSHSP also undertakes extensive histopathological examination of spleen, kidney, heart, brain, pancreas, intestine, skin, muscle, gills and liver and any lesion as deemed appropriate by the veterinary pathologist managing the case. A total of 664 histological samples were examined from 86 fish from Springfield in 2008/09. The fish sampled were targeted "active" surveillance samples showing signs of gross pathology at examination on routine surveillance visits or were fish submitted to the laboratory as part of a disease investigation. A total of 2074 fish were sampled from Springfield in 2008/09 (includes all ovarian fluid and fish samples tested for histopathology, microbiology, molecular biology and/or virology) (Biosecurity Australia Submission in support of the proposed export to Chile of Atlantic salmon ova from Springfield hatcheries in Tasmania, Australia, 2010).

Conclusion:

Based on the additional information provided, we conclude that Salmonid Pancreas Disease Virus (SPDV) meets the criteria set out in Chapter 1.2 of the *Aquatic Code* to be listed as an OIE disease and in view of the above, suggests the possible review of the Alphaviruses situation affecting the fish.

Chile requests, according to the background study presented, that OIE, through the Commission of Aquatic Animal Health Regulations can deliver an expert opinion accepting these diseases as listed by the OIE.

If required to analyze the official certification documents, these can be requested.

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Annex 21 (contd)

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Annex 22

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

Original: English

January 2012

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 31 January–2 February 2012

The OIE *ad hoc* Group on the Responsible Use of Antimicrobials in Aquatic Animals (*ad hoc* Group) met at the OIE Headquarters from 31 January to 2 February 2012.

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

On behalf of Dr Bernard Vallat, Director General of the OIE, Dr Gillian Mylrea, Deputy Head of the International Trade Department, welcomed the *ad hoc* Group members, and thanked them for their continued work on this important area in aquatic animals.

The *ad hoc* Group considered comments received from the following Members: Australia, Canada, Chile, the European Union, New Zealand, People's Republic of China, Norway, Thailand and the United States of America.

1. Chapter 6.4. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals

The *ad hoc* Group considered Member comments and amended the text as appropriate.

Article 6.4.1.

A Member suggested the addition of the words 'aquatic animal microbes' after 'to evaluate exposure of' in paragraph 2 of Article 6.4.1. The *ad hoc* Group agreed that exposure should be qualified but felt that aquatic animal microbes was too specific and excluded other groups of microorganisms important to the selection and dissemination of antimicrobial resistance. Therefore, the *ad hoc* Group amended the sentence as follows: 'evaluate exposure of microorganisms to antimicrobial agents.'

Annex 22 (contd)

A Member suggested the inclusion of other factors in the evaluation of usage patterns. The *ad hoc* Group agreed but considered that these factors are now addressed in the amended Articles 6.4.4. (point 3) and 6.4.5.

The *ad hoc* Group agreed with a Member's comment that lack of professional consultation or supervision may be a constraint in some countries regarding the collection of antimicrobial usage data, and amended the text accordingly. However, the *ad hoc* Group did not agree with the Member's proposal to include the words 'that leads to illegal use' after 'lack of professional consultation or supervision' as they noted that many countries may lack a regulatory infrastructure for veterinary medicines.

Article 6.4.2.

In response to a Member comment, the *ad hoc* Group amended the last sentence in Article 6.4.2. to highlight the importance of the publication of primary data and their interpretation. The proposed sentence is:

'The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.'

Article 6.4.3.

The *ad hoc* Group added a definition for 'antimicrobial agent' which currently appears in Chapter 6.3. of the OIE *Aquatic Animal Health Code* (*Aquatic Code*)When this chapter is adopted, the definition will be moved into the Glossary in the *Aquatic Code* which is standard practice when a definition appears in more than one chapter.

Article 6.4.4.

In response to several Member comments, the *ad hoc* Group amended and reorganised this Article to better describe the sources of data on antimicrobial agents. The *ad hoc* Group also expanded some sections to provide a clearer explanation of potential sources of data.

Article 6.4.5.

In response to several Member comments regarding different factors for the interpretation for antimicrobial use data, the *ad hoc* Group added additional factors to ensure a comprehensive list.

The revised Chapter 6.4. is presented at Annex IV.

2. Chapter 6.5. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals

The *ad hoc* Group considered Member comments and amended the text as appropriate.

Article 6.5.1.

The *ad hoc* Group deleted the reference to 'the rearing environment' as a consequence of the removal of the article entitled 'Surveillance and monitoring for antimicrobial resistance in microorganisms present in the aquatic environment' (previous Article 6.5.6.).

Article 6.5.2.

In response to a Member comment the *ad hoc* Group amended the last sentence in Article 6.5.2. to highlight the importance of the publication of primary data and their interpretation.

'The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.'

Annex 22 (contd)

Article 6.5.3.

The *ad hoc* Group added a definition for 'antimicrobial agent' which currently appears in Chapter 6.3. of the *Aquatic Code*. When this chapter is adopted, the definition will be moved into the Glossary in the *Aquatic Code* which is standard practice when a definition appears in more than one chapter.

Article 6.5.4.

The *ad hoc* Group deleted to last sentence which made reference to the environment, as a consequence of the removal of the article entitled 'Surveillance and monitoring for antimicrobial resistance in microorganisms present in the aquatic environment' (see note below under Article 6.5.6.).

Article 6.5.5.

Two new paragraphs were added at the beginning of this Article to address comments from several Members on the use of standardized methods for antimicrobial susceptibility testing, as well as the lack of methods for some microorganisms.

Points 5, 6 and 7 in this article were rewritten to address Member comments and to provide additional clarity and detail on the use of epidemiological cut-off values and clinical breakpoints.

The *ad hoc* Group developed an annex (presented at Annex III) on the issue of interpretive criteria and appropriate nomenclature for application to quantitative antibiotic susceptibility data. This annex provides Members with more detailed information on this issue and the rational for the inclusion of the terms epidemiological cut-off values and clinical breakpoints in this article.

Article 6.5.6.

Two Members commented that it was undesirable to exclude commensal bacteria from monitoring and surveillance programmes. The *ad hoc* Group agreed and amended the article to include intestinal microflora under certain circumstances.

Article 6.5.6. Surveillance and monitoring for antimicrobial resistance in microorganisms present in the aquatic environment

A number of Members expressed concern as to whether there is sufficient scientific evidence to identify the appropriate elements of a surveillance and monitoring programme for antimicrobial resistance in microorganisms present in the aquatic environment.

The *ad hoc* Group had drafted this article because the Joint FAO/OIE/WHO expert consultation on antimicrobial use in aquaculture and antimicrobial resistance (Seoul [Republic of Korea], 13–16 June 2006) argued that 'the greatest potential risk to public health associated with antimicrobial use in aquaculture is thought to be the development of a reservoir of transferable resistance genes in bacteria in aquatic environments from which such genes can be disseminated by horizontal gene transfer to other bacteria and ultimately reach human pathogens'.

This article described the challenges associated with the development of a surveillance and monitoring programme, namely lack of scientific information, and complex, poorly understood biological pathways. The article proposed the elements that should be considered for inclusion in a surveillance and monitoring programme.

Nevertheless, in consideration of Member comments and the lack of sufficent scientific information on the *ad hoc* Group deleted this article.

The *ad hoc* Group recommended that the OIE Aquatic Animal Health Standards Commission (Aquatic Animals Commission) continue to monitor developments in this field and revist the issue at such a time that scientific information warrants.

Annex 22 (contd)

The *ad hoc* Group noted a useful and recent reference on this topic is the paper 'Bottlenecks in the transferability of antibiotic resistance from natural ecosystems to human bacterial pathogens (José L. Martínez, 2012, Volume 2, Article 265).

The revised Chapter 6.5. is presented at Annex V.

3. Harmonisation with OIE *Terrestrial Animal Health Code* chapters

The *ad hoc* Group requested that the *ad hoc* Group on Antimicrobial Resistance who are reviewing the chapters on antimicrobial resistance in the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) consider the amended text in Chapter 6.5., Article 6.5.4., points 5, 6 and 7. As these are cross cutting issues relevant to the *Terrestrial Code*, the *ad hoc* Group requested that they review this approach to see if it is consistent for the approach for terrestrial animals and adopt it in the relevant chapters of the *Terrestrial Code*.

4. Discussion papers

Dr Gillian Mylrea informed the *ad hoc* Group that the OIE *Bulletin*, issue 3/12, would have the theme 'aquatic animals'. The *ad hoc* Group agreed to draft a paper titled 'Antimicrobial resistance in aquatic animals' for inclusion in this issue.

Monitoring and surveillance of antimicrobial agent resistance in bacteria isolated from aquatic animals

The *ad hoc* Group acknowledged the support of the Aquatic Animals Commission recommending that the *ad hoc* Group prepare a short paper on the priority bacteria for the development of methods of antimicrobial resistance testing in aquatic animals. The *ad hoc* Group explored the possibility of publishing this paper in the September 2012 issue of the OIE *Bulletin.* On reflection, the *ad hoc* Group decided that an expanded paper titled 'Monitoring and surveillance of antimicrobial agent resistance in bacteria isolated from aquatic animals' addressing the broad issues involved in the design and implementation of monitoring and surveillance programmes would be more valuable. Therefore, the *ad hoc* Group decided to draft such a paper for submission to the Plurithematic issue of the OIE *Scientific and Technical Review* to be published in 2012.

Antimicrobial resistance risk analysis in aquaculture

The *ad hoc* Group acknowledged the support of the Aquatic Animals Commission recommending that the *ad hoc* Group prepare a paper on antimicrobial resistance (AMR) risk analysis in aquaculture. The *ad hoc* Group explored the possibility of publishing this paper in the September 2012 issue of the OIE *Bulletin.* On reflection, the *ad hoc* Group decided that an expanded paper addressing the broad issues involved in conducting risk analysis in aquaculture would be more valuable. Therefore, the *ad hoc* Group decided to draft such a paper for submission to the Plurithematic issue of the OIE *Scientific and Technical Review* to be published in 2012.

The *ad hoc* Group acknowledged the recommendation from the Aquatic Animals Commission that a new chapter in the *Aquatic Code* on risk analysis in aquaculture should not be commenced until after the adoption of the Chapters 6.4. and 6.5. and the current work on the revision of the *Terrestrial Code* chapters on antimicrobial resistance is finalised and adopted. However, the *ad hoc* Group considered that work on this chapter was important to progress as there is an equivalent chapter in the *Terrestrial Code* and this chapter would complete the series of chapters originally envisaged for the *Aquatic Code*. The *ad hoc* Group considered that this work could be advanced out of session and requested that the Commission endorse the commencement of work on this chapter.

Annex 22 (contd)

5. Conferences

Dr Elisabeth Erlacher-Vindel (Deputy Head of the OIE Scientific and Technical Department), informed the *ad hoc* Group that the OIE would be hosting an 'OIE Global Conference on the Prudent Use of Antimicrobial Agents for Animals' in Paris (France) from 13 to 15 March 2013. She indicated that responsible antimicrobial usage in aquatic animals would be included in the programme. The *ad hoc* Group welcomed this conference and the inclusion of issues relevant to aquatic animals.

The *ad hoc* Group also noted that the Aquatic Animals Commission had encouraged members of the *ad hoc* Group to consider presenting papers on the topic of antimicrobial use in aquaculture in relevant scientific meetings and congresses. The *ad hoc* Group members have attended various conferences during the past year and will continue to actively seek opportunities to present the current OIE position on responsible antimicrobial usage in aquatic animals.

.../Annexes

Annex 22 (contd)

Annex I

MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 31 January–2 February 2012

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Annex 22 (contd)

Annex II

MEETING OF THE OIE *AD HOC* GROUP ON THE RESPONSIBLE USE OF ANTIMICROBIALS IN AQUATIC ANIMALS

Paris, 31 January–2 February 2012

Adopted agenda

Welcome and introduction

1. Consider Member comments on draft Chapter 6.4. Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals, and amend text as appropriate.

2. Consider Member comments on draft Chapter 6.5. Development and harmonisation of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals, and amend text as appropriate.

3. Short paper on priority bacteria for the development of methods of antimicrobial resistance testing in aquatic animals:

   – update regarding publication in the September 2012 issue of the OIE *Bulletin* that will be dedicated to aquatic animals (due mid-May 2012).

4. Discussion paper on risk assessment for antimicrobial resistance in aquatic animals:

   – update regarding publication in the September 2012 issue of the OIE *Bulletin* that will be dedicated to aquatic animals (due mid-May 2012).

Annex 22 (contd)

Annex III

Interpretive criteria and appropriate nomenclature

There are two sets of interpretive criteria that have been proposed for application to quantitative antibiotic susceptibility data. These are clinical breakpoints and epidemiological cut-off values.

Clinical breakpoints (CB)

Aim

The categorization of isolates on the basis of their response to therapeutic administrations of an agent.

Setting

The setting of CB requires consideration of susceptibility data and the pharmacokinetics (PK) and pharmacodynamics (PD) of therapies. They are frequently set using either PK/PD data or clinical correlation data or both.

Advantages/Limitations

The major advantage of the use of CBs is that the categorical classifications generated are clinically significant. The major limitation is that a particular CB can only be applied with respect to specified (dose, host and environment) therapeutic treatments.

Use

The use of CB is recommended when the primary concern is the clinical treatment of animals. They are, therefore, appropriate for laboratories involved in clinical diagnosis and in monitoring programmes that have the aim of generating data to advise these laboratories or professionals responsible for therapeutic treatments.

Nomenclature of categories generated

There is a long tradition of using the S/I/R system to name the categories generated by CB. Thus the categories identified are known as sensitive, intermediate or resistant.

Epidemiological (microbiological) cut-off values (ECV or ECOFF)

Aim

The categorization of isolates on the basis of whether they are fully susceptible or not.

Setting

ECVs can be set from a consideration of the distribution of *in vitro* susceptibility data.

Advantages/Limitations

The major advantages of ECVs is that they are relatively easy to generate and are not affected by differences if the conditions of therapeutic treatments. ECVs, therefore, have major advantages in situation where significant agent use is extra/off-label. The major limitation is that the categorical classifications achieved by application of ECVs have no inherent clinical meaning.

Annex 22 (contd)

Annex III (contd)

Use

The use of ECVs is recommended when the primary concern is the epidemiology of reduce susceptibility (resistance). They also are frequently applied when no relevant CB is available.

Nomenclature of categories generated

EUCAST (see attached) and CLSI (2011) both use the terms wild type (WT) and non-wild type (NWT) to refer to the two categories generated by application of ECVs.

Annex 22 (contd)

Annex IV

CHAPTER 6.4.

MONITORING OF THE QUANTITIES AND USAGE PATTERNS OF ANTIMICROBIALS ~~S~~ AGENTS USED IN AQUATIC ANIMALS

Article 6.4.1.

Purpose

The purpose of these recommendations is to describe approaches to the monitoring of quantities of antimicrobial agents used in *aquatic animals*, including species reared for food and ornamental purposes.

These recommendations are intended for use ~~by OIE Members to~~ in the collection of objective and quantitative information to evaluate usage patterns by antimicrobial class, route of administration and *aquatic animal* species in order to evaluate exposure of microorganisms to antimicrobial agents.

The collection of data on the use of antimicrobial agents in *aquaculture* may be constrained in some countries by the lack of available resources, lack of accurately labelled products, ~~and~~ poorly ~~understood~~ documented distribution channels and lack of professional consultation or supervision. This chapter may therefore be seen as indicating the direction in which countries should develop with regard to collecting data and information on the use of antimicrobial agents in *aquatic animals*.

Article 6.4.2.

Objectives

The information provided in these recommendations is essential for conducting *risk analyses* and for planning purposes. This information can be helpful in interpreting antimicrobial resistance surveillance data and can assist in the ability to respond to problems of antimicrobial resistance in a precise and targeted way. The continued collection of this basic information would help identify trends in the use of antimicrobial agents in *aquatic animals* and the potential association with antimicrobial resistance in *aquatic animal* bacteria, including potentially zoonotic bacteria. This information may also assist in *risk management* when evaluating the effectiveness of efforts to ensure responsible and prudent use and mitigation strategies and indicate where alteration of prescribing practices for antimicrobial agents in *aquatic animals* might be appropriate. The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.4.3.

Definitions

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that at *in vivo* concentrations exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Annex 22 (contd)

Annex IV (contd)

Article 6.4.~~3~~4.

Development and standardisation of monitoring systems for antimicrobial agents

Competent Authorities may, for reasons of cost and administrative efficiency, collect medical, agricultural, aquacultural and other antimicrobial agent use data in a single programme. Where livestock and *aquatic animal* industries are under multiple authorities in a single country, collaboration between the authorities to develop a coordinated monitoring system is necessary to facilitate the collection of data. Additionally, a consolidated programme would facilitate the comparison of *aquatic animal* use data with human use data necessary for a comprehensive risk analysis.

Systems to monitor usage of antimicrobial agents may consist of the following elements:

1. Sources of data on antimicrobial agents

   a) Basic sources

      Data from basic sources may include general information without specific attribution (such as, weight, quantity and class of antimicrobial agents).

      Sources of data will vary from country to country. Such sources may include customs, import, export, manufacturing and sales data.

   b) Direct sources

      Data from direct sources may include more specific information (such as target *aquatic animal* species, route of administration and active ingredient).

      Data from veterinary medicinal product registration authorities, manufacturers, wholesalers, retailers, feed stores and feed mills might be useful sources. A possible mechanism for the collection of this information is to make the provision of appropriate information by veterinary antimicrobial manufacturers to the registration authority one of the requirements of marketing authorisation (registration of the antimicrobial agent).

   c) End-use sources ~~(veterinarians, aquatic animal health professionals and producers)~~

      Data from end-use sources has the advantage of providing more detailed information on the type and purpose of use and can be complimentary to the other sources.

      End-use sources of data may include *veterinarians*, *aquatic animal* health professionals and *aquatic animal* producers. ~~This source has the advantage of providing more detailed information on the type and purpose of use and can be complementary to the other sources. This~~ End-use sources may be useful when more accurate and locally specific information is needed (such as extra-/off-label use).

      ~~Because c~~Collection of this type of information can be resource intensive, therefore, periodic collection of this type of information may be sufficient. Data collection should be targeted to the most relevant period of use.

      In some countries end-use sources may be the only practical source of information ~~at the moment~~.

   d) Other sources

      Pharmaceutical industry associations and *aquatic animal* producer associations, veterinary and allied health professional associations, and other stakeholders with indirect knowledge of the quantities of antimicrobial agents used may be another source of this information.

Annex 22 (contd)

Annex IV (contd)

Non-conventional sources including Internet sales data related to antimicrobial agents may ~~could~~ be collected where available. Internet sales data may be particularly useful with respect to ornamental species.

~~Registration of products with labeling that accurately reflects the intended use of the antimicrobial agent will facilitate collection of information on the quantities and usage patterns. OIE Members are encouraged to support each other in the development of this infrastructure.~~

~~OIE Members may also wish to consider, for reasons of cost and administrative efficiency, collecting medical, agricultural, aquacultural and other antimicrobial use data in a single programme. A consolidated programme would also facilitate comparisons of animal use with human use data for relative *risk analysis* and help to promote optimal usage of antimicrobial agents. Additionally, where livestock and aquatic animal industries are under multiple authorities in a single country, coordination between the authorities is encouraged.~~

2. Elements for data collection ~~Types~~ and reporting ~~formats of antimicrobial usage data~~

~~If a Member has the infrastructure for capturing basic animal use data for a specific antimicrobial agent, then additional information can be considered to cascade from this in a series of subdivisions or levels of detail. Such a cascade of levels should include the following:~~

a) Basic data to be collected should include:

i) the ~~A~~absolute amount in kilograms of the active ingredient of the antimicrobial agent(s) used per year, divided into antimicrobial class/subclass.

For active ingredients present in the form of compounds or derivatives, the mass of active entity of the molecule should be recorded. For antimicrobial agents expressed in International Units, the calculation required to convert these units to mass of active entity should be stated. It may be possible to estimate total usage by collecting sales data, prescribing data, manufacturing data, export/import data or any combination of these;

ii) the total number of *aquatic animals* treated ~~cultured~~ and their weight in kilograms ~~is important basic information~~.

b) ~~Subdivision of antimicrobial use into species of finfish, crustacean, or mollusc treated.~~ Additional data may be collected to further categorise the exposure of microorganisms to antimicrobial agents and may include:

i) species of fish, crustaceans, molluscs or amphibians treated;

~~c~~ii) ~~Subdivision by~~ purpose e.g. *aquatic animals* for human consumption, use as ornamental species ~~fish~~ and baitfish;

~~d~~iii) ~~Subdivision of the data into the~~ route of administration (medicated feed, bath treatment, parenteral delivery) and the method used to calculate the dose (biomass of ~~fish~~ *aquatic animals*, volume of water treated);

iv) indication for use.

The antimicrobial agents/classes/sub-classes to be included in data reporting should be based on current known mechanisms of antimicrobial activity / antimicrobial resistance mechanism.

Annex 22 (contd)

Annex IV (contd)

Nomenclature of antimicrobials agents should comply with international standards where available.

When making information publically available, the *Competent Authority* should ensure confidentiality and anonymity of individual enterprises.

3. Considerations for data collection

Antimicrobial usage data may could be collected on a routine basis and / or at a specific point in time depending on availability of resources and / or the need to monitor usage of antimicrobial agents or address a specific antimicrobial resistance problem.

When collecting and interpreting the data it is important to take into account factors such as Ttemperature, disease conditions (epizootiology), species and age affected, aquacultural systems (i.e. intensive / extensive), dosage and duration of treatment with antimicrobial agents.

Registration of products with labelling that accurately reflects the intended use of the antimicrobial agent will facilitate collection of information on the quantities and usage patterns.

Collection, storage and processing of data from end-use sources requires careful design but should have the advantage of producing accurate and targeted information.

Article 6.4.45.

Elements for interpretation of data on the use of antimicrobial agents

In order to maximize the value of usage data, it may be beneficial to collect additional information. Such information will, w When available, the following information may support aid in the interpretation of antimicrobial usage data and further characterisation of exposure pathways interpretation of usage data:

These are examples of some factors that can be considered:

a) type of aquaculture system (extensive or intensive, ponds or tanks, flow-through or recirculating, hatchery or grow-out, integrated system);

b) animal movements (transfer between facilities or from wild to the facility, grading);

c) species, and life stage, and/or stage of the production cycle;

d) environmental and culture parameters (seasonality, temperature, salinity, pH);

e) geographical location, specific rearing units;

f) weight/biomass, dosage regimes and duration of treatment with antimicrobial agents.;

g) basis for treatment (historical, empirical, clinical, clinical with laboratory confirmation and sensitivity testing).

Factors such as the number/percentage of animals / culture units treated, treatment regimens, type of use and route of administration are key elements to consider for *risk assessment*.

When comparing use of antimicrobial agents over time, changes in size and composition of animal populations should also be taken into account.

Annex 22 (contd)

Annex IV (contd)

Regarding data coming from end user sources, analysis of the use of antimicrobial agents may be possible at the regional, local, farm, and the level of the individual *veterinarian* or other *aquatic animal* health professional.

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Annex 22 (contd)

Annex V

CHAPTER 6.5.

DEVELOPMENT AND HARMONISATION OF NATIONAL ANTIMICROBIAL RESISTANCE SURVEILLANCE AND MONITORING PROGRAMMES FOR AQUATIC ANIMALS

Article 6.5.1.

Purpose

This chapter provides criteria relevant to *aquatic animals*~~,~~ and ~~products of~~ *aquatic animal products* ~~origin~~ intended for human consumption ~~and their rearing environment~~ for:

1. the development of national antimicrobial resistance surveillance and monitoring programmes and

2. the harmonisation of existing national antimicrobial resistance surveillance and monitoring programmes.

Article 6.5.2.

Objective of surveillance and monitoring programmes

~~Countries~~ *Competent Authorities* should conduct active antimicrobial resistance surveillance and monitoring programmes for *aquatic animals*.

Surveillance and monitoring of antimicrobial resistance is necessary to:

1. establish baseline data on the prevalence of antimicrobial resistant microorganisms and determinants;

2. collect information on antimicrobial resistance trends in relevant microorganisms;

3. explore the potential relationship between antimicrobial resistance in *aquatic animal* microorganisms and the use of antimicrobial agents;

4. detect the emergence of antimicrobial resistance mechanisms;

5. conduct *risk analyses* as relevant to *aquatic animal* and human health;

6. provide recommendations on human health and *aquatic animal* health policies and programmes;

7. provide information to facilitate prudent use, including guidance for professionals prescribing the use of antimicrobial agents in *aquatic animals*.

Cooperation at a regional level between countries conducting antimicrobial resistance surveillance should be encouraged.

Annex 22 (contd)

Annex V (contd)

The findings of surveillance and monitoring programmes should be shared at the regional and international level to maximise understanding of the global risks to *aquatic animal* health and human health ~~and animal health~~. The publication of these data and their interpretation is important to ensure transparency and to allow all interested parties to assess trends, to perform *risk assessments* and for *risk communication* purposes.

Article 6.5.3.

Definitions

Antimicrobial agent: means a naturally occurring, semi-synthetic or synthetic substance that at *in vivo* concentrations exhibits antimicrobial activity (kill or inhibit the growth of micro-organisms). Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition.

Article 6.5.3~~4~~.

General considerations for the design of surveillance and monitoring programmes

Surveillance of antimicrobial resistance at targeted intervals or ongoing monitoring of the prevalence of resistance in microorganisms from *aquatic animals*, *aquatic animal products* intended for human consumption ~~food~~ ~~,~~ ~~environment~~ and humans constitutes a critical part of *aquatic animal* health and public health strategies aimed at limiting the spread of antimicrobial resistance and optimising the choice of antimicrobial agents used in therapy.

For *aquaculture* it is important to conduct surveillance and monitoring of microorganisms that infect *aquatic animals* and microorganisms, including human pathogens, present on food derived from *aquatic animals*. ~~It may be also important to consider surveillance and monitoring of microorganisms that may potentially serve as a reservoir of resistance determinants in the environment.~~

Article 6.5.4~~5~~.

Design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect aquatic animals

An important consideration for the design of surveillance and monitoring programmes for antimicrobial susceptibility of microorganisms that infect *aquatic animals* is the lack of standardised and validated antimicrobial testing methods for a significant number of bacterial species of aquatic importance. When validated methods are available they should be used. Any deviations from standard methodology should always be clearly reported. For tests performed on bacterial species for which standard methods have not been developed full details of the methods used should be provided.

A preliminary requirement for the development of a surveillance and monitoring programme may be the identification and prioritisation of bacteria isolated from *aquatic animals* for methods development.

1. Selection of microorganisms

   Information on the occurrence of antimicrobial resistance in microorganisms that infect *aquatic animals* should be derived from regular monitoring of isolates obtained from diagnostic laboratories. These isolates should have been identified as primary causal agents of significant disease epizootics in *aquatic animals*.

   It is important that monitoring programmes focus on microorganisms that are associated with the commonly encountered *infections* of the major aquatic species farmed in the region / local growing area.

Annex 22 (contd)

Annex V (contd)

Selection should be designed to minimise bias resulting from over representation of isolates obtained from severe epizootics or epizootics associated with therapeutic failures.

Microorganisms belonging to a specific species or group may be selected for intensive study in order to provide information on a particular problem.

2. Methods used to analyse microorganism susceptibility to antimicrobial agents

Participating laboratories may perform disc diffusion, minimum inhibitory concentration (MIC) or other susceptibility tests to monitor frequencies of resistance. Protocols that have been standardised internationally and validated for application to the study of ~~aquatic~~ microorganisms isolated from *aquatic animals* should always be used.

3. Requirements for laboratories involved in monitoring resistance

Laboratories involved in national or regional monitoring of antimicrobial resistance should be of sufficient capability and have relevant expertise to comply with all the quality control requirements of the standardised test protocols. They should also be capable of participating in all necessary inter-laboratory calibration studies and ~~on-going validation studies~~ method standardisation trials.

4. Choice of antimicrobial agents

Representatives of all major classes of antimicrobial agents used to treat *disease* in *aquatic animal* species should be included in susceptibility testing ~~programmes~~.

5. Reporting of results

The results of ~~monitoring and~~ surveillance and monitoring programmes, including susceptibility data, should be published and made available for use by relevant stakeholders. Both ~~raw~~ primary quantitative data and the ~~epidemiological cut-off values or clinical breakpoints used to make interpretations of the data~~ interpretive criteria used should ~~always~~ be reported.

6. Surveillance and monitoring for epidemiological purposes

For epidemiological surveillance purposes, use of the epidemiological cut-off value (also referred to as microbiological breakpoint), which is based on the distribution of MICs or inhibition zone diameters of the specific microbial species tested, is preferred.

When reporting interpretations made by application of epidemiological cut-off values, the resultant categories should be referred to as wild type (WT) or non-wild type (NWT). When interpretations are made by the application of breakpoints the resultant categories should be referred to as sensitive, intermediate or resistant.

For microbial species and antimicrobial agent combinations, where internationally agreed epidemiological cut-off values have not been set, laboratories may establish their own laboratory specific values provided the methods they use are clearly reported.

Annex 22 (contd)

Annex V (contd)

7. Surveillance and monitoring for clinical purposes

The application of clinical breakpoints may be appropriate when the aim of the programme is to provide information to facilitate prudent use, including guidance for professionals in prescribing antimicrobial agents in *aquatic animals*. Selecting antimicrobial agents for therapeutic administration on the basis of information gained from the application of validated clinical breakpoints to antimicrobial susceptibility test data for microorganisms isolated from *aquatic animals* is an important element in the prudent use of these agents.

Use of these clinical breakpoints allows microorganisms to be identified as unlikely to respond to the *in-vivo* concentrations of antimicrobial agents achieved by a given standard therapeutic regime. In order to facilitate the development of these breakpoints, data is required that allows clinical correlation to be completed. For this purpose, where possible, data that relates *in-vitro* susceptibility of isolates to the clinical outcome of treatments with specified dose regimes under specific environmental conditions should be collected and reported.

Valuable information with respect to setting clinical breakpoints can be gained from situations where therapeutic failure is reported. The *Competent Authority* should include, in a surveillance and monitoring programme, systems for capturing details of failed treatments and the laboratory susceptibility test of the microorganisms involved.

Article 6.5.~~5~~6.

Design of surveillance and monitoring programmes for microorganisms in or on ~~food derived from~~ aquatic animal~~s~~ product~~s~~ intended for human consumption

For details of the sampling protocols and analytical procedures required for *surveillance* and monitoring programmes for antimicrobial resistance in microorganisms present in ~~products of~~ *aquatic animal products* ~~origin~~ intended for human consumption, ~~the relevant section~~ Chapter 6.7. of the *Terrestrial Animal Health Code* should be consulted.

It is important to note that the word 'commensal' as used in Chapter 6.7. of the *Terrestrial Animal Health Code* has less relevance due to the transient nature of the intestinal microflora of *aquatic animals*. ~~Therefore~~ The inclusion of intestinal microflora ~~commensal bacteria should not be included~~ in surveillance and monitoring programmes should only be considered when there is evidence that these are resident for sufficient time to be a risk factor affected by antimicrobial agents.

When designing a sampling programme it is important to consider that contamination of *aquatic animal products* with resistant microorganisms that are capable of infecting humans may arise from sources other than the *aquatic animal*. All sources of contamination should be taken into account, for example entry of raw manure into the aquatic environment. The number of ~~zoonotic~~ such microorganisms ~~of~~ associated with *aquatic animals* is much less than that found in terrestrial animals. However the following species should be included, as a minimum, in a ~~monitoring or~~ surveillance and monitoring programme:

a) *Salmonella* spp.;

b) *Vibrio parahaemolyticus*;

c) *Listeria monocytogenes*.

Annex 22 (contd)

Annex V (contd)

Article 6.5.6.

~~**Surveillance and monitoring for antimicrobial resistance in microorganisms present in the aquatic environment**~~

~~The development of a reservoir of resistance determinants in microorganisms in the aquatic environment has been identified as a potential risk arising from the use of antimicrobial agents in *aquaculture*. The objective of a surveillance and monitoring programme for these resistance determinants is to generate the data needed to conduct *risk analysis*.~~

~~The development and implementation of these programmes is significantly challenged by the complexity of the biological pathways, the lack of culture and susceptibility testing methods, and the diversity of *aquaculture* operations.~~

~~These programmes should focus on:~~

~~a) resistance determinants rather than on resistant microorganisms;~~

~~b) the use of quantitative molecular methods rather than traditional culture and susceptibility testing methods;~~

~~c) generating baseline data on the prevalence of resistance determinants (a) prior to exposure to the outputs of the aquaculture operation and (b) following exposure to the outputs of the aquaculture operation;~~

~~d) investigating a possible relationship between the emergence and persistence of resistance determinants and the use of antimicrobial agents.~~

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Annex 23

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

Original English
September 2011, revised version 27 Feb 2012

OIE *AD HOC* GROUP ON ASSESSING THE CRITERIA FOR LISTING AQUATIC ANIMAL SPECIES AS SUSCEPTIBLE TO INFECTION WITH A SPECIFIC PATHOGEN

OIE Headquarters, Paris, 27–28 September 2011

1. Opening, designation of the Chair and Rapporteur, and adoption of the Agenda

The meeting of the OIE *ad hoc* Group on Assessing the Criteria for Listing Aquatic Animal Species as Susceptible to Infection with a Specific Pathogen was held from 27 to 28 September 2011, at the OIE Headquarters in Paris. The participants were welcomed by Dr Kazuaki Miyagishima, Deputy Director General of the OIE and Head of the OIE Scientific and Technical Department.

Dr Miyagishima informed the Group of the change of approach that would be implemented in coming years by the Terrestrial Animal Health Code Commission in the *Terrestrial Animal Health Code* whereby the Code chapters would be restructured by pathogen rather than categorised by species affected. This was seen as a more progressive scientific approach. The work of this *ad hoc* Group was at the forefront of this approach and put the Aquatic Animal Health Code Commission ahead of the Terrestrial Animal Health Code Commission.

The meeting was chaired by Dr Edmund Peeler; Dr Haenen was appointed Rapporteur. The agenda and list of members of the *ad hoc* Group are given in Appendices I and II.

2. Terms of reference for the *ad hoc* Group meeting

The Terms of Reference were adopted and are given at Appendix III.

3. Assessment and further development of the current criteria

The members of the *ad hoc* Group had worked on the draft criteria, by electronic consultation, before the meeting. The version that they discussed was therefore an updated version of that sent with the report of the February 2011 meeting of the Aquatic Animals Commission for Member Country comment. The Group asserted that it had expanded and improved the criteria while keeping the principles of the document that had been circulated. The Group also consulted a document that had been developed by the European Food Safety Authority (EFSA) entitled: Aquatic species susceptible to diseases listed in Directive 2006/88/EC, Scientific Opinion of the Panel on Animal Health and Welfare (AHAW) (adopted on 11 September 2008).

The main development was guidance to experts in how the criteria should be interpreted in the definition of species as definite, possible and unlikely susceptible species. A clear distinction was made between criteria that provided direct evidence of susceptibility (multiplication and transmission) and those that provided indirect evidence (viability, pathology, location).

Annex 23 (contd)

Dr Haenen presented the draft *ad hoc* Group criteria in her oral presentation at the 15th Conference of the European Association of Fish Pathologists, Split, Croatia and gathered reflections from the audience on these criteria.

At this *ad hoc* Group meeting, the Group discussed these comments, the OIE Member Country comments on the February version of the criteria, and the above-mentioned EFSA criteria.

The Group reviewed the Member Country comments that had been received and made minor amendments to the criteria as appropriate.

One of the proposed amendments put forward by the Group was to separate the criteria for transmission and for viability into two categories; they constituted together one criterion in the EFSA document.

On the issue of using taxonomic relationship in deciding susceptibility, the Group was aware that this was controversial and needed further development. The updated criteria can be found at Appendix IV. The entry on koi herpesvirus (KHV) could be used as an example to help complete the other diseases in Table 1 of the guidance.

4. Development of a worked example using these criteria: koi herspesvirus disease

The Group did not consider it necessary to review all the literature on *Cyprinus carpio*. The first publications demonstrating susceptibility of these species to KHV were sufficient. Before the meeting, Drs Bergmann and Haenen had collated all the literature on species susceptibility to KHV. A list of potential susceptible species was drawn up and the literature for each species was reviewed against each of the agreed criteria.

In reviewing the KHV literature, a number of issues arose that led to amending the criteria. From these discussions, the Group proposed the following guidelines:

– The Group only used peer-reviewed literature for the assessment but some relevant grey literature is mentioned in Table 1. Moreover, some scientific papers were in preparation on additional species and these would need to be reviewed in the future.

– The Group considered susceptibility to infection with KHV, which does not necessarily result in KHV disease.

– Tests that could be judged to be equivalent to those described in the *Aquatic Manual* were acceptable to identify the agent. The Group considered that some tests provided good evidence in support of some of the criteria but were not in the *Aquatic Manual* because they are not suitable for screening or confirmation of infection, e.g. *in situ* hybridisation and quantitative PCR.

– Types of scientific evidence that could be used to show multiplication of the agent were identified. The Group concluded that among others, signs of clinical disease on experimental challenge were accepted as signs of multiplication.

– Identification of the agent in gills, skin or gut was not alone considered to be evidence of infection unless it was proven that the virus was present inside cells of these tissues. Presence of the virus only on the surface of the gut or on the skin or gills might indicate that the species could act as a mechanical vector, but vectors were not considered to fall within the scope of the Terms of Reference of the Group.

The Group completed the entry on KHV in Table 1 of the criteria (examples of evidence to support the criteria)

The current *Aquatic Code* chapter on KHV defined common carp and its hybrids as susceptible species. Following the Group's review of the scientific literature, three additional species would be listed as definite susceptible species and two as possible susceptible species (see Appendix V, an Excel spread sheet, for complete details of the analysis carried out). Carp and its hybrids were the only listed susceptible species to show clinical sings of KHV disease.

Annex 23 (contd)

Definitely susceptible to KHV	**Possibly susceptible to KHV**
Cyprinus carpio and its hybrids	*Ctenopharyngodon idella*
Carassius auratus	*Leuciscus idus*
Acipenser gueldenstaetii	
Acipenser oxyrinchus	

The proposed guidance on susceptibility based on taxonomic relationships was applied to KHV. Based on the available literature two members of the *Acipenser* genus were determined to be definitely susceptible species. No evidence was found to suggest that other members of the genus were not susceptible. Thus the Group concluded that all members of the *Acipenser* genus were definitely susceptible to KHV. There were two species that were definitely susceptible representing two genera in the family Cyprinidae. According to the criteria, all other members of the Cyprinidae were classed as possibly susceptible species.

5. Taxonomy

The guidance in the original draft criteria (February 2011) could have resulted in large numbers of species being listed as susceptible because there were few, if any, reports of resistance to infection in the scientific literature. For this reason, the Group agreed to considerably revise the section to restrict definite susceptibility based on taxonomic relationships to the genus level, and possible susceptibility to the family level.

Guidance now allowed for susceptibility based on taxonomy at higher levels but very solid evidence of a wide host range would be required.

6. Definite versus possible susceptible species

The Group recommended that only definitely susceptible species be listed in the *Aquatic Code*. The listing of "possibly susceptible" species allowed to conduct informed risk assessments. Possibly susceptible species needed further research to determine their true susceptibility.

The Group considered that species might be categorised as "unlikely" to be susceptible because of the lack of published evidence or conflicting reports.

7. Conclusion

The *ad hoc* Group adapted the criteria for listing susceptible species and applied them to KHV as a 'worked' example, as illustrated in the Excel file. Based on the KHV assessment, the criteria were further amended. The assessment resulted in the addition of one Cyprinid species and all members of the genus *Acipenser* to the susceptible species list, and two species were added to the possibly susceptible list. The current guidance worked well for KHV. For the other pathogens of Table 1, these would need to be reviewed and completed, including the new column on transmission.

Annex 23 (contd)

Appendix I

OIE *AD HOC* GROUP ON ASSESSING THE CRITERIA FOR LISTING AQUATIC ANIMAL SPECIES AS SUSCEPTIBLE TO INFECTION WITH A SPECIFIC PATHOGEN

Paris, 27–28 September 2011

Adopted agenda

1. Opening, Designation of Chair and Rapporteur, Adoption of Agenda
2. Terms of Reference for the meeting
3. Assessment and further development of the current criteria
4. Development of a worked example using these criteria: koi herpesvirus disease
5. Taxonomy
6. Definite versus possible susceptible species
7. Conclusion

Annex 23 (contd)

Appendix II

OIE *AD HOC* GROUP ON ASSESSING THE CRITERIA FOR LISTING AQUATIC ANIMAL SPECIES AS SUSCEPTIBLE TO INFECTION WITH A SPECIFIC PATHOGEN

Paris, 27–28 September 2011

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Annex 23 (contd)

Appendix III

OIE *AD HOC* GROUP ON ASSESSING THE CRITERIA FOR LISTING AQUATIC ANIMAL SPECIES AS SUSCEPTIBLE TO INFECTION WITH A SPECIFIC PATHOGEN

Paris, 27–28 September 2011

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Terms of reference

1. Assess the current draft Criteria for Listing Aquatic Animal Species as Susceptible to Infection with a Specific Pathogen, the aim of which is to assist the authors of disease chapters in the *Manual of Diagnostic Tests for Aquatic Animals*, and in the *Aquatic Animal Health Code*, to assess species for susceptibility to the disease in question. The *ad hoc* Group should further develop the criteria and submit a finalised draft to the OIE Aquatic Animal Health Standards Commission, which will seek Member comment and ultimately approval for adoption as a new chapter in the *Aquatic Manual* in May 2012.

2. Develop a worked example using these criteria for Koi herpesvirus disease (KHVD) to aid authors to correctly apply the criteria.

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Annex 23 (contd)

Appendix IV

CRITERIA FOR LISTING SPECIES AS SUSCEPTIBLE TO INFECTION WITH A SPECIFIC PATHOGEN

Scope

Susceptible species as defined in the *Aquatic Code* means a species of aquatic animal in which infection has been demonstrated by natural exposure or by experimental exposure to the disease agent in a manner that mimics a natural pathway for infection. Each disease chapter in the *Aquatic Code* and *Aquatic Manual* contains a list of currently known susceptible species. The scope of these guidelines is to provide criteria to determine which species should be listed as susceptible to listed infectious agents. These guidelines do not provide criteria for identifying mechanical vectors (i.e. species that may carry the pathogen without replication).

Approach

There are three stages outlined in this chapter to assessing susceptibility of a species to infection with a specified infectious agent:

1. Screen the available evidence to determine if the route of infection used is consistent with the definition of susceptible species (i.e. by natural exposure or experimental challenge that mimics natural exposure). Only evidence that meets this requirement should be used in stages 2 and 3);

2. Determine whether the infectious agent has been identified using an acceptable technique (only evidence that meets this requirement should be used for stage 3);

3. Determine whether the evidence indicates that presence of the agent constituted an infection (as defined in the *Aquatic Code*) using the five suggested criteria.

Stage 1: Screening the available evidence to determine route of infection

The available evidence should be classified as from i) natural occurrence, ii) cohabitation studies, iii) bath challenge, iv) other non-invasive experimental procedure, or v) invasive experimental procedure.

Evidence should only be used to define a species as susceptible to the infectious agent in question if they are classified as from natural disease occurrence, non-invasive experimental procedures (e.g. cohabitation, bath challenge, predation, or, when relevant, via intermediate hosts or vectors). Evidence from invasive experimental procedures should only be used when justification can be provided that they mimic the natural routes of exposure.

Peer-reviewed publications should be used. Strong justification is needed to use evidence from non-peer reviewed sources (e.g. grey literature).

Stage 2: Identification of the infectious agent

The presence of the causative infectious agent or a viable organism, in or on (in the case of ectoparasites) the aquatic animal must be demonstrated in accordance with methods described in section 7 (corroborative diagnostic criteria) of disease chapter for the specified infectious agent in the *Aquatic Manual,* or other methods that have been demonstrated to be equivalent.

Stage 3: Criteria to determine infection

The following criteria should then be used to determine whether identification of the agent (in or on the host) constitutes an infection (as defined by the *Aquatic Code*):

A. Evidence that the agent is multiplying in or on the host, or that developing or latent stages of the agent are present in or on the host;

Annex 23 (contd)

Appendix IV (contd)

B. Demonstrated transmission from infected individuals of the proposed susceptible species to other aquatic animals by routes meeting the criteria of stage 1;

C. Viable infectious agent isolated from the proposed susceptible species, or viability demonstrated via transmission to naive individuals (by natural routes);

D. Clinical and/or pathological changes associated with the infection;

E. Specific location of the pathogen (e.g. in one or more tissue types).

Criteria A or B may be considered direct evidence of multiplication and therefore susceptibility of the putative host species. Criteria C, D and E are indirect evidence of multiplication.

The type of available scientific evidence to support the criteria will depend on the disease agent and potential host species under consideration. Examples of evidence required to support the criteria are given in Table 1.

Table 1. *Types of evidence required to support the criteria for listing susceptible species by pathogen*

Disease[1]	A: Multiplication	B: Transmission	C: Viability	D: Pathology	E: Location
EUS	Multiplication cannot be demonstrated for *A. invadans* following the definitions provided in section		Isolation by culture	Granulomatosis or necrosis of muscle tissue associated with invasive infection with fungal like structures	Muscle tissue
EHN	Sequential virus titration showing increase in viral titres. TEM showing virions in host cells. Products of virus replication detected. Serial passage from individual to individual		Isolation by cell culture. Cohabitation with passage to a susceptible host	Tropism for vascular endothelium and haematopoietic necroses. Perivascular mononuclear inflammatory response in liver	Gills, cardiovascular system, kidney, liver
VHS	Isolation by cell culture. Virus titration showing a growth curve. TEM showing virions in host cells. Products of virus replication detected. Serial passage from individual to individual		Isolation by cell culture. Cohabitation with passage to a susceptible host	Lethargy or abnormal swimming, skin darkening, exophthalmia, anaemia, haemorrhages, peritoneal oedema. Petechial haemorrhages. necrotic kidney, moderately swollen spleen, pale liver. Gastro-intestinal tract is empty. Primarily endothelial cells in the vascular system are affected. The kidney, liver and spleen show extensive focal necrosis and degeneration. Haemorrhages in skeletal muscle bundles and fibres.	Recover virus from internal organ. PCR from internal organ

[1] Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Viral haemorrhagic septicaemia (VHS), Infectious salmon anaemia (ISA), Koi herpesvirus disease (KHVD), Infectious haematopoietic necrosis (IHN), Spring viraemia of carp (SVC), Gyrodactylosis (*Gyrodactylus salaris*) (Gyro), Red sea bream iridoviral disease (RSBID), Infection with *Bonamia ostreae* (IBO), Infection with *Bonamia exitiosa* (IBE), Infection with *Marteilia refringens* (IMR), Infection with *Perkinsus marinus* (IPM), Infection with *Perkinsus olseni* (IPO), Infection with *Xenohaliotis californiensis* (IXC), Infection with abalone herpes-like virus (IAHV), Taura syndrome (TS), Yellow head disease (YHD), White spot disease (WSD), Infectious hypodermal and haematopoietic necrosis (IHHN), Crayfish plague (*Aphanomyces astaci*) (CP), Infectious myonecrosis (IMN), White tail disease (WTD), Infection with *Batrachochytrium dendrobatidis* (IBD), Infection with ranavirus (IR).

Annex 23 (contd)

Appendix IV (contd)

Disease[2]	A: Multiplication	B: Transmission	C: Viability	D: Pathology	E: Location
ISA	Virus titration showing a growth curve. TEM showing virions in host cells. Products of virus replication detected. Serial passage from individual to individual		Isolation by cell culture. Cohabitation with passage to a susceptible host	Pale gills, exophthalmia, distended abdomen, and petechia in the eye chamber, possibly with abdominal skin haemorrhages and scale oedema. Internally, darkening of the liver, swollen kidney and haemorrhages within the intestinal wall. Associated mortality. Haemorrhagic liver necrosis, renal interstitial haemorrhage and tubular necrosis. Haematocrit <10 in end stages may be observed	Samples for virus isolation from Internal organs
KHVD	1. Serial transmission from individual to individual (cohabitation). 2. TEM observation of virions in host cells. 3. Intranuclear inclusion bodies (histology). 4. Characteristic clinical signs following viral exposure. 5. Increase in titre over time demonstrated by qPCR or virus isolation. 6. Presence of mRNA transcribed from viral genes. 7. Re-isolation of virus from internal organs following challenge	1. Cohabitation of infected individuals with naive individuals, resulting in infection (as defined by OIE)	1. Isolation by cell culture. 2. Cohabitation with transmission to a susceptible host	1. Focal gill necrosis (gross or histopathological). 2. Enophthalmus. 3. Focal areas of epithelial necrosis (gross or histopathological). 4. Increased mucous production. 5. Intranuclear inclusion bodies. 6. Interstitial nephritis	1. Identified in internal organs (e.g. kidney, spleen) by molecular methods (e.g. in-situ hybridisation, PCR), or serological methods (e.g. IFAT, immunohistochemistry) 2. Identified in leucocytes by molecular or serological methods. 3. Virus demonstrated inside gill or skin cells by serological or molecular methods
IHN	Virus titration showing a growth curve. TEM. IFAT. Serial passage from individual to individual. Products of virus replication detected		Isolation by cell culture. Cohabitation with passage to a susceptible host	Lethargy interspersed with bouts of frenzied, abnormal activity, darkening of the skin, pale gills, ascites, distended abdomen, exophthalmia, and petechial haemorrhages internally and externally. Internally, fish appear anaemic and lack food in the gut. Liver, kidney and spleen are pale. Degenerative necrosis in haematopoietic tissues, and digestive tract. Reduced haematocrit, leukopenia, degeneration of leukocytes and thrombocytes.	Samples for virus isolation from Internal organs. PCR from internal organ

[2] Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Viral haemorrhagic septicaemia (VHS), Infectious salmon anaemia (ISA), Koi herpesvirus disease (KHVD), Infectious haematopoietic necrosis (IHN), Spring viraemia of carp (SVC), Gyrodactylosis (*Gyrodactylus salaris*) (Gyro), Red sea bream iridoviral disease (RSBID), Infection with *Bonamia ostreae* (IBO), Infection with *Bonamia exitiosa* (IBE), Infection with *Marteilia refringens* (IMR), Infection with *Perkinsus marinus* (IPM), Infection with *Perkinsus olseni* (IPO), Infection with *Xenohaliotis californiensis* (IXC), Infection with abalone herpes-like virus (IAHV), Taura syndrome (TS), Yellow head disease (YHD), White spot disease (WSD), Infectious hypodermal and haematopoietic necrosis (IHHN), Crayfish plague (*Aphanomyces astaci*) (CP), Infectious myonecrosis (IMN), White tail disease (WTD), Infection with *Batrachochytrium dendrobatidis* (IBD), Infection with ranavirus (IR).

Disease[2]	A: Multiplication	B: Transmission	C: Viability	D: Pathology	E: Location
SVC					
Gyro					
RSBID					
IBO	Binucleated plasmodia in TEM or impression smears		Purification and cell viability test. Cohabitation with passage to a SPF susceptible host	Focal to disseminated haemocytic infiltration of the connective tissues, Intracellular parasite present in haemocytes	Systemic
IBE	Binucleated plasmodia in TEM or impression smears		Cohabitation with passage to a SPF susceptible host	Focal to disseminated haemocytic infiltration of the connective tissues, Intracellular parasite present in haemocytes	Systemic
IMR	Presence of different stages of the parasite that include tertiary cells		Purification and cell viability test. Spore viability in faeces. Experimental transmission to intermediate host	Possible haemocytic infiltration, intercellular parasite observed in epithelia of target organs	Gills, palps and digestive tract
IPM	Presence of different stages of the parasite		Isolation on Ray Fluid Thioglycolate medium. Cohabitation with passage to SPF susceptible species	Disseminated haemocytic infiltration, intra or intercellular parasite	All connective tissues and digestive epithelia
IPO					
IXC					
IAHV					
TS	Presence of characteristic inclusion bodies and positive labelling of inclusion bodies by ISH or IFAT. Serial passage from individual to SPF individual		Passage bioassay to a SPF susceptible host	Characteristic inclusion bodies, with pycknosis and karyorrhectic nuclei in target tissues and no haemocytic infiltration	Cells of tissues of ectodermic and endodermic origin
YHD	Presence of characteristic inclusion bodies and positive labelling of inclusion bodies by ISH or IFAT. Presence of virions in inclusions bodies by TEM. Serial passage from individual to SPF individual		Passage bioassay to a SPF susceptible host	Characteristic inclusion bodies, with pycknosis and karyorrhectic nuclei in target tissues and no haemocytic infiltration	Haemocytes, heart , lymphoid organ and sinuses, connective tissue
WSD	Presence of characteristic intranuclear inclusion bodies. Presence of virions in inclusions bodies by TEM. Positive labelling of inclusion bodies by ISH or IFAT. Serial passage from individual to SPF individual		Passage bioassay to a SPF susceptible host	Eosinophilic inclusions within nuclei of target organs and tissues	Cells of tissues of ectodermic and endodermic origin
IHHN					
CP					

Disease[2]	A: Multiplication	B: Transmission	C: Viability	D: Pathology	E: Location
IMN					
WTD	Presence of characteristic cytoplasmic inclusion bodies. Presence of two types viral particles of different sizes in target cells. Serial passage from individual to individual		Passage bioassay to a SPF susceptible host	Presence of large oval or irregular basophilic cytoplasmic inclusion bodies in infected muscles	Gill tissue, head muscle, heart, abdominal muscle, ovaries, pleopods and tail muscle
IBD					
IR					

IFAT: Indirect fluorescent antibody test; ISH: *In-situ* hybridisation; qPCR: Real-time quantitative polymerase chain reaction; SPF: Specific pathogen free; TEM: Transmissible electron microscopy

Presenting evidence for susceptibility

In presenting the available scientific data the following should be considered:

1. Whether the data derived from natural infections, experimental work using cohabitation or methods reflecting natural pathways of infection (e.g. immersion challenge) or other experimental designs;

2. Confidence that the causative agent was correctly identified (e.g. characteristics of tests used);

3. Extent to which criteria A–E are supported.

The outcomes of the assessment should be displayed as definite, possible or unlikely.

Definite susceptible species: There is consistent scientific evidence for multiplication of the agent in (on) the suspect host species and/or transmission of the agent from infected to other individuals. Solid evidence to support criteria A or B alone is sufficient to conclude that a species is susceptible. In the absence of evidence to meet A or B, satisfying at least two of criteria C, D or E would be required to conclude a species is a definite susceptible species.

Possible susceptible species: There is sparse or conflicting evidence for multiplication of the agent in (on) the suspect host species and/or transmission of the agent from infected to other individuals. Only one of criteria C, D or E was met.

Unlikely susceptible species: There is no evidence for multiplication of the agent in (on) the suspect host species and / or transmission of the agent from infected to other individuals. No solid evidence supporting criteria C, D or E.

The decision to list a species as susceptible should be based on a finding that the evidence is definite. However, possible susceptibility of a species is also important information and this should also be included in Section 2.2.1. of the disease chapter of the *Aquatic Manual*.

Taxonomic relationship of susceptible species

In the absence of direct evidence, the taxonomic relationship of a species to other known susceptible species may be used to assess susceptibility. Species can be classed as ‘definite’ susceptible species if they reside in a genus that includes two or more ‘susceptible’ species and in which there is no strong evidence of resistant (i.e. not susceptible) species. In cases where there is a family with two or more susceptible species in more than one genus, and no evidence of resistant species, all species in the family with unknown susceptibility are considered possible susceptible species.

Evidence of resistance would include the following:

1. Appropriate testing reveals no evidence of infection when animals are exposed to the pathogen in natural setting where the pathogen is known to be present and to cause disease in susceptible species.

Annex 23 (contd)

Appendix IV (contd)

2. Appropriate testing reveals no evidence of infection when animals are exposed through controlled challenges by natural routes.

Defining species as possible susceptible on the basis on a taxonomic relationship at levels higher than family requires solid evidence that the pathogen has a very wide host range (e.g. the *Aquatic Code* defines all decapods crustaceans as susceptible to white spot syndrome virus).

References

Scientific Opinion of the Panel on Animal Health and Welfare on a request from the European Commission on aquatic animal species susceptible to diseases listed in the Council Directive 2006/88/EC. *The EFSA Journal* (2008), **808**, 1–145.

Annex 24

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

Original: English

January 2012

REPORT OF THE MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY EDUCATION

Paris, 11–13 January 2012

The meeting of the OIE *ad hoc* Group on Veterinary Education (the *ad hoc* Group) was held at the OIE Headquarters in Paris (France) from 11 to 13 of January 2012. A list of participants to the meeting may be found at Annex I and the adopted agenda at Annex II.

Meeting with Dr Vallat, Director General of the OIE

Dr Bernard Vallat joined the Group for a discussion of achievements and priorities for future work.

He welcomed all members and observers and thanked the Group for its ongoing work on behalf of the OIE. Dr Vallat noted that the 'public good' component of veterinary services is essential to obtain sustainable financial support for veterinary education. He explained that Members have requested guidance from the OIE on the minimum core curriculum for training veterinarians. The goal is to ensure that the veterinary profession continues to play a critically important role with benefit to society. It is not the objective of the OIE to accredit veterinary education establishments (VEEs). Rather, the OIE aims to identify the topics that should be addressed within the core veterinary curriculum. In addition to the global list, a part of the curriculum, perhaps 50%, will be tailored to specific national priorities.

Dr Vallat outlined his vision on promotion of the basic core curriculum. The first step is to develop recommendations that are supported by all OIE Members. The aim is not necessarily to produce a new *Terrestrial Animal Health Code* (*Terrestrial Code*) text. Rather, the recommendations could be published on the website in the form of OIE guidance to Members.

Dr Vallat explained that these recommendations will be used by the OIE and Veterinary Services of Member countries in work with governments and donors to promote the funding of twinning projects between VEEs in developed and developing countries, based on the OIE's very successful global Laboratory Twinning Initiative. The concept is to develop a framework for candidate and parent establishments to operate according to the principles of universality and flexibility.

Dr Saeb Nazmi El-Sukhon commented that it would not be sufficient in the longer term to provide a simple list of topics. The important distinction is in the manner of teaching the topics, the time allocated and so forth. He recommended that the OIE consider entering into direct contact with those responsible for curriculum development. Dr Vallat indicated that this level of detail would need to be addressed in twinning agreements, which would be the subject of agreement between parent and candidate VEEs, the OIE and relevant donors.

Annex 24 (contd)

Dr Vallat also commented on some materials provided by the World Bank (WB) as background information to this meeting. He also noted that the OIE welcomes the support of the WB for strengthening veterinary education globally and supports the proposal for projects with developing countries of Eastern Europe and Asia. Dr Vallat considered that the World Veterinary Association role in assuring the quality of veterinary education should be more clearly recognised and supported. He restated that the OIE objective is to provide support for improving veterinary education globally, not to enter into competition with organisations and associations with a specific role in the accreditation of VEEs.

Dr Ron DeHaven thanked Dr Vallat for sharing this insight with the group. Dr DeHaven suggested that the 'Day 1 competencies' document would provide the basis for development of the core curriculum.

Dr Vallat noted that the OIE definition of veterinary services covers both the government and the private sector veterinarians. The concept of the basic core curriculum applies equally to those working in the private and the public sector. Of course, senior level veterinarians in the public sector will need additional training and recommendations on this point will be made in the document 'Post Professional and Continuing Education for Graduate Veterinarians'. Dr Vallat highlighted the importance of regional specificities in determining needs for veterinary education.

Dr Timothy Ogilvie noted the strong autonomy of universities and cautioned the OIE against developing standards, at least in the short term. He noted that VEEs are increasingly being asked to base their curricula on desired outcomes, i.e. attainment of competencies. Dr Vallat agreed with Dr Ogilvie that an outcome based approach was preferable to the traditional focus on hours studied in listed subjects. Dr Vallat noted that the debate on 'outcomes' versus 'inputs' arises also in connection with animal welfare standards and confirmed that the OIE policy is based on outcomes, not on input criteria.

1. Adoption of the agenda

Dr DeHaven presented the draft agenda for the meeting. He indicated that the priorities for this meeting were to finalise the 'Day 1 competencies' document and to continue to progress the 'continuing education' document. In addition, the new OIE global initiative for Twinning of Veterinary Education Establishments (VEE) would be discussed. Last but not least, Dr DeHaven indicated that the Group would be asked to consider the development of a Core Curriculum.

2. Addressing Members comments - Revise document 'Minimum competencies expected of Day 1 Veterinary Graduates to assure the delivery of high quality national veterinary services"

The *ad hoc* Group worked through the Minimum competencies document (Annex III), modifying it as appropriate to address the written comments received from the OIE Animal Production Food Safety Working Group (APFSWG) and the Aquatic Animal Health Standards Commission (AAHSC).

Dr Sarah Kahn briefly outlined the work of the OIE AAHSC, which is developing a modified approach to the OIE PVS Tool for specific application to Aquatic Animal Health Services (AAHS). Dr Kahn indicated that the AAHSC has proposed for consideration of OIE Members a definition of 'aquatic animal health professional'. While veterinarians may not necessarily have a central role in AAHS in all countries, they should be involved in certain aspects, such as the prescription of veterinary drugs. With this in mind, the Group agreed to consider competence in aquatic animal health as an area of post-graduate specialisation, which could be addressed with the relevant document.

The *ad hoc* Group reviewed the comments provided by the APFSWG.

The Group did not agree to add basic information on global trends in food production, food trade and food security, as it considered that this would add text without adding relevant information.

The suggested replacement of 'clinical veterinary sciences' by 'clinical veterinary medicine' was not accepted. Dr DeHaven noted that this issue had been discussed at a previous meeting and that 'sciences' had been considered as the most appropriate term.

The Group considered that knowledge on zoning and compartmentalisation was more relevant as an advanced competency; appropriate text was added to point 2.3.4.

The Group discussed the APFSWG proposal to develop a new point 1.2.6.2. The risk-based approach to food control is clearly important. However, the Group considered that understanding these principles was more relevant as an advanced competency. The Group did not see a need to modify point 2.5. (Application of Risk Analysis).

The Group agreed to add 'risk based' in point 2.4.1.

The Group did not see a need to include reference to 'specialised monitoring programmes' in point 2.4.2., as the goal is to keep the document clear and simple.

The proposal to modify the text in point 2.5. was not accepted as the Group preferred to maintain the text taken from the *Terrestrial Code*. In the absence of a rationale for deleting the two sentences in the chapeau of point 2.5., the Group did not recognise a need to make modifications.

Following the APFSWG recommendation, the Group clarified point 2.5.1.

In relation to the recommendation to modify point 2.5.2. the Group was concerned that the proposed modification was too limiting – for example, it did not cover radiological or physical hazards. In relation to the recommendation to modify point 2.5.4., the Group did not agree that the proposed modification improved the text. The definitions of hazard identification, risk assessment, risk management and risk communication are those in the *Terrestrial Code* and the Group considered that it was useful for these definitions to appear in the Day 1 competencies document.

The group proposed that the final version of the document be put on the OIE website for guidance of Members. In future, the Code Commission may wish to consider including a reference to this document in Chapter 3.2. once adopted.

3. Review of draft document: Graduate and Continuing Education for Graduate Veterinarians

Definitions were added to clarify the distinction between basic and advanced competencies. Day 1 veterinary graduates should have a mastery of all basic competencies and should have received an introduction to the advanced competencies. Basic competencies comprise general and specific competencies, the latter being directly related to the OIE mandate. For the advanced competencies, veterinary graduates need further education, via on the job training or specific post graduate training courses. The *ad hoc* Group modified the entire document to make this clear.

The *ad hoc* Group also included definitions for key terms used in the document, including 'Day 1 veterinary graduate' and 'competencies', the latter term including 'basic competencies' and 'advanced competencies'. It was agreed that inclusion of a definition of 'veterinary products' in the *Terrestrial Code* Glossary may be valuable.

A sentence was added to the introduction to highlight that, given the expanding scientific knowledge base and demands on the veterinary profession, it is essential that veterinarians be capable of accessing appropriate information sources.

Under 'Scope', the *ad hoc* Group added text to highlight the need for close collaboration between veterinary education establishments, national veterinary services and veterinary statutory bodies to ensure that veterinary education meets the needs of the country and, as appropriate, the region.

Critical skills needed by senior level veterinarians in the Veterinary Authority

The *ad hoc* Group worked through the document, making modifications based on the consensus views of members.

Annex 24 (contd)

The examples that had been presented in the draft document were removed. Many such examples could be given but the Group considered that there was little to be gained by trying to list them all.

Discussion on the proposal to develop a core ('minimum') veterinary curriculum

Drs Tjeerd Jorna and Etienne Bonbon outlined the EU approach to professional qualifications, which prescribes the subjects to be taught to health professionals, including veterinarians. While implementation by the VEE of the EU Member States may vary, there is nonetheless a minimum harmonised level of education which facilitates the movement of professionals within the EU.

Dr Aaron S. Mweene commented that there is a clear need for guidelines to African countries on the core veterinary curriculum. Dr Louis Joseph Pangui agreed that this would be a tool to help secure the support of governments and donors for improving the standard of veterinary education.

Dr El-Sukhon commented that it would not be sufficient in the longer term to provide a simple list of topics. The important distinction is in the manner of teaching the topics, the time allocated and so forth. He recommended that the OIE consider entering into direct contact with those responsible for curriculum development.

Dr Ogilvie reminded members of the discussion with the Director General, where it was clear that the competence of the graduate veterinarian is the key consideration rather than the specific subjects to be taught.

4. Twinning project

Dr Alain Dehove, OIE's World Animal Health and Welfare Fund Coordinator, joined the *ad hoc* Group on Day 2 to discussed matters related to Twinning Projects. He comprehensively explained to the Group Members that, in order to facilitate capacity building and networking, and to bring communities together, the OIE started to apply this concept in 2007 to laboratories to build expertise for the most important topics or animal diseases and zoonoses in priority regions, in direct support of the OIE's strategy to improve global capacity for disease prevention, detection, and control through better veterinary governance. Dr Dehove mentioned that each Twinning project links a parental establishment with a beneficiary establishment and that knowledge and skills are exchanged through this link over a determined project period.

Dr Dehove clarified that to support the OIE Laboratory Twinning programme relatively few documents are necessary: (i) a concept note, (ii) a guide on the preparation of twinning projects, (iii) a template agreement and (iv) a template budget for twinning projects. A very similar approach could be followed (and similar documents could be prepared) for a VEE Twinning Programme.

Dr Dehove mentioned the importance and the role of veterinary officers within the Veterinary Services (VS) for improving animal and public health and enhancing compliance with SPS and OIE standards, at the national, regional and international level. Twinning projects between Veterinary Educational Establishments (VEE) would indeed support these goals within the framework of the OIE PVS Pathway which looks for a sustainable improvement of national VS' compliance with OIE standards on the quality of Veterinary Services.

Dr Stephane Forman stated that the OIE PVS Pathway is recognised by the World Bank (WB) as the reference tool when investing on a project to strengthen VS within a country. He mentioned the document "Assessment tool for basic elements of a veterinary school" that is being developed by the WB and designed to provide the school and the evaluation team with an overview of the capacity and capabilities of veterinary education in the school.

The difference between assessment and evaluation was discussed. In response, Dr Dehove clarified that OIE does not have the intention to use VEE Twinning projects as a tool for evaluation, assessment or accreditation of VEE. An assessment tool is not required for the preparation of twinning projects. Indeed, this would create confusion between two distinct concepts, ie twinning as a means to build capacity; and the evaluation/assessment/accreditation of VEEs.

In accordance with the recommendations adopted by the OIE World Assembly of Delegates at the 79th General Session in May 2011, and based on the principles established under the successful Laboratories Twinning Programme, a draft document 'OIE Guidelines on Twinning Projects for VEE' had been prepared. These would be used in negotiation with donors to receive financial support for Twinning projects between VEE. Members of the *ad hoc* group were asked to provide comments on the draft Guidelines.

Dr DeHaven closed the meeting by acknowledging the special attendance of Dr Mweene and Dr Forman and by thanking the work of the Group in support of OIE's Mandate to improve Veterinary Services, through education.

5. Future work

The Group agreed to provide comments on the draft document 'OIE Guidelines on Twinning Projects for VEE' to Dr. Dehove by 1 March 2012. A revised draft will then be prepared and distributed to the Group by 1 April 2012. Utilizing this revised version of the Guidelines, the members will obtain feedback from relevant parties and submit further comments to Dr. Dehove by 1 June 2012. These comments will be considered by the Group at its meeting on 25-26 July 2012.

The Group also agreed to prepare a document to be used as a basis for Core Curriculum within VEE and including a reference to the "Day 1 Competencies" document and introductory comments for each subject identified in the Core Curriculum.

Additionally, each member of the group will submit a proposed list of topics/subjects to be included in a Core Curriculum, using the FVE document as a guide. This list should be submitted to Dr. Kahn by 1 May 2012 to enable consolidation of the lists and the preparation of draft introductory comments for each topic/subject proposed for inclusion in the Core Curriculum.

The *ad hoc* Group will continue to submit its reports to the Terrestrial Animal Health Standards Commission, with a view to obtaining the views of the Commission and the input of OIE Members on this important area of work.

6. Dates for next meeting

It was agreed that the next meeting would take place at OIE Headquarters in Paris on 25-26 July 2012. Members agreed to inform the OIE International Trade Department of their availability.

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…/ Annexes

Annex 24 (contd)

Annex I

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY EDUCATION

Paris, 11–13 January 2012

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Annex 24 (contd)

Annex I (contd)

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Annex 24 (contd)

Annex II

MEETING OF THE OIE *AD HOC* GROUP ON VETERINARY EDUCATION

Paris, 11–13 January 2012

Adopted agenda

Day 1 (11 January 2012) Morning

- Welcome, adoption of the agenda, and introductory remarks
- Review Terms of Reference for *ad hoc* Group (to ensure final meeting addresses all charges)
- Discussion with the OIE Director General
- Review *Minimum Competencies* document developed in August 2011
  - Comments from the September 2011 meeting of the Code Commission
  - Comments from the October 2011 meeting of the Aquatic Animals Commission
  - Comments from the November 2011 meeting of the OIE Animal Production Food Safety Working Group
  - Comments from OIE Members submitted in the second semester of 2011
- Finalize *Minimum Competencies* document based on comments received

Day 1 (11 January 2012) Afternoon

- Begin review of draft document (working title: *Postgraduate Skills and Education Needed for Delivery of National Veterinary Services*) developed after August 2011 meeting that combines earlier documents developed by the *ad hoc* Group:
  - Critical skills needed by senior level veterinarians in the veterinary authority
  - Continuing education topics for private veterinarians who are conducting work for the Veterinary Authority
  - Delivery methods and sources of continuing education

Day 2 (12 January 2012) Morning 9h30

- Refine and finalize draft document: *Postgraduate Skills and Education Needed for Delivery of National Veterinary Services*
- Review and finalize draft text that will be provided to Code Commission to capture key points of *Minimum Competencies* (and potentially *Postgraduate Skills*) document for insertion into the *Terrestrial Code* as deemed appropriate by the Code Commission (as per the report of the August 2011 meeting of the *ad hoc* Group; see section titled Future Work).

Annex 24 (contd)

Annex II (contd)

Day 2 (12 January 2012) Afternoon

- Discussion items
  - Veterinary Education Twinning Project between the US Veterinary Education consortium (faculty from University of Nebraska/Lincoln, North Carolina State University, Pennsylvania State University, and University of Connecticut) and the Veterinary College of the Agrarian State University of Armenia (ASUA)
  - Development of a Day 1 curriculum and its application in developing countries
  - Funding to promote veterinary education in developing countries as a means to address gaps in Public Health

Day 3 (13 January 2012) Morning and Afternoon

- Conclude discussion items from 12 January 2012 and develop any recommendations to move forward through the Code Commission
- Discussion of next/final steps
- Summary of actions of *ad hoc* Group over its four meetings
- Closing remarks and conclusion of the OIE *ad hoc* Group on Veterinary Education

Annex 24 (contd)

Annex III

MINIMUM COMPETENCIES EXPECTED OF DAY 1 VETERINARY GRADUATES TO ASSURE DELIVERY OF HIGH-QUALITY NATIONAL VETERINARY SERVICES

Final Version

Background

Veterinarians in every nation are responsible for the delivery of national veterinary services- that is, services provided under the legislative framework and the auspices of the governmental authority of a given country to implement animal health to assure the health and wellbeing of animals, people and ecosystems. The term "Veterinary Services" refers to the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) definition, which includes both public and private components of the veterinary profession involved in the promotion of animal and public health as well as animal welfare.

National Veterinary Services should be able to meet standards adopted by each country, but should also be able to comply with appropriate international standards and recommendations, particularly those in the OIE's *Terrestrial Code*. In delivering National Veterinary Services, veterinarians serve as an integral partner in the **One Health** effort—a collaboration of multiple disciplines working locally, nationally, and globally, to address critical challenges and attain optimal health for people, animals and the environment (www.onehealthcommission.org).

Although only some veterinarians will focus their careers on the delivery of national veterinary services, all veterinarians, regardless of their professional area of practice after graduation, are responsible for promoting animal health, animal welfare, veterinary public health, and food hygiene and food safety, act frequently as sub-contractors for National Veterinary Services and in many instances opt for career changes into National Veterinary Services. As such, veterinary education is a cornerstone to assure that the Day 1 veterinary graduate not only has received a level of education and training that ensures sound overall competencies, but also has the required knowledge, skills, attitudes and aptitudes to understand and be able to perform entry-level national veterinary service tasks that relate to the security and promotion of animal and public health. In addition, basic education that includes instruction in the minimum competencies will establish a basis on which those veterinarians seeking national veterinary service careers can build expertise through on-the-job training and quality postgraduate continuing education.

Scope

Taking into account the vast societal, economic, and political differences among OIE Member Countries, including the different existing veterinary education establishments accreditation schemes, this document sets ~~forth~~ out the competencies necessary for the Day 1 veterinary graduate to be adequately prepared to participate in National Veterinary Services at the entry-level.

While the minimum competencies outlined in this document are those relevant to the delivery of national veterinary services, no attempt is made to dictate in which specific course or during which educational year each competency should be taught. Indeed, it may be that many of the following competencies cross course boundaries and can be integrated across the curriculum in multiple courses. The document does not suggest how many credit hours of educational contact are required to teach each competency, as this might vary depending on the needs and resources of each country. Close collaboration between veterinary education establishments, national veterinary services and veterinary statutory bodies is encouraged in order to ensure the provision of veterinary education appropriate to the needs of each country. Education in the following minimum competencies during the course of each veterinary school's curriculum will prepare the Day 1 veterinary graduate to promote global veterinary public health and provide an excellent base for advanced training and education for those veterinarians wishing to pursue a career in both public and private components of National Veterinary Services. Given the expanding scientific knowledge base and increasing demands on the veterinary profession, it is essential that graduates be competent in locating, accessing and using appropriate information sources. It is important to note that veterinary education includes not only undergraduate education but also postgraduate continuing education and on-the-job training. The authorities should bear in mind the importance of life-long learning to ensure the various competencies of veterinary graduates such as protecting animal and public health.

Annex 24 (contd)

Annex III (contd)

Animal production, in particular the growing sector of aquaculture, is key to satisfy the growing global demand for food. Aquatic animal health programmes need to be strengthened and, to this end, the involvement of veterinarians with competence in aquatic animal health should be ~~promoted and~~ assured. Competencies in this document cover both terrestrial and aquatic animals. However, the aquaculture sector is not of equal importance to all countries. Therefore, veterinary education establishments should address competence in aquatic animal health as appropriate to the importance of the aquaculture sector in the country or region.

Definitions

- Competencies means:
    - knowledge: cognitive abilities, meaning mental skills
    - skills: ability to perform specific tasks
    - attitude: affective abilities, meaning feelings and emotions, and
    - aptitude: a student's natural ability, talent, or capacity for learning.

- Basic competencies means:
  the minimum knowledge, skills, attitudes and aptitudes required for a veterinarian to be licenced by a Veterinary Statutory Body. This comprises general competencies, as well as specific competencies that directly relate to the OIE mandate.

- Advanced competencies means:
  the minimum knowledge, skills, attitudes and aptitudes required for a veterinarian to work within the Veterinary Authority.

- Day 1 veterinary graduate means:
  a veterinarian who has just graduated from a veterinary education establishment.

Competencies

The Day 1 veterinary graduate should have basic competencies and should have received an introduction to advanced competencies.

1. Basic competencies

1.1. General competencies

1.1.1. Basic veterinary sciences, which are normally taught early in the curriculum and are prerequisite to clinical studies.

1.1.2. Clinical veterinary sciences, which provide the competencies necessary to diagnose, treat and prevent animal diseases.

1.1.3. Animal production, which includes health management and economics of animal production.

1.2. Specific competencies

1.2.1. Epidemiology

Epidemiology is the study of factors affecting the health and illness of populations, and serves as the foundation and logic of interventions made in the interest of veterinary public health and preventive medicine.

Annex 24 (contd)

Annex III (contd)

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.1.1. know and understand the general principles of descriptive epidemiology, its application to disease control and the ability to access and use appropriate information sources;

1.2.1.2. understand and participate appropriately in an epidemiological inquiry in case of occurrence of a reportable disease, including collection, handling, and transport of appropriate specimens or samples.

1.2.2. Transboundary animal diseases

Transboundary animal diseases (TADs) are epizootic diseases that are highly contagious or transmissible and have the potential to spread very rapidly irrespective of national borders. TADs agents may or may not be zoonotic, but regardless of zoonotic potential, the highly contagious nature of these diseases invariably impacts global economy, global trade and global public health. Examples of TADs include highly pathogenic avian influenza, rinderpest, classical swine fever and foot and mouth disease.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.2.1 identify the clinical signs, clinical course, transmission potential (including vectors), and pathogen associated with TADs;

1.2.2.2 describe the current global distribution of TADs or know where to find up-to-date distribution information;

1.2.2.3 use or explain the collection and handling of samples and the rationale for the use of appropriate diagnostic and therapeutic tools to prevent and combat TADs and pathogens;

1.2.2.4 understand regulatory implications of TADs and ~~their~~ pathogens (eg, the Official Veterinarian who should be contacted if an ~~TAD~~ epizootic pathogen is identified or suspected) and know where to find relevant up-to-date information.

1.2.3. Zoonoses (including food borne diseases)

Zoonoses are diseases or infections that are naturally transmissible from animals or their products to humans. Many food borne pathogens are zoonotic and most emerging human pathogens have an animal (livestock or wildlife) origin. As such, zoonoses have major implications for human health and trade in animals and animal products.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.3.1 identify the clinical signs, clinical course, transmission potential, and pathogen associated with common zoonotic and food borne diseases;

1.2.3.2 use or explain the use of current diagnostic and therapeutic tools for common zoonotic and food borne diseases;

1.2.3.3 understand the implications of common zoonotic and food borne diseases for human health (e.g., how does the disease spread from animals to humans) and know where to find up-to-date information;

Annex 24 (contd)

Annex III (contd)

1.2.3.4 understand regulatory implications (e.g., the Official Veterinarian who should be contacted if a zoonotic pathogen is identified or suspected) of common zoonotic and food borne diseases and pathogens and know where to find up-to-date and reliable information.

1.2.4. Emerging and re-emerging diseases

An emerging disease is a new infection resulting from the evolution or change of an existing pathogenic agent, a known infection spreading to a new geographic area or population, or a previously unrecognised pathogenic agent or disease diagnosed for the first time. A 're-emerging disease' is a resurgence in a defined time period and location, of a disease considered to have been eradicated or controlled in the past. Both emerging and re-emerging diseases have significant impacts on animal (naïve populations) and/or public health.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.4.1. define "emerging disease" and "re-emerging disease" and provide contemporary examples;

1.2.4.2. detect suspicious signs and report them to the relevant veterinary authority;

1.2.4.3. understand the reasons/hypotheses to explain the emergence and /re-emergence of diseases;

1.2.4.4. know where to find up-to-date and reliable information regarding emerging and re-emerging diseases.

1.2.5. Disease prevention and control programmes

Disease prevention and control programmes, whether or not approved, managed or supervised by the veterinary authority, include movement controls, vaccination and treatment. Disease prevention and control programmes will be specific to each country or region and should comply with applicable OIE standards, as appropriate.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.5.1 describe established programs for the prevention and/or control of common zoonotic or contagious diseases or emerging/re-emerging diseases, to include animal identification and traceability and oversight by the relevant veterinary authority;

1.2.5.2 understand and participate in the implementation of contingency plans to control transboundary diseases, including humanely killing animals;

1.2.5.3 understand and participate in regular or emergency vaccination campaigns, as well as in regular test-and-cull/treat programmes;

1.2.5.4 explain the concept of "early detection system," which is defined as a system, under the control of the veterinary services, for the timely detection and identification of an incursion or emergence of diseases/infections in a country, zone or compartment;

1.2.5.5 know which diseases of animals (including companion animals) require compulsory notification by the veterinarian to the ~~veterinary~~ prescribed national authority in order to mitigate disease transmission;

1.2.5.6 know where to find up-to-date and reliable information regarding specific disease~~,~~ prevention and control measures, including rapid response mechanisms.

Annex 24 (contd)

Annex III (contd)

1.2.6. Food hygiene

Food hygiene means all conditions and measures necessary to ensure the safety and suitability of food of animal origin.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.6.1 understand and explain on-farm food safety practices;

1.2.6.2 participate in slaughter inspection: this includes ante-mortem, post-mortem and humane slaughter;

1.2.6.3 understand and explain the integration between animal health controls and veterinary public health: the role of veterinarians in conjunction with physicians, public health practitioners, and risk analysts to ensure safety ~~safe food~~.

1.2.7. Veterinary products

Veterinary products means drugs, insecticides/acaricides, vaccines, and biological products used or presented as suitable for use to prevent, treat, control, or eradicate animal pests or diseases; or to be given to animals to establish a veterinary diagnosis; or to restore, correct or modify organic functions in an animal or group of animals.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.7.1 use common veterinary products in the appropriate manner, including appropriate record keeping;

1.2.7.2 explain and utilize the concept of drug withdrawal time as a means to prevent drug residues in products of animal origin meant for human consumption, and know how to find up-to-date and reliable information regarding specific withdrawal times;

1.2.7.3 understand common mechanisms leading to development of antimicrobial resistance in common pathogens;

1.2.7.4 know where to find and how to interpret up-to-date and reliable information regarding the link between use of antimicrobials in food animals and development of antimicrobial resistance in pathogens of human importance;

1.2.7.5 know the appropriate use of drugs and biologicals to ensure the safety of the food chain and the environment (e.g., proper disposal of biological waste).

1.2.8. Animal welfare

Animal welfare means how an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear, and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter (when relevant), management, nutrition, humane handling, and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment. Veterinarians should be the leading advocates for the welfare of all animals, recognizing the key contribution that animals make to human society through food production, companionship, biomedical research and education.

Annex 24 (contd)

Annex III (contd)

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.8.1 explain animal welfare and the related responsibilities of owners, handlers, veterinarians and others responsible for the care of animals;

1.2.8.2 identify animal welfare problems and participate in corrective actions;

1.2.8.3 know where to find up-to-date and reliable information regarding local, national and international animal welfare regulations/standards in order to describe humane methods for:

- animal production;
- transport;
- slaughter for human consumption and killing for disease control purposes.

1.2.9. Veterinary legislation and ethics

Veterinary legislation is an essential element of the national infrastructure that enables veterinary authorities to carry out their key functions, including surveillance, early detection and control of animal diseases and zoonoses, animal production food safety and certification of animals and animal products for export. Furthermore, Veterinary Education Establishments' should teach ethics and value issues to promote high standards of conduct and maintain the integrity of the profession.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.9.1 have a general knowledge of the fundamentals of national veterinary legislation-and of specific rules and regulations governing the veterinary profession at the local, provincial, national, and regional level (in some countries this information may be delivered to the graduates by the Veterinary Statutory Body after graduation);

1.2.9.2 know where to find up-to-date and reliable information regarding veterinary legislation and the rules and regulations governing the veterinary profession in his/her own state, province, region and/or country;

1.2.9.3 understand and apply high standards of veterinary medical ethics in carrying out day-to-day duties;

1.2.9.4 provide leadership to society on ethical considerations involved in the use and care of animals by humans.

1.2.10. General certification procedures

Certification means an official document, completed by an authorised veterinarian, for purposes of verifying the health or sanitary status of animals and animal products, respectively, most often prior to transport.

Veterinarians are responsible to certify the health status of an animal or herd in private practice or as an element of official certification.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.10.1. examine and monitor an animal or a group of animals with a view to certifying freedom from specified diseases or conditions according to established procedures;

1.2.10.2. fill out, sign and provide health certificates according to the national rules.

Annex 24 (contd)

Annex III (contd)

1.2.11. Communication skills

Effective communication skills are as important to success in veterinary medicine as are technical skills. In general, communication entails the exchange of information between various individual, institutional and public audiences for purposes of informing, guiding and motivating action. The application of the science and technique of communication involves modulating messages according to situations, objectives and target audiences.

Specific learning objectives for this competency include the Day 1 veterinary graduate being able to:

1.2.11.1 communicate technical information in a way that the general public can understand;

1.2.11.2 communicate effectively with fellow health professionals to exchange scientific and technical information and practical experience.

2. Introduction to advanced competencies

Mastery of these advanced competencies is not expected of Day 1 veterinary graduates. However, they should have a general awareness and appreciation of the following topics.

2.1. Organisation of Veterinary Services

Veterinary Services means the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the OIE *Terrestrial Code* and the *Aquatic Animal Health Code* in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. An objective in the delivery of national veterinary services is to bring a country, territory, or region in line with international standards in terms of legislation, structure, organisation, resources, capacities, and the role of the private sector and veterinary paraprofessionals.

Learning objectives include the Day 1 veterinary graduate having a general awareness of and appreciation for:

2.1.1. the delivery of National Veterinary Services as a global public good;

2.1.2. how Veterinary Services are organized within his/her own country/region (e.g., central and local levels, epidemiological networks);

2.1.3. the function and authority of the National Veterinary Service within his/her own country/region;

2.1.4. how his/her country's National Veterinary Service agencies interact with veterinary services in other countries and international partners;

2.1.5. the relationship between private and public sector veterinarians in delivery of national veterinary services within his/her own country;

2.1.6. the essential need to evaluate the quality of Veterinary Services as provided for in the OIE PVS Pathway;

2.1.7. where to find up-to-date and reliable information should deeper knowledge be needed or desired.

Annex 24 (contd)

Annex III (contd)

Other learning objectives include understanding the following definitions:

2.1.8. Veterinary Authority: The governmental authority of a country, territory, or region that comprises veterinarians, other professionals, and paraprofessionals and with the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification, international standards and recommendations such as those in the OIE *Terrestrial Code*, and other relevant legislation related to animal and public health and animal welfare. The Veterinary Authority typically accredits or approves private-sector organisations, veterinarians, and veterinary paraprofessionals to deliver veterinary service functions.

2.1.9. Veterinary Statutory Body means an autonomous authority (typically at the national level) that regulates veterinarians and veterinary para-professionals.

2.2. Inspection and certification procedures

Inspection means examination and evaluation of animals and animal products by an authorized veterinarian prior to completing a certificate to document the health or sanitary status, respectively. Certification means an official document, completed by an authorised veterinarian, for purposes of verifying the health status of animals and safety of animal products.

Learning objectives include the Day 1 veterinary graduate having a general awareness of and appreciation for:

2.2.1. the processes used to assess the health status of animals and safety of animal products for the purpose of transport / export;

2.2.2. the process of ante and post-mortem risk-based inspection of animals, and of the inspection of animal products;

2.2.3. the drafting of health certificates.

2.3. Management of contagious disease

Prevention and control of contagious diseases, whether or not approved, managed or supervised by the veterinary authority, include movement controls, vaccination and treatment. Disease prevention and control programmes will be specific to each country or region and should comply with applicable OIE standards, as appropriate.

Learning objectives include the Day 1 veterinary graduate having a general awareness of and appreciation for:

2.3.1. the management of samples and the use of appropriate diagnostic and therapeutic tools;

2.3.2. tracing the source and spread of a disease;

2.3.3. monitoring and conducting initial surveillance of diseases, to include communication of epidemiological information to other public health practitioners;

2.3.4. the methods to:

- identify and trace animals;
- control movement of animals, animal products, equipment, and people;
- quarantine infected and at-risk premises/areas;
- humanely kill infected or exposed animals;

Annex 24 (contd)

Annex III (contd)

- dispose of infected carcasses in an appropriate manner;
- disinfect or destroy contaminated materials
- zoning and compartmentalisation

2.4. Food hygiene

Food hygiene means all conditions and measures necessary to ensure the safety and suitability of food of animal origin.

Learning objectives include the Day 1 veterinary graduate having a general awareness of and appreciation for:

2.4.1. the risk-based performance of slaughter inspection including ante-mortem, post-mortem, humane slaughter and hygienic dressing;

2.4.2. residue testing programmes;

2.4.3. the traceability of animal products;

2.4.4. sanitation at food processing plants, proper storage of processed animal products, in-home food storage and preparation safety, and health and cleanliness of all humans involved in the food chain from farm to fork.

2.5. Application of risk analysis

Risk means the likelihood of the occurrence and likely magnitude of the biological and economic consequences of an adverse event or effect to animal or human health. The process of risk analysis involves hazard identification, risk assessment, risk management, and risk communication. The importation of animals and animal products involves a degree of risk to the importing country. Risk analysis as applied to importation provides the importing country with an objective and defensible method of assessing the disease risks associated with the importation of animals, animal products, animal genetic material, feedstuffs, biological products and pathological material using, particularly as a basis, relevant existing OIE standards.

Learning objectives include the Day 1 veterinary graduate having a general awareness of and appreciation for:

2.5.1. how risk analysis can be applied to assessment of risk of animal disease ~~related risks~~ and residues of veterinary drugs, including importation of animals and animal products and other related veterinary services activities;

2.5.2. how risk analysis can be used to ensure veterinary services adequately protect animal and human health;

2.5.3. where to find up-to-date and reliable information should deeper knowledge be needed or desired (e.g. the OIE *Handbook on Import Risk Analysis*);

2.5.4. the following risk analysis concepts:

- hazard identification: the process of identifying pathogenic agents which could potentially be introduced in the commodity (e.g., food of animal origin);
- risk assessment: evaluation of the likelihood and the biological and economic consequences of entry, establishment, and spread of a hazard within a territory;
- risk management: the process of identifying, selecting, and implementing measures that can be applied to reduce the level of risk;

Annex 24 (contd)

Annex III (contd)

- risk communication: the interactive transmission and exchange of information and opinions throughout the risk analysis process concerning risk; risk-related factors; and risk perceptions among risk assessors, risk managers, risk communicators, the general public, and other interested parties (e.g., stakeholders).

2.6. Research

Research means testing a hypothesis by appropriately designing and implementing a protocol, analysing the data, drawing conclusions and publishing the results.

Learning objectives include the Day 1 veterinary graduate having a general awareness of and appreciation for how translational and interdisciplinary research is essential to advance veterinary knowledge in the areas relevant to delivery of National Veterinary Services (e.g., zoonoses, transboundary diseases, (re-)emerging diseases, epidemiology, animal welfare, veterinary drugs and biologicals) so that future generations are better equipped to assure the health of animals, the public, and the ecosystem.

2.7. International trade framework

The framework on which regulations governing safe international trade in animals and animal products relies on the interaction and cooperation among several organisations as well as on the latest scientific advances so as to improve animal health world-wide and to promote and preserve the safety of the international trade in animals and animal products.

Learning objectives include the Day 1 veterinary graduate having a general awareness of and appreciation for:

2.7.1. the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (i.e. SPS Agreement);

2.7.2. the role and responsibilities of the WTO standard setting organisations such as the OIE and the Codex Alimentarius Commission (CAC) in developing science-based current regulations governing international trade in animals and animal products;

2.7.3. current international regulations, that govern the safe trade of animals and animal products;.

2.7.4. the potential implications of transboundary diseases, including zoonoses, on international trade, e.g., does presence of a disease in one country potentially impede international trade of the affected animal species and its products, and knowing where to find up-to-date and reliable information regarding these implications. the process leading to certification of commodity quality and wholesomeness as it relates to sanitary matters for export;

2.7.5. the import control mechanisms and certification processes related to protection of the health of animals, the public, and the ecosystem in the importing country.

2.8. Administration and management

Administration can be defined as the universal process of organising people and resources efficiently so as to direct activities toward common goals and objectives, with management comprising planning, organising, staffing, leading or directing, and controlling an organisation or effort for the purpose of accomplishing a goal. In the broadest sense, administration consists of the performance or management of business or organisational operations and, thus, the making or implementing of major decisions, whereas management is the act of getting people together to accomplish desired goals and objectives.

Annex 24 (contd)

Annex III (contd)

Learning objectives for this competency include the Day 1 veterinary graduate having a general awareness of and appreciation for:

2.8.1. best practices in administration and management;

2.8.2. the importance of excellent interpersonal communication skills, to include self-knowledge and knowledge of others;

2.8.3. the importance of effective communication (public awareness and advocacy);

2.8.4. where to find up-to-date and reliable information should detailed knowledge be needed or desired;

2.8.5. the need to have proficiency in at least one of the official languages of the OIE.

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Annex 24 (contd)

Annexe IV

POST-GRADUATE AND CONTINUING EDUCATION FOR GRADUATE VETERINARIANS TO ASSURE ONGOING DELIVERY OF HIGH-QUALITY NATIONAL VETERINARY SERVICES

DRAFT at January 2012

Background

Only some veterinarians will focus their careers on the delivery of National Veterinary Services that is, services provided under the legislative framework and the auspices of the governmental authority of a given country to implement animal health programmes to assure the health and wellbeing of animals, people and ecosystems. For those veterinarians that do choose National Veterinary Services as a career direction, considerably greater expertise will be needed than that described in the *Minimum Competencies Expected of Day 1 Veterinary Graduates to Assure Delivery of High-Quality National Veterinary Services* document developed by the OIE *ad hoc* Group on Veterinary Education. In addition, private practice veterinarians who may act as sub-contractors for National Veterinary Services will need ongoing continuing education to ensure their knowledge and skills are up-to-date.

This guidance document provides a broad overview of methods of delivering higher-level educational modules or continuing education and training programmes focused on delivery of national veterinary services for both veterinarians in the veterinary authority as well as private practice veterinarians working under the auspices of the veterinary authority. In addition, essential knowledge and skills for veterinarians in the veterinary authority are outlined, as are topics for continuing education relevant to ensuring currency of knowledge and skills of private practice veterinarians delivering national veterinary services.

After Day 1 competencies have been assured through a rigorous educational program leading to the awarding of the first veterinary professional degree, those veterinarians who wish to focus their careers on the delivery of National Veterinary Services through a path leading to a senior veterinarian position in the Veterinary Authority will need to gain additional expertise in topics specific to the National Veterinary Services. This may be best done either through additional degree programmes or/and continuing education including on-the-job training. Assuring currency of knowledge of both private veterinarians and those working for the veterinary authority is best done through continuing education, which may be required for ongoing employment, promotion, or, in the case of private veterinarians, certification to allow ongoing subcontracting with the veterinary authority.

Definitions

- The term "Veterinary Services" refers to the OIE *Terrestrial Animal Health Code* (*Terrestrial Code*) definition, which includes both public and private components of the veterinary profession involved in the promotion of animal and public health as well as animal welfare.

- Also from the *Terrestrial Code*, Veterinary Authority means the Governmental Authority of an OIE Member, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the *Terrestrial Code* in the whole territory.

- For the purpose of this document "Senior-Level Veterinarian in the Veterinary Authority" means a veterinarian who has responsibility for staff and resources and has regulatory authority to implement regulatory programmes.

Post-Graduate Education Programmes

- Research oriented
    - Masters of Sciences (MSc) or equivalent programmes
    - Combination of the first professional veterinary degree with either a MSc or a PhD

Annex 24 (contd)

Annexe IV (contd)

- Specialisation oriented
    - Masters in Preventive Veterinary Medicine
    - Masters in Veterinary Public Health
    - Other specialised degree programmes or certification programmes, in addition to the first professional veterinary degree and supporting the National Veterinary Services in:
        - technical areas such as aquatic animals, wildlife, human and animal epidemiology and ecological systems
        - non-technical areas such as communication and economics.

Continuing Education

Education that is relevant to the National Veterinary Services activities comes from an approved source and includes certification for attendance or completion.

- Employer directed training

  Employer directed training is of particular relevance to those veterinarians who focus their careers on National Veterinary Service; in other words, those veterinarians on track to become a "senior-level veterinarian" in the veterinary authority. The veterinary authority should have in place plans for training employees so that they are fully competent in the regulations and programmes overseen by that authority.

- Conferences

  Examples include the conventions offered by international, national, or regional veterinary professional organisation, which often provide various continuing education tracks; specialty organisations, such as the American College of Veterinary Preventive Medicine or the International Aquatic Veterinary Medical Association which provide continuing education sessions focused on the organisations specific area of expertise; meetings sponsored by one or more organisations focusing on a specific topic; such as the June 2011 OIE Global Conference on Aquatic Animal Health Programmes.

- Distance learning

  Distance learning encompasses any type of learning done via electronic means, to include webinars; online, self-directed courses; virtual meetings (either via teleconference or video conference); collaborative spaces

- Other sources

  Notwithstanding the above, there are other valuable sources of continuing education including peer reviewed scientific journals, peer to peer professional interactions, both in person and virtual, and On-the-Job experience.

Continuing Education Topics for Private Veterinarians Delivering National Veterinary Services for terrestrial and aquatic animals:

- Emerging and re-emerging animal diseases
- Regulatory programmes for animal diseases, such as brucellosis, tuberculosis, bluetongue, infectious salmon anaemia and other diseases important to the region, to include detection, control, and eradication programmes.
- Food safety programmes at the primary production (farm) level

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Annexe IV (contd)

- Slaughter inspection procedures
- Certification requirements and procedures
- Surveillance methods and programmes for transboundary diseases, including contingency plans
- Notifiable diseases: reporting procedures
- Animal welfare
- One Health issues including the collaboration between veterinarians and physicians, wildlife disease surveillance and control programmes and zoonotic disease prevention.
- Legislative regulatory and ethical framework of the functions delegated to private veterinarians
- Familiarisation with new diagnostic tools and laboratory methodologies, including sample collection, handling and submission
- Prudent use of veterinary products, both medicines (e.g. antibiotics) and biologics (e.g. vaccines).
- On-premise (e.g. farms) biosecurity programmes
- Preparedness and response to emergencies (both natural [e.g. earthquakes] and man-made [e.g. nuclear plant accidents] events)
- Where to find up-to-date and reliable information
- Other topics relevant to the country or region

Continuing education topics for Veterinarians working within the Veterinary Authority

Additional details for these topics can be found in the "Day 1 competencies" document, Section 2, Introduction to advanced competencies (insert link to Day 1 Document).

- Organisation of veterinary services
- Inspection and certification procedures
- Management of contagious diseases including quarantine and movement restriction, compensation, vaccination and surveillance plans, etc.
- International trade framework
- Public law and regulation including administrative law, regulatory enforcement of health policy and justice
- Effective written and verbal communication in the primary language of Member Country to a variety of audiences (i.e. public, legislative, professional audiences)
- Promoting the welfare and protection of animals requires a working knowledge of the relevant national legislation and means to implement these. This implies knowledge of the activities of relevant national organisations including NGOs.
- Animal food production systems and economics
- Knowledge of when risk assessment is indicated

Annex 24 (contd)

Annexe IV (contd)

- Audit, checks and certification
- Food safety and hygiene including HACCP, antimicrobial resistance, residues and food processing techniques

Additional continuing education topics for Senior Level Veterinarians working within the Veterinary Authority

- Language training appropriate to the needs of the National Veterinary Services and taking into account the three official languages of the OIE (English, French, Spanish).
- Best practices in administration and management.
- Human resources management including being able to effectively and efficiently utilise employees and others to accomplish the mission and goals of the organisation.
- Obtaining and management of financial resources, including effectively securing financial resources and efficiently utilising these resources.
- Effective written and verbal communication in the primary language of Member Country to the media.
- Project management including project design, evaluation of feasibility, obtaining of funding, implementation including measuring progress against established milestones, evaluation and reporting of results.
- Welfare and protection of animals including working knowledge of the relevant international standards, the means to implement these, and the activities of relevant regional and international organisations including NGOs.
- Advocating for science-based policies in a given political and sociological context.
- Application of risk analysis: drafting of appropriate questions for risk assessment and proposing risk management measures.
- Risk communication to the public and other relevant audiences.
- International trade regulations and procedures.
- Role and activities of International organisations, and their relevant standards and applications i.e. WTO, OIE, FAO, Codex Alimentarius Commission (CAC) and WHO.
- Audit the efficiency and effectiveness of veterinary services, their organisation, programmes and activities.
- Knowledge and management of databases and other sources of information relevant to the veterinary services.
- Broad knowledge of ongoing research in the areas relevant to delivery of National Veterinary Services.

Annex 25

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

Original: English

November 2011

REPORT OF THE OIE EXPERT MEETING:

Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive

Paris, 30 November–1 December 2011

An OIE expert meeting was convened to conduct brainstorming to provide guidance for Member Countries needing to assess the risk of non-native ('alien') animals becoming invasive. The meeting took place on 30 November and 1 December 2011 and was chaired by Dr William Karesh. The list of participants and the Terms of Reference (ToR) are attached as Annexes I and II.

1. Opening

Dr Kazuaki Miyagishima, Deputy Director General of the OIE and Head of the Scientific and Technical Department, opened the meeting and welcomed the participants. He outlined the purpose of the meeting, highlighting the interest of the OIE in providing Member Countries with guidance on assessing the risk of non-native ('alien') animals becoming invasive when introduced into a new country, area of a country or ecosystem.

Dr Junko Shimura, representative of the secretariat of the Convention on Biological Diversity (CBD), expressed her gratitude for the OIE convening this expert meeting, noting that addressing invasive alien species (IAS) is one of the Aichi Biodiversity Targets (Target 9) of the Strategic Plan for Biodiversity 2011-2020 of the CBD.

After short self-introduction by each participant, the agenda of the meeting was adopted (see Annex III).

OIE's activities relevant to the CBD were presented by Dr Masatsugu Okita (see Annex IV).

Subsequently, relevant CBD activities were presented by Dr Shimura.

2. Discussion

2.1. General discussion and scope of the Group's work

In accordance with the ToR, the Group discussed the feasibility of developing guidance for use by OIE Member Countries, including the recommended scope of this work.

The Group discussed the CBD definitions of 'IAS' and 'alien species'. It noted that the CBD definition of IAS would include OIE listed diseases in instances where the diseases are both non-native and harmful to biodiversity. The Group agreed that the focus of its work should be animal species, not diseases, as the latter topic, which is a core part of ongoing OIE activities, is already the subject of standards in the OIE *Terrestrial* and *Aquatic Codes* and introduction risks posed by all diseases may be assessed using standards already adopted by the OIE.

Annex 25 (contd)

The term 'alien species' is defined by the CBD as 'a species, subspecies or lower taxon, introduced includes any part, gametes, seeds, eggs or propagules of such species that might survive and subsequently reproduce outside its natural past or present distribution'.

The Group agreed that this definition provided an appropriate basis for the drafting of OIE guidelines and that there was no need to develop specific definitions of the terms 'alien species' and 'non-native animal species'. The Group agreed that the purpose of the risk assessment was to determine whether or not a non-native species was likely to be an IAS in a specific context and the non-native species was considered to be a 'hazard' in the risk assessment context.

The Group recognised that the OIE did not (yet) have a formal mandate for setting official standards on assessing the risk of a non-native animal species becoming invasive. However, it noted that there was congruence between this work and the OIE's general mandate to improve animal health, veterinary public health and animal welfare and to contribute to healthy ecosystems. Based on its experience in import risk assessment, the OIE could make a valuable contribution to the management of risks associated with the movement of animals in international trade related to a non-native animal species becoming invasive. The Group encouraged OIE Member Countries to consider animal health in the broadest sense, taking into account that a non-native animal species can threaten terrestrial and aquatic animal health, not only via the entry of OIE listed pathogens (already addressed through the international standards published in the OIE *Codes* and *Manuals*) but also through mechanisms, such as competition for food, destruction of habitat, and predation. The Group noted precedence for this approach in the case of the Small Hive Beetle and Honey Bees.

The Group also highlighted that addressing non-native animal species becoming invasive related to animal health and the relationship with wildlife and human health and biodiversity is in line with the 5th Strategic Plan of the OIE and the recommendations adopted at the OIE Global Conference on Wildlife held in February 2011 in Paris. The topic of IAS related to the concept of the animal-human-ecosystems interface was therefore relevant to the strategy of the OIE in contributing to veterinary services as a global public good and implementing the 'One Health' concept[3].

The Group discussed the potential value for the OIE to define the concept of "animal health". Considering that the OIE's mandate is not limited to disease control but encompassed new challenges, including 'One Health' and climate change, the Group encouraged the OIE to define the factors that should be considered when referring to 'animal health'.

The Group noted that there are several tools available to countries wishing to assess IAS-related risks, including several risk assessment methodologies, information sources, lists of potential IAS and national guidelines on risk assessment for IAS. The Group considered that the development of an additional or new list of IAS would be impractical; whether or not a species is invasive is a context specific issue that is best determined through science-based analysis. However, the Group noted the need for international guidelines as a basis for harmonisation of risk analysis approaches, where warranted.

The Group acknowledged that OIE standards as published in the *Codes* and *Manuals* have a specific status under the World Trade Organization Agreement (WTO) on the application of Sanitary and Phytosanitary measures (the WTO SPS Agreement), which recognises the OIE as the reference standard setting organisation for animal health and zoonoses, alongside the Codex Alimentarius Commission (CAC) for food safety and the International Plant Protection Convention (IPPC) for plant health. While the IPPC standards cover IAS for the plant world, the OIE has not yet addressed IAS in its standards.

The Group noted that the general approach to risk analysis was the same but that details on the factors to be considered within an IAS differed from what one might considered for a disease RA, necessitating additional guidelines.

[3] http://www.oie.int/for-the-media/editorials/detail/article/one-world-one-health/

In discussing the most appropriate means of providing guidance to Member Countries, the Group noted that the OIE *Codes* (both *Terrestrial* and *Aquatic*) contain standards on Import Risk Analysis and discussed the need to avoid possible duplication or confusion.

The Group concluded that complementary approaches should be adopted, i.e. the OIE *Codes* cover OIE listed diseases and provide standards for import risk analysis, which is relevant to both listed and non-listed diseases. The proposed new guidelines would deal with assessing the risk of a non-native animal species becoming invasive.

The Group stressed the importance, in the OIE context, of analysing both:

1) the risk of animal invasiveness; and

2) the risk of pathogen movement as separate but complementary processes.

Related to the possible formats for guidelines on assessing the risk of non-native (alien) animals becoming invasive, the Group has two options, i.e.:

– draft a chapter for inclusion in the OIE *Terrestrial Animal Health Code* (and possibly the *Aquatic Animal Health Code)*;

– develop guidelines to be published on the OIE website or elsewhere as appropriate.

In the absence of a formal OIE mandate for setting standards with respect to IAS, the Group decided to develop guidelines for consideration by the OIE specialist commissions, which could then recommend either the development of a *Terrestrial Code* chapter or publication on the OIE website.

2.2. Drafting the guidelines

The Group thanked Dr MacDiarmid for developing a draft text on assessing the risk of a non-native animal species becoming invasive and noted that the proposed draft guidelines, which were based closely on Chapter 2.1. of the *Terrestrial Code* (Import risk analysis), were a good starting point.

The Group agreed that the guidelines should deal with the assessment of the probability of non-native animals introduced into a specified area becoming established, spreading and causing harm (consistent with the CBD's concept of "invasive,") or of posing a threat to health of the human, animal or ecosystem.

The definition of 'animal' in the *Terrestrial Code* is 'a mammal, bird or bee'. The Group decided that, to address the broader scope of the draft guidelines, the following definition of 'animal' should be used in the guidelines:

Animal means: all species, subspecies or lower taxon of the kingdom Animalia, with the exception of the species that are causative agents of diseases. Note: the experts did not discuss or conclude if 'species that are causative agents of disease' should or should not be limited to infectious and parasitic diseases.

The Group proposed as title for the document "Guidelines for assessing the risk of non-native ('alien') animals becoming invasive". The choice of the title reflected the scope of the document discussed and agreed by the Group.

The Group agreed that the scope of these guidelines should cover intentional and unintentional introduction of animals. However the unintentional introduction of animals would not be described in detail but rather only mentioned to sensitise the veterinary services of Member Countries that animals can be introduced into a country intentionally or unintentionally and that both could occur through a number of pathways.

Annex 25 (contd)

The Group noted that OIE standards were normally addressed to the veterinary services but, in the case of invasive animals, other governmental agencies are also involved. There is a need for coordination and collaboration on IAS issues across ministries and sectors.

The Group decided that most of the *Terrestrial Code* definitions that were relevant to IAS needed no modification. However, some terms would need to be clarified for the purpose of the draft Guidelines, e.g. 'hazard' and 'hazard identification'. In addition, the Group recommended the development of a definition of the term 'non-native animal' ('alien animal') used in the guidelines.

The CBD Secretariat proposed to define stakeholder in a broader sense than traditionally identified by the OIE and veterinary services (e.g. including indigenous and local communities).

The Group reviewed and discussed the draft document provided by Dr MacDiarmid in detail, and began the process of modifying it consistent with the views of members. As a general comment, it was noted that the guidelines should provide flexibility to OIE Member Countries, given that invasiveness was context specific to the species and country, area or ecosystem in question.

Owing to time constraints, the Group was not able to finalise the draft document at the meeting and agreed to do this by electronic means by the time of the next meetings of the two Specialist Commissions (February 2012).

The draft guidelines are attached in Annex VI.

2.3. General recommendations

- The Group recognised the importance of formalising a cooperation agreement between the OIE and the CBD.

- The Group highlighted the importance of encouraging research and investigation on the various pathways and processes involved in the entry, establishment and spread of non-native animals.

3. Discussion with the Director General

The Group presented some recommendations arising from the discussion held during the first day, to Dr Bernard Vallat, the Director General of the OIE.

Dr Vallat expressed his gratitude for the contribution of the participants, noting that One Health and associated approaches had been included in the 5th Strategic Plan of the OIE with consensual support of Members. He thanked Dr MacDiarmid for his initiative in providing a draft text. Dr Vallat also noted that the role of the OIE was broader than international trade and animal health; the contribution of environmental health to these was also of critical importance, hence the need for the OIE to be involved in this area.

Dr Vallat noted the importance of the OIE continuing to collaborate with the CBD.

For the purpose of the Group's work, Dr Vallat noted the need to avoid duplication and confusion that could arise from the inclusion of OIE listed pathogens as IAS. Dr Karesh replied that that issue had been discussed and addressed by the Group on the first day of the meeting.

Dr Shimura highlighted the importance of collaboration between the CBD Secretariat and the OIE. Dr Vallat agreed with her and noted that the OIE had proposed a first draft for an official agreement between the two organisations.

4. Next steps

The Group concluded the meeting by proposing the following next steps to the OIE:

- To finalise the revision of the draft guidelines by electronic consultation in time for submission to the Scientific and Terrestrial Animal Health Standards Commissions at their next meetings in February 2012.

- Once the guideline was available as a public document, it could be presented by the OIE to the CBD Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), which would hold its 16th meeting in April/May 2012.

- The guidelines should be reviewed periodically to ensure consistency with other OIE activities and guidelines, and to ensure that they are up to date with current knowledge in the field of IAS.

- If so desired by the specialist Commissions, in the context of Member Countries' responses to the draft guidelines and the present report, to request the Director General to consider convening an *ad hoc* Group on Invasive Alien Species to 1) explore OIE´s further actions in addressing IAS issues, 2) integrate input from an STDF workshop on IAS to be held in July 2012, 3) support OIE's work on IAS under the Liaison Group and through the pending official agreement (termed a Memorandum of Cooperation by CBD) with the CBD.

_____

…/ Annexes

Annex 25 (contd)

Annex I

THE OIE EXPERT MEETING: Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive

Paris, 30 November–1 December 2011

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Annex 25 (contd)

Annex I (contd)

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Annex II

THE OIE EXPERT MEETING: Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive

Paris, 30 November–1 December 2011

Draft Terms of Reference

Considering:

- that the Conference of the Parties to the Convention on Biological Diversity (CBD), at its sixth meeting (2002), adopted Guiding principles for the prevention, introduction and mitigation of impacts of alien species that threaten ecosystems, habitats or species;
- that the Conference of the Parties to the CBD, at its ninth meeting, requested the Executive Secretary of the CBD to continue to collaborate with the secretariats of the international organisations relevant to invasive alien species (IAS)
- that the OIE actively participated in the interagency liaison group (ILG) on IAS established by the CBD;
- that the objectives set out in the OIE 5th Strategic Plan (2011-2015) include 'developing tools for the analysis of the impact of environmental and climate change, including the problems linked with invasive species, especially in relation to vector-borne diseases and to aquatic animal health':

The expert meeting is asked to conduct a brainstorming and make recommendations on:

- use of risk assessment as a tool to evaluate and manage the risks to ecosystems presented by trade in animals and a proposed definition of 'invasive animals' for the purposes of this work.

Annex 25 (contd)

Annex III

THE OIE EXPERT MEETING: Brainstorming on guidance for Member Countries to assess the risk of non-native ('alien') animals becoming invasive

Paris, 30 November–1 December 2011

Adopted agenda

Day 1 (Wednesday 30 November)

09:30 / 11:00 – Opening

- Introduction of all participants
- Adoption of the agenda
- Presentation of relevant activities of the OIE
- Presentation of relevant activities of the CBD

11:00 / 13:00 – Brainstorming on guidance for Members to assess the risk of non-native animals becoming invasive

- Definition of Invasive Alien Species (IAS)
- Drafting guidelines for assessing the risk of non-native animals becoming invasive

13:00 / 14:00 – Lunch break

14:00 / 18:00 – Continued discussion

Day 2 (Thursday 1 December) – meeting with the Director General of the OIE

9:00 / 13:00 – Continued discussion

- Discussion with the Director General

13:00 / 14:00 – Lunch break

14:00 / 17:00 – Discussion on the next steps and drafting report

17:00 – End of the meeting

Annex 25 (contd)

Annex IV

OIE's activities relevant to the Convention on Biological Diversity

Invasive Alien Species (IAS)

OIE brainstorming meeting,
Paris 30 Nov – 1 Dec 2011

Masatsugu Okita
Chargé de mission
International Trade Dept.

OIE 5th Strategic Plan (2011-2015)

OIE mandate

- The improvement of animal health, veterinary public health and animal welfare world-wide

OIE 5th Strategic Plan (2011-2015)

Extract

- To ensure transparency in the global animal disease situation;
- To ensure safety of world trade in animals and animal products by preparing, adopting and promoting the application of relevant health standards for such trade;
- To provide expertise in the control of animal diseases including at the animal–human–ecosystems interface;
- To provide expertise to Members in understanding and managing the effects of environmental and climate changes on animal health and welfare;

Annex 25 (contd)

Annex IV (contd)

OIE 5th Strategic Plan (2011-2015)

Cross-Cutting Areas (extract relevant to IAS)

CLIMATE AND ENVIRONMENTAL CHANGES

The OIE will address the role of climate and environmental changes with respect to emerging and re-emerging animal diseases and animal production over the short, medium and long term.
In particular, the OIE, in collaboration with other international organisations, will assist veterinary authorities to develop foresight and other decision-making frameworks that take into account new information about the evolving relationship between ecosystems, invasive species and emerging and re-emerging animal diseases, recognising the need for adaptive policy responses.
Within this overall framework, particular attention will be paid to the effects of climate and environmental changes on aquatic animal health, including problems linked with invasive species.

OIE Activities relevant to IAS

The current mandate addresses diseases eg:

- Transboundary animal diseases (rinderpest, avian influenza)
- Vector-borne diseases: including standards relating to surveillance for disease vectors
- Pests and parasites eg small hive beetle infestation

New challenges

- One Health: animal/human/ecosystem interface
- Role of wildlife as disease reservoirs
- Climate change: vector-borne disease, (re)emerging disease

CBD and OIE relationship

May 2008: CBD Conference of the Parties (COP 9 Decision IX/4)

3. Invites the International Committee of the World Organisation for Animal Health (OIE) to note the lack of international standards covering invasive alien species, in particular animals, that are not pests of plants under the International Plant Protection Convention, and to consider whether and how it could contribute to addressing this gap, including for example by:

a) Expanding the OIE list of pathogens to include a wider range of diseases of animals, including diseases that solely affect wildlife; and

b) Considering whether it may play a role in addressing invasive animals that are not considered as causative agents of diseases under OIE and whether, for this purpose, it would need to broaden its mandate;

Annex 25 (contd)

Annex IV (contd)

CBD and OIE relationship

Since 2010, the OIE has participated in an Inter-Agency Liaison Group (IALG) comprising: CBD, IPPC, OIE, FAO, WTO, ICAO, IMO, CITES, IUCN and GISP

Two meetings have been held to date:
- hosted by the OIE 19-20 April 2010
- hosted by the WTO 14-15 February 2011.

CBD and OIE

November 2011: The CBD Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) 15 (Nov 2011) received advice from the Ad hoc Technical Expert Group recommending that the OIE consider:

- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health.....;
- Building further on the precedent of listing the amphibian diseases, ... in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code ...; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, ...;

CBD and OIE

Regarding the advice of the Ad hoc Technical Expert that;

(ii) The OIE could consider:

- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health.....;
- Building on the precedent of listing the amphibian diseases, ... in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code ...; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, ...;

Annex 25 (contd)

Annex IV (contd)

OIE Activities relevant to IAS

Aquatic Animal Health Code

Ch 1.2.2. Criteria for listing aquatic animal diseases

Relevant parameters

A. Consequences
   1. … (production loss) or
   2. The disease has been shown to … that it is likely to **negatively affect wild aquatic animal populations** … or
   3. …(Public health concern)

Diseases of amphibians (2008 ~)

Ch 8.1.
Infection with batrachochytrium dendrobatidis
Ch 8.2.
Infection with ranavirus

CBD and OIE

Regarding the advice of the Ad hoc Technical Expert Group that;
(ii) The OIE could consider:

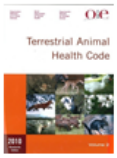
- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health…..;
- Building on the precedent of listing the amphibian diseases, … in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code …; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, …;

OIE Activities relevant to IAS

Terrestrial Animal Health Code

Chapter 1.2. Criteria for listing diseases (Proposed text)

Article 1.2.2



The criteria for the inclusion of a *disease* or *infection* in the OIE List are as follows:

1. … (international spread)
2. … (naïve susceptible population)
3. a) … (zoonotic character)

   OR

   b) … (significant impact on domestic animals)

   OR

   c) The *disease* has been shown to… that it would cause significant morbidity or mortality in *wild animal* populations

Annex 25 (contd)

Annex IV (contd)

OIE Activities relevant to IAS

- Terrestrial Animal Health Code
  In future, wildlife will be addressed in all disease chapters, with notification and surveillance standards applied primarily where infection of wildlife is of epidemiological importance
- On-line notification system for diseases in wildlife (WAHIS-wild)

CBD and OIE

Regarding the advice of the Ad hoc Technical Expert Group that;
(ii) The OIE could consider:

- Broadening its mandate by considering the impacts of invasive alien species on ecosystems as falling within the scope of animal health…..;
- Building on the precedent of listing the amphibian diseases, … in the consideration of additional animal diseases impacting aquatic ecosystems and wild aquatic animals under the OIE Aquatic Code;
- Continuing to develop recommendations on diseases that primarily affect wild rather than domestic animals, including by revision of the OIE Terrestrial Code …; and
- Providing advice and guidance on the assessment of risk of invasive alien species on ecosystems, …;

Annex 25 (contd)

Annex IV (contd)

OIE Activities relevant to IAS

December 2011: brainstorming meeting to consider the feasibility of developing guidance on risk assessment in relation to invasive animals

- Definition of "IAS" for the purpose of this work
- Guidance for use by Member countries
- Not intended as a text in the Terrestrial or Aquatic Code
- Guidance to be published on the OIE website

OIE Activities relevant to IAS

Definition of IAS by CBD (annex to decision VI/23)

- "alien species" refers to a species, subspecies or lower taxon, introduced outside its natural past or present distribution; includes any part, gametes, seeds, eggs, or propagules of such species that might survive and subsequently reproduce;
- "invasive alien species" means an alien species whose introduction and/or spread threaten biological diversity

Future work

The OIE mandate traditionally addresses diseases rather than animals. It is for Members to decide what, if any, new approaches may be appropriate in future.

Any recommendation to broaden the mandate would need to take account of the resources available to the OIE – both at headquarters and in Member countries.

Note: any decision to modify the OIE mandate can only be taken on the basis of adoption of a decision by the World Assembly, meeting at the General Session (May, Paris).

Annex 25 (contd)

Annex V

Activities of the Convention on Biological Diversity

Invasive alien species
A cross-cutting issue of the CBD

Junko Shimura
Secretariat of the Convention on Biological Diversity

Convention on Biological Diversity

- The Convention on Biological Diversity was inspired by the world community's growing commitment to sustainable development.
- It represents a dramatic step forward in :
  - the conservation of biological diversity,
  - the sustainable use of its components, and
  - the fair and equitable sharing of benefits arising from the use of genetic resources
- As of 2011 **193**Parties, one of the largest framework conventions under the United Nations

Convention bodies and Parties

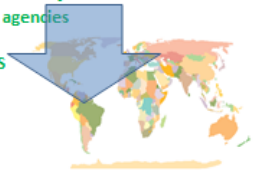
The Convention on Biological Diversity

- Subsidiary Body for Scientific, Technical and Technological Advice
- The Conference of Parties

COP Decisions

- **The Strategic Plan for Biodiversity 2011-2020**

Engagement of implementation agencies
Partners – INTNL ORGs
Inter agency liaison group on IAS



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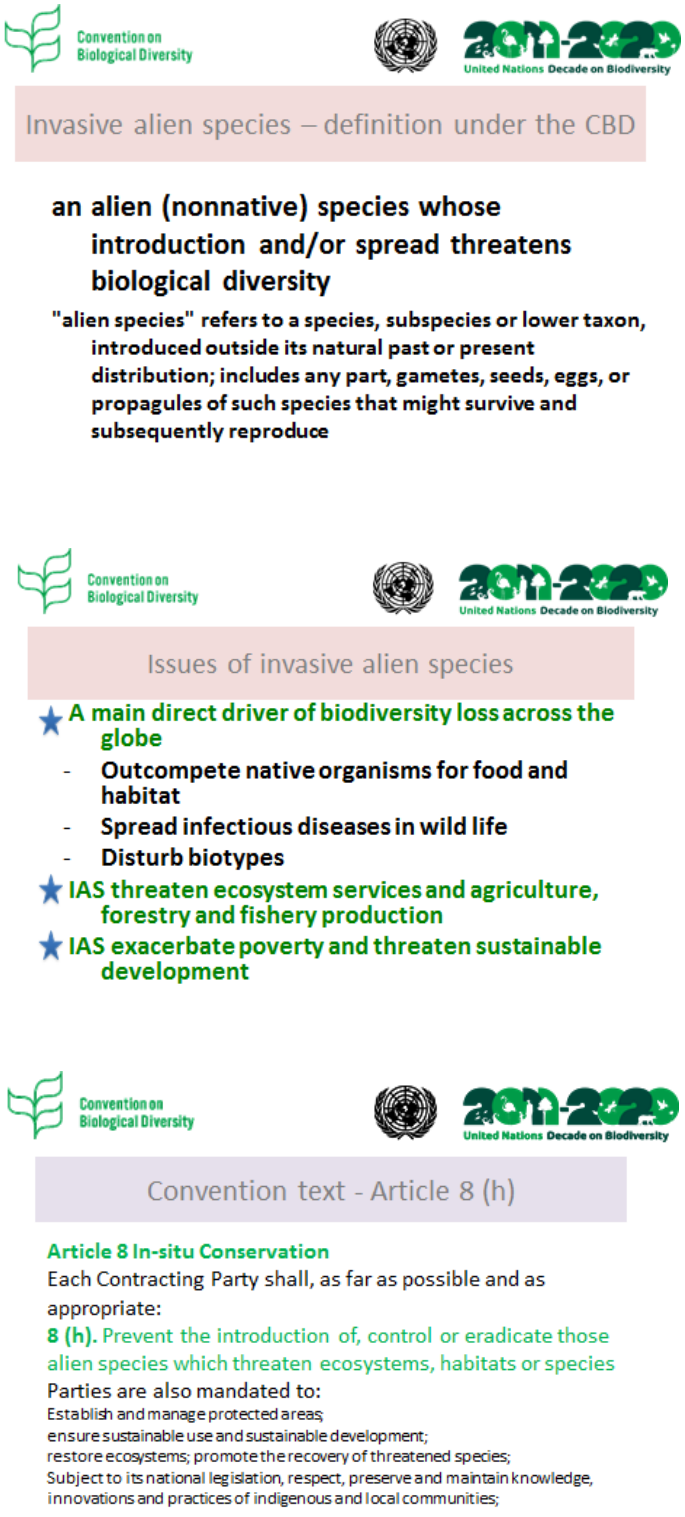

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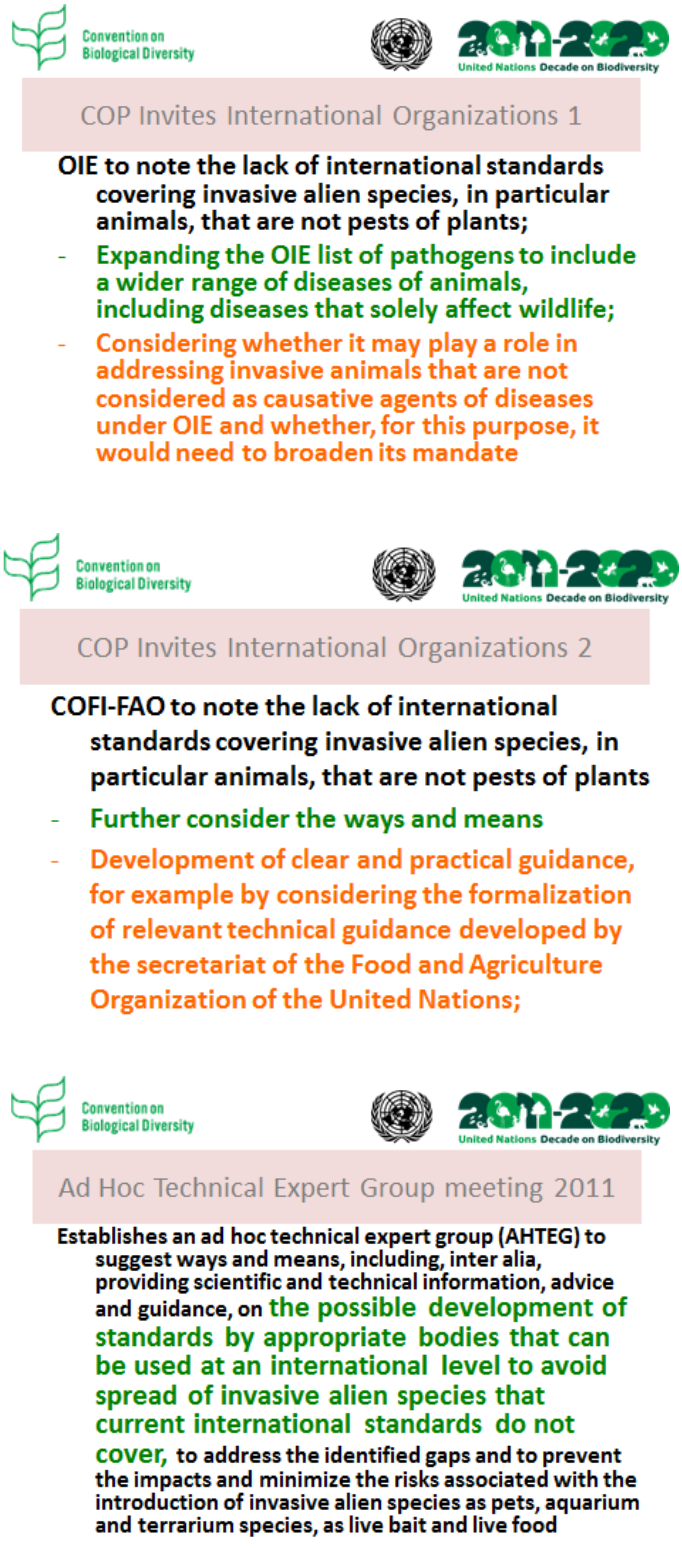

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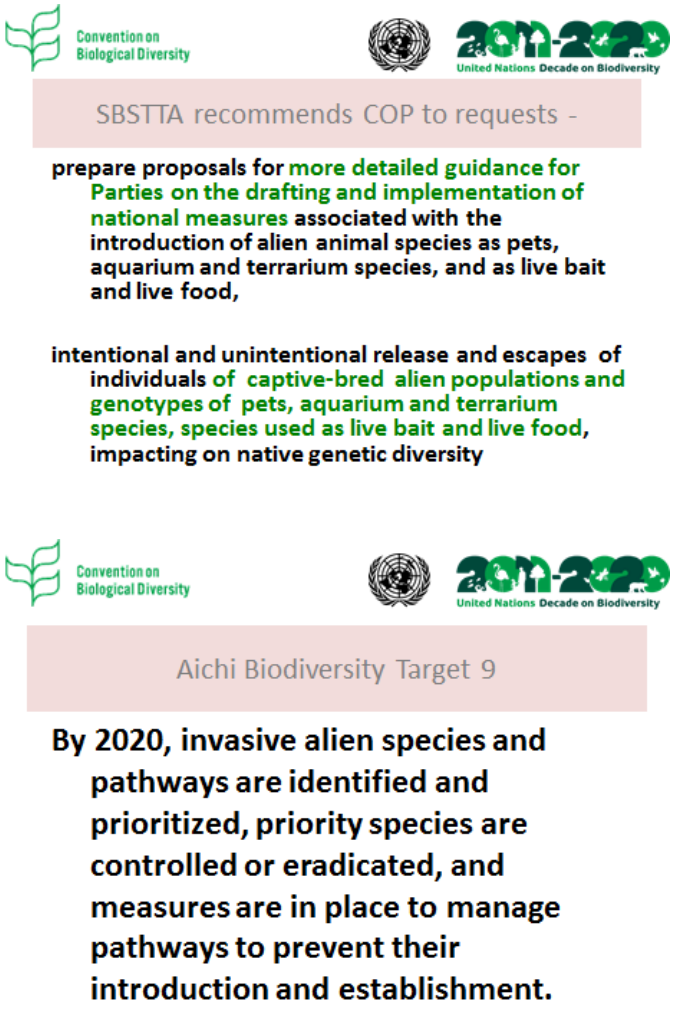

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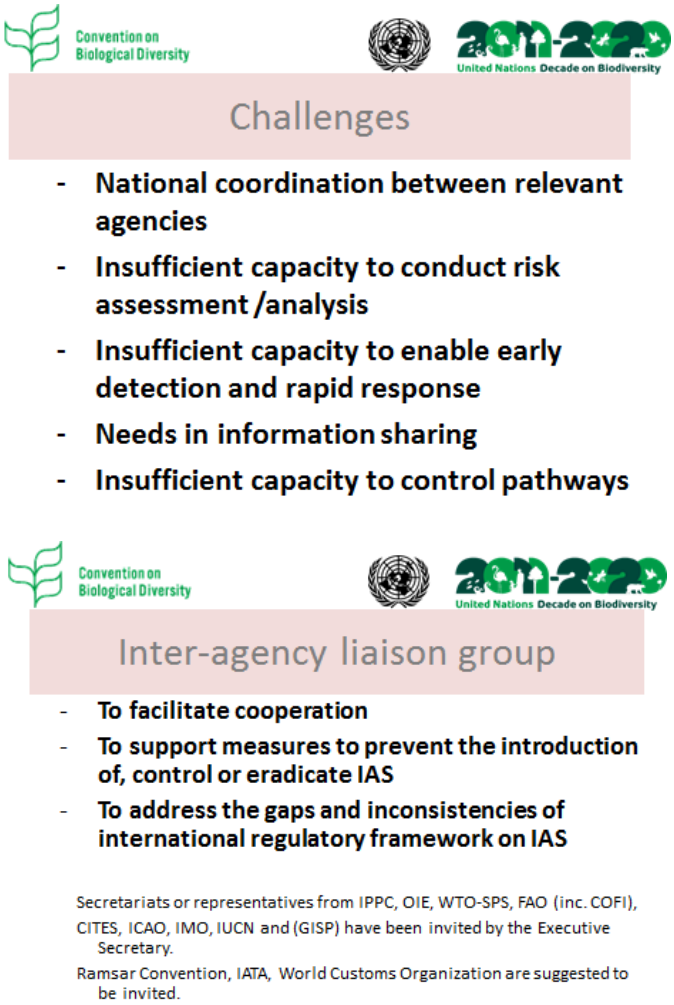


Annex VI

GUIDELINES FOR ASSESSING THE RISK OF NON-NATIVE ANIMALS BECOMING INVASIVE

I. Definitions for the purpose of this document

Animal: means any species, subspecies or lower taxon of the kingdom animalia with the exception of pathogens.

Non-native (or alien) animal: means an animal that is not a native to the country or ecosystem to which it could be intentionally or unintentionally introduced.

Invasive non-native (or invasive alien) animal: means an animal that has been introduced and subsequently become established and spread outside its native distribution area and caused harm to the environment, animal or human health, or the economy.

Hazard: means a non-native animal**.**

Hazard identification: means the process of identifying whether an animal is native or not in the importing country or region.

Hitchhiker organism: means an organism that has an opportunistic association with a commodity or vehicle/vessel or container and which may be transported unintentionally to a new environment.

II. Scope

In the framework of the international movement of animals, it is important to analyse both the risk of a non-native animal becoming invasive and the risk of pathogens being introduced with the animal. These different risks should be assessed as separate, sequential and complementary processes.

The OIE standard for import risk analysis covers the potential movement of pathogens. The guidelines developed in this document are intended to address the complementary process of assessing the risk of non-native animals becoming invasive.

III. Introduction

Organisms that have been introduced outside their native distribution and which subsequently become established and harmful to the environment, animal or human health, or the economy are considered "invasive non-native species." Invasive non-native species are one of the major drivers of biodiversity loss world-wide and are particularly a threat to geographically and evolutionarily isolated ecosystems (e.g., islands).

Trade is responsible for the movement of large numbers of live animals, comprising a wide diversity of species, around the world. Although the majority of these animals are not intended for release into the natural environment, some are, and others either escape or are subsequently released when their owners no longer wish to care for them. Trade in live animals thus plays a major role in facilitating invasions by non-native species world-wide. Because of the potential for non-native animals to become invasive, science-based risk analysis should be conducted before decisions are made with respect to the proposed importation of non-native animal species into a country or area. Risk analysis is also an important tool when considering the risks posed by so-called 'hitchhiker' organisms which may be associated with imported commodities or the vehicle/vessel or container in which they are imported.

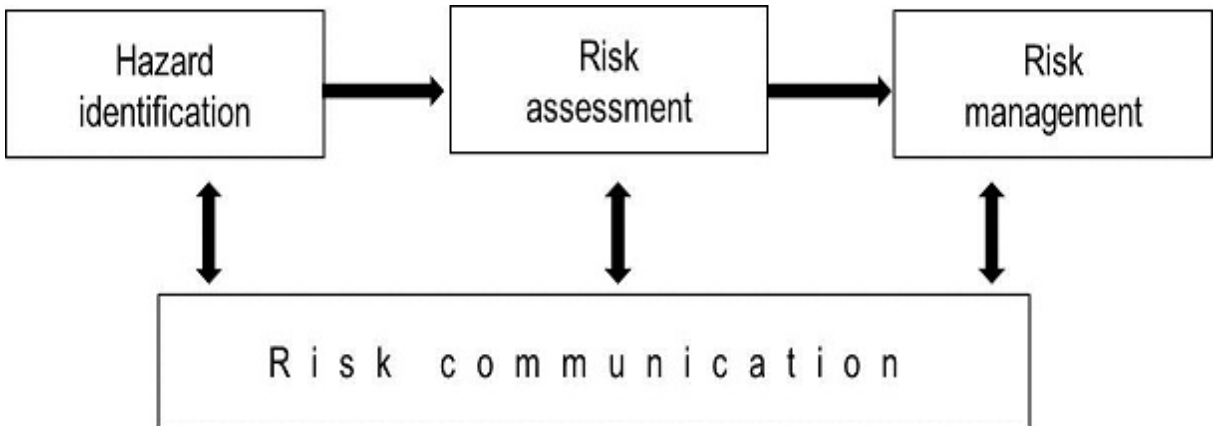
Annex 25 (contd)

Annex VI (contd)

The principal aim of assessing the risk of non-native animals becoming invasive is to provide importing countries with an objective and defensible method of determining whether such imported animal species are likely to become harmful to the environment, animal or human health, or the economy. The risk analysis should be transparent and participatory, providing stakeholders with the opportunity to contribute to the process and understand the reasons for decisions made. Transparency is also essential because data are often uncertain or incomplete and, without full documentation, the distinction between facts and the analyst's value judgements may blur.

These guidelines provide recommendations and principles for conducting transparent, objective and defensible analyses of the risks posed by the importation of non-native animal species. The guidelines are also useful in assessing the risks posed by hitchhiker organisms. The components of risk analysis described in these guidelines are hazard identification, risk assessment, risk management and risk communication (Figure 1).

Fig. 1. ***The four components of risk analysis***



A risk analysis is initiated either by a request to import a new species or a species for a new purpose. However, even non-native species that are already within a country's borders may be considered for risk analysis, especially if there is a high likelihood of them being introduced, or escaping, into the natural environment. All pathways showing a potential for the introduction of non-native animals should receive some degree of risk assessment, with those pathways that show a high potential for introducing non-native animals being subject to in-depth risk assessment.

IV. Hazard identification

In the case of trade in non-native animals, the animal under consideration is the hazard. This hazard should usually be identified to the level of species although in some instances identification to the level of genus may suffice while in others, identification to the level of breed, subspecies, hybrid or biotype may be required.

In the case of so-called hitchhiker organisms, the hazard identification involves identifying species which could potentially produce adverse consequences if introduced in association with an imported commodity (animals or animal products) or the vehicle/vessel or container in which it is imported.

It is necessary to identify whether each potential hazard is already present in the importing country or area into which the animals are imported. This is not always easy for animals traded widely for a diversity of commercial and private purposes and which may already be present in private collections.

Identifying whether a species is present in a country or region requires historical information on the abundance and distribution of animals and therefore typically requires consultation with a variety of stakeholders. Ecological boundaries, as opposed to political boundaries, should be considered. Consultation and coordination with appropriate authorities in neighbouring countries may help to determine species distribution and abundance. The presence of a particular species in the importing country or area does not necessarily eliminate the need for risk assessment, since the likelihood of non-native animals becoming invasive is also dependent on a number of additional importation factors such as size and frequency of importations, transport methods, intended use, containment etc.

Hazard identification is a categorisation step, identifying animals dichotomously as hazards or not. For the purpose of these guidelines all non-native animals are considered a hazard.

V. Principles of risk assessment

The risk assessment is the component of the risk analysis which estimates the risks associated with a hazard. Risk assessments may be qualitative or quantitative. Qualitative risk assessment does not require mathematical modelling skills to carry out and so is often the type of assessment used for routine decision making.

Risk assessment should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases and different methods may be appropriate in different circumstances. Risk assessment should be able to accommodate the variety of non-native animal species that may be considered for importation, entry and spread scenarios, and types and amounts of data and information.

The aim of a risk assessment is to assist in decision making in the face of uncertainty.

Both qualitative risk assessment and quantitative risk assessment methods are valid.

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

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

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

The risk assessment should be amenable to updating when additional information becomes available.

In addition to the general principles of risk assessment, assessment of the risk of non-native animals becoming invasive needs to consider certain unique aspects such as:

– The risk assessment need not be at a country level, but at an ecosystem level that may be sub-national.

– The risks may be borne by multiple subjects such as people, other animals or landscapes, thus requiring a systems-based approach to risk assessment.

– An invasive animal species may cause harm though a variety of mechanisms, both direct and indirect.

– The effects of an invasive animal species are often dependent on environmental conditions and may thus change over time in response to factors such as climate change.

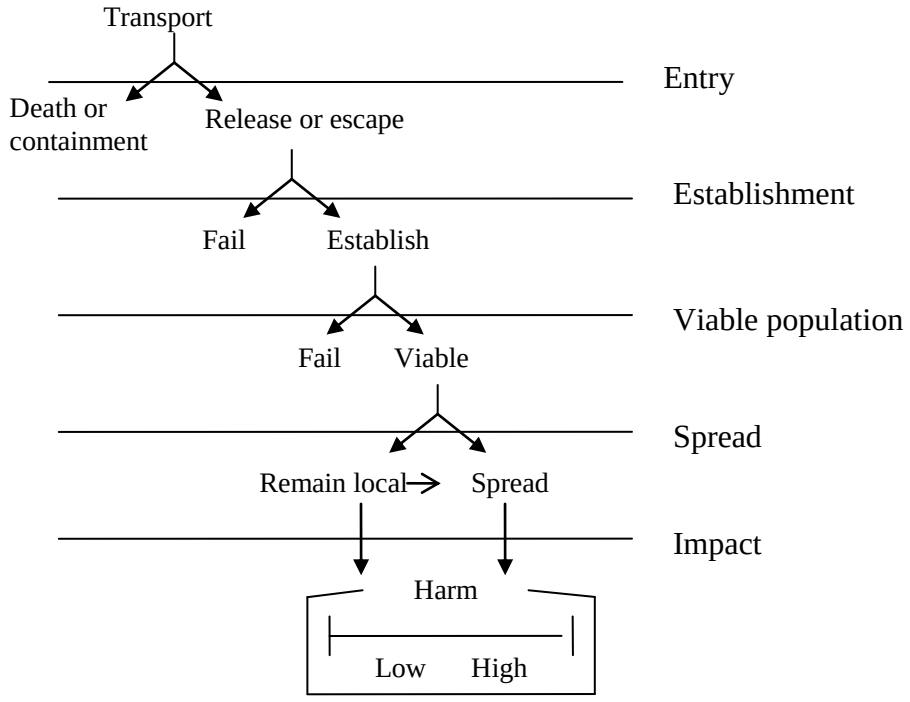
Annex 25 (contd)

Annex VI (contd)

VI. Risk assessment steps

The risk assessment examines the entire process by which a non-native animal species could enter a country, be introduced (escape or release) into the environment, become established, spread and cause harm. The steps in this process of invasion are illustrated in Figure 2.

Fig.2. ***The stages in the process of invasion by non-native animal species***



1. Entry assessment

Entry assessment consists of describing the pathway(s), biological or non-biological, necessary for an importation activity to introduce non-native animal species into a particular environment, and estimating the probability of that complete process occurring, either qualitatively (in words) or quantitatively (as a numerical estimate). The entry assessment describes the probability of the entry of each of the hazards (the non-native animals) under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

a) Circumstances of entry and containment. Do the circumstances of transportation and containment on arrival prevent escape or release? Examples of the kind of inputs that may be required are:

- whether entry is intentional or unintentional;
- whether different commodities, vehicles/vessels or containers are capable of harbouring the animal under consideration;
- security of containment, if any;
- planned movement, use and holding conditions upon and after arrival.

b) Biological factors. What are the features of the animal that may affect its survival during transport and in its initial holding? Examples of the kind of inputs that may be required are:

- species, subspecies or lower taxon, sex, age and breed of animals;
- the ability of the organism to survive the conditions and duration of transport;
- the number of individual animals per importation;
- ease of escape or release from containment;
- ability to survive in the environment of the importing country.

If the entry assessment demonstrates no significant risk, the risk assessment does not need to continue.

2. Establishment and spread assessment

Establishment and spread assessment consists of describing the biological conditions necessary for the hazards (in this case the non-native animals) to survive escape or release and estimating the probability of establishment and spread occurring, either qualitatively or quantitatively.

The probability of establishment and spread of the non-native animals is estimated for the local environment with respect to the number, size, frequency and season of escapes or releases.

a) Biological factors: What are the feature of the animals that may affect the probability of establishment and spread of the animals? Examples of the kind of inputs that may be required are:

- history of invasiveness elsewhere;
- number and size of releases or escapes (propagule pressure);
- reproductive biology and capacity (fecundity, age of sexual maturity, breeding frequency, gestation length, etc.);
- diet;
- whether the animals under consideration are wild or domesticated;
- whether the animals under consideration are generalist or specialised species;
- range of tolerance and adaptability to environment and climate;
- dispersal mode and capacity;
- longevity;
- density dependence.

b) Receiving environment: What are the features of the receiving environment that may affect the probability of establishment and spread of the animals? Examples of the kind of inputs that may be required are:

- climate match with the species native environment;
- presence of suitable food source;
- presence of suitable breeding sites;
- geographical and environmental characteristics;
- presence of predators, competitors, parasites and pathogens.

Annex 25 (contd)

Annex VI (contd)

c) Containment factors: What are the management factors that may affect the probability of establishment and spread? Examples of the kind of inputs that may be required are:

– security capacity for housing, handling and transportation;

– intended use of the imported animals (e.g. pets, zoological collections, live food or bait, research etc.);

– the nature and frequency of human-assisted animal movements;

– live animal disposal practices (euthanasia, release, rehoming, etc.).

If the establishment and spread assessment demonstrates no significant risk, the risk assessment may conclude at this step.

3. Consequence assessment

The consequence assessment describes the potential consequences of a given establishment and spread of the animals and estimates the probability of them occurring. This estimate may be either qualitative or quantitative. The social and biological costs associated with the effects of invasive non-native species are often very difficult to assess and measuring socio-economic impacts of invasive animal species requires data of sufficient magnitude and quality, which are often not available. Examples of consequences include:

a) Direct consequences:

– harm to ecosystems;

– harm to native species;

– economic damage;

– impacts on human health and well-being.

b) Indirect consequences:

– Surveillance, containment, control and eradication costs;

– compensation costs;

– potential trade losses;

– impacts on socio-cultural values.

4. Risk estimation

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

For a qualitative assessment, the final outputs may include:

– estimated costs for surveillance and control in descriptive terms such as ‘high’, ‘medium’ or ‘low’;

– estimated level of impact on animals, ecosystems or habitats, or people in terms such as ‘high’, ‘medium’ or ‘low’;

– lists of potential evidence-based impacts of significance warranting consideration in decision making;

– description of relative risk and range in terms such as 'high to very high' etc.

For a quantitative assessment, the final outputs may include:

– estimated costs for surveillance and control;

– estimated numbers of herds, flocks, animals, ecosystems or habitats, or people likely to experience health impacts of various degrees of severity over time;

– probability distributions, confidence intervals, and other means for expressing the uncertainties in these estimates;

– portrayal of the variance of all model inputs;

– a sensitivity analysis to rank the inputs as to their contribution to the variance of the risk estimation output;

– analysis of the dependence and correlation between model inputs.

VII. Principles of risk management

Risk management is the process of deciding upon and implementing measures to achieve the Member's appropriate level of protection in a cost-effective manner, whilst at the same time ensuring that negative effects on trade are minimised. The objective is to manage risk appropriately to ensure that a balance is achieved between a Member's desire to minimise the likelihood of incursions of non-native invasive species and their consequences and its desire to import commodities and fulfil its obligations under international trade agreements.

VIII. Risk management components

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

2. Option evaluation – the process of identifying, evaluating the efficacy and feasibility of, and selecting measures to reduce the risk associated with an importation in order to bring it into line with the Member's appropriate level of protection. The efficacy is the degree to which an option reduces the likelihood or magnitude of adverse consequences for biodiversity, animal and human health, and the economy. Evaluating the efficacy of the options selected is an iterative process that involves their incorporation into the risk assessment and then comparing the resulting level of risk with that considered acceptable. The evaluation for feasibility normally focuses on technical, operational and economic factors affecting the implementation of the risk management options but because the assessment of risk from non-native animals must consider socio-cultural aspects, option evaluation must also consider the cultural, ethical and political acceptability of the various risk management options.

3. Implementation – the process of following through with the risk management decision and ensuring that the risk management measures are in place.

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

Annex 25 (contd)

Annex VI (contd)

IX. Principles of risk communication

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

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

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

4. The principal participants in risk communication include the authorities in the exporting country and other stakeholders such as domestic environmental and conservation groups, local communities and indigenous peoples, domestic livestock producers and consumer groups.

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

6. Peer review is a component of risk communication which is carried out in order to obtain scientific critique and to ensure that the data, information, methods and assumptions are the best available.